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Contents

Original Papers

Early Reports

Viewpoints

Corrigenda and Addenda

Original Paper

Preferences for Mobile-Supported e-Cigarette Cessation Interventions Among Young Adults: Qualitative Descriptive Study

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Abstract

Background: Despite the steady rise in electronic cigarette (e-cigarette) uptake among young adults, increasingly more young people want to quit. Given the popularity of smartphones among young adults, mobile-based e-cigarette cessation interventions hold significant promise. Smartphone apps are particularly promising due to their varied and complex capabilities to engage end users. However, evidence around young adults' preferences and expectations from an e-cigarette cessation smartphone app remains unexplored.

Objective: The purpose of this study was to take an initial step toward understanding young adults' preferences and perceptions on app-based e-cigarette cessation interventions.

Methods: Using a qualitative descriptive approach, we interviewed 12 young adults who used e-cigarettes and wanted to quit. We inductively derived themes using the framework analysis approach and NVivo 12 qualitative data analysis software.

Results: All participants agreed that a smartphone app for supporting cessation was desirable. In addition, we found 4 key themes related to their preferences for app components: (1) flexible personalization (being able to enter and modify goals); (2) e-cigarette behavior tracking (progress and benefits of quitting); (3) safely managed social support (moderated and anonymous); and (4) positively framed notifications (encouraging and motivational messages). Some gender-based differences indicate that women were more likely to use e-cigarettes to cope with stress, preferred more aesthetic tailoring in the app, and were less likely to quit cold turkey compared with men.

Conclusions: The findings provide direction for the development and testing of app-based e-cigarette cessation interventions for young adults.

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KEYWORDS

qualitative research; electronic nicotine delivery systems; e-cigarette; cessation; young adults; smartphone apps; mHealth; mobile phone

Introduction

Electronic cigarettes, or e-cigarettes, deliver nicotine via inhaled vapor [1], which is why e-cigarette use is often called "vaping." The use of e-cigarettes has risen exponentially in North America, especially among young adults. According to the Canadian Tobacco and Nicotine Survey conducted between December 2020 and January 2021 [2], 15% of those aged 20-24 reported e-cigarette use in the past month and 48% reported having tried e-cigarettes once at some point. Similarly, in the United States, there has been a surge of nicotine-based e-cigarette uptake among young adults, with 20% of Americans aged 18-29 using e-cigarette products [3]. Uptake of e-cigarettes among young adults is occurring among both smokers and nonsmokers, with curiosity (27%) and smoking cessation (20%) the primary reasons for uptake among 20-24 year olds, and smoking

cessation (41%) and avoidance of cigarettes (17%) the primary reasons for uptake among those 25 and older in Canada [4].

Regardless of the reason for e-cigarette uptake, an increasing number of young people have indicated a desire to quit. Between 2018 and 2019, Canadian young adults who used e-cigarettes indicated that they were planning to quit in the next 6 months [5]. According to a recent study by Sanchez et al [6], 44% of Canadian young adults between 18 and 29 years of age had tried to quit, 33% were thinking about quitting, and 15% made plans to quit e-cigarettes. In the United States, 62.4% of current adult e-cigarette users, with the majority consisting of young adults (ages 18-34 years), planned to quit e-cigarettes for good, and 25% reported a past-year quit attempt [7]. Moreover, a similar study conducted by Berg et al [8] found that 20.8% of young adult e-cigarette users reported their willingness to quit e-cigarettes in the next 6 months and 32.3% reported past-year quit attempts.

Providing interventions to help support reduction and cessation of nicotine dependence associated with e-cigarettes is a promising way to help young adults in their cessation journey. e-Cigarette cessation support is in a nascent stage of development and to date, includes in-person counseling, group-based counseling, and quit lines [9]. Given the popularity of smartphones among young adults [10], a few mobile-based interventions are now on the market. One of them includes an SMS text messaging intervention to promote e-cigarette cessation among young adults [11], for which preliminary evidence in relation to user engagement and effectiveness is promising [11,12].

Smartphone apps provide promising ways to engage young adults in behavior change interventions, including the opportunity to incorporate gamification [13-15]. Not surprisingly, smartphone apps for e-cigarette cessation have received widespread support among young adults [8,16]. However, evidence around young adults' preferences and expectations from an e-cigarette cessation app remains unexplored. Therefore, in this study, we took an initial step toward understanding young adults' preferences and perceptions on app-based e-cigarette cessation interventions.

Methods

Design

We used a qualitative descriptive study approach. Qualitative description is appropriate because it aims to help researchers explore and understand end user perspectives or experiences on a topic where little is known [17,18]. This aligns with the goal of this study, which is to provide a rich description of young adults' perspectives and preferences for an app-based e-cigarette cessation support.

Ethics Approval

Ethics approval for this study was obtained from the University of British Columbia (Okanagan campus) Behavioral Research Ethics Board (BREB #: H21-00272).

Participants

We purposively recruited 12 young adults' aged 20-29 (mean age 25.5 [SD 2.66] years) who were current e-cigarette users and wanted to quit or reduce the use of e-cigarettes. The recruitment procedure included a single online advertisement that was distributed across 3 platforms (Kijiji [19], Castanet [20], and university web postings) with the caption "If you vape and want to quit, we want to hear from you!" All participants were recruited within 2 weeks of releasing the online recruitment advertisements. All participants provided informed consent prior to data collection.

Data Collection

Data collection included semistructured interviews conducted online using Zoom (Zoom Video Communications, Inc.). At the start of the interview, participants were asked to answer a short questionnaire to gather demographic (eg, age, gender) and e-cigarette information (eg, e-cigarette usage history, quit attempts, app use). For each interview, the same interview guide was followed. During the interviews, participants reported on their perceptions and preferences for receiving app-based support for reducing and quitting e-cigarettes, with interview prompts centered on common behavior change app features (eg, personalization, behavior tracking, social support, and notifications). The interviews were audio recorded and lasted approximately 45 minutes each. Each participant received a CAD $40 (US $32) e-gift card for their participation. The interview questions are presented in Multimedia Appendix 1.

Data Analysis

We adopted the framework analysis approach [21] to inductively develop themes within the qualitative data. The framework approach is a flexible and systematic approach that is ideal for developing themes from semistructured interviews [22]. This approach is hallmarked by a series of clear stages so that a coherent audit trail is provided during thematic development [22]. This process of thematic development allowed us to compare and contrast findings, particularly to assess gender influences.

The interviews were first transcribed verbatim and uploaded in the qualitative data analysis software program NVivo version 12 (QSR International) [23]. We disaggregated the data by gender to identify notable differences in e-cigarette patterns as well as needs and preferences related to e-cigarette cessation. After a detailed reading of the transcripts in their entirety to become familiar with the data, 2 researchers (ZH and LS) iteratively developed a coding framework using data from the interviews with young women and young men. All authors then reviewed and approved the framework. One author (ZH) then coded major themes and subsequent subthemes in relation to the analytical framework in NVivo, which were revised or added to as new data were collected.

Results

Sample Characteristics

We interviewed 12 e-cigarette users who were interested in quitting. The mean age of participants was 25.5 (ranging from

19 to 29) years, 50% (6/12) were male, 50% (6/12) were Caucasian, and most (9/12, 75%) completed postsecondary education (diploma or degree), and worked either part-time or full-time (7/12, 58%; Table 1). Most participants vaped more than once/day (9/12, 75%), having been using e-cigarettes for 6 months to a year (7/12, 58%), and primarily used devices with refillable cartridges (9/12, 75%). Men mostly reported e-cigarette uptake to replace smoking, while women also reported e-cigarette uptake to manage stress, or due to peer influence. Most participants reported wanting to quit for the last 6 months (7/12, 58%), and have made more than 3 quit attempts (8/12, 67%). Health and money were the primary reasons for quitting. While more men preferred to quit cold turkey compared with women, an equal number also preferred gradual reduction. None of the participants had used an app to help them quit e-cigarettes.

Table 1. Participant demographic and e-cigarette[a] information.

Demographic and e-cigarette information	Male (n=6)	Female (n=6)	Total (n=12)
Education			
Some postsecondary	1	2	3
Certificate/diploma	3	2	5
University degree	2	2	4
Employment			
Full-time	3	2	5
Part-time	1	1	2
Other (student, unemployed, caregiver)	2	3	5
Ethnicity			
White/Caucasian	4	2	6
Asian	1	2	3
Black/African American	1	2	3
White/East Indian	0	1	1
Reasons for e-cigarette			
Smoking alternative	5	2	7
Something new	1	0	1
Manage stress	0	2	2
Peer influence	0	2	2
Frequency of e-cigarette			
More than once/day	5	4	9
About once/day	1	0	1
A few times/week	0	2	2
Preferred vape device			
Device with prefilled cartridges	6	3	9
Device that allows user to fill	0	1	1
Disposable	0	2	2
History of e-cigarette			
More than a year	3	1	4
6 months to 1 year	3	4	7
Less than 6 months	0	1	1
How long been trying to quit			
More than a year	1	1	2
6 months to 1 year	2	1	3
Less than 6 months	3	4	7
Number of quit attempts			
More than 3	5	3	8
Less than 3	1	2	3
Reasons for quitting			
Health	3	3	6
Money	2	1	3
Money and health	1	2	3
Preferred quit approach			

Demographic and e-cigarette information	Male (n=6)	Female (n=6)	Total (n=12)
Cold turkey	3	1	4
Gradual reduction	3	3	6
Gradual reduction and nicotine replacement therapy	1	2	3
Ever used quit e-cigarette app			
Never	6	6	12

[a]e-cigarette: electronic cigarette.

In addition to the closed questions, we asked 3 open-ended questions. First, we asked if they could tell us what they did on a day that they left to do something and forgot to bring their vape. Both women and men said that they did 1 of 3 main things: smoked a cigarette, went back to get their e-cigarette, or bought a new vape device altogether. Second, we asked about what their friends and family did to support their quit efforts. Both women and men said that they received encouragement from family and friends, but women were more likely to report unhelpful support from family and friends, including telling them not to vape, and telling them that e-cigarettes are bad for them. Finally, we asked from whom they sought advice for quitting. While friends were the primary go to for both women and men, more men went to their family than women, and more women were likely to keep it to themselves compared with men.

Desirability of an e-Cigarette Cessation App

All young adults unanimously agreed that reaching them through a smartphone app for supporting e-cigarette cessation aligned with their preferences for behavior change interventions. It aligned with their interest and proficiency in navigating new technologies:

> *I actually find the idea really quite smart. I think it's would definitely help like younger people who are on their phones a lot like I have a smartwatch, so I am already used to kind of depending on technology. So, I think that it would be really beneficial to the people who are like techno natives.* [P12, male, 21]

Preferences for App Features and Content

Overview

Analysis of the data resulted in 4 categories related to app preferences: (1) flexible personalization (2) e-cigarette behavior tracking, (3) safely managed social support, and (4) positively framed notifications.

Flexible Personalization

Participants indicated that personalization was very important so that they felt supported in their individual quit journey. Key to this personalization was flexibility in terms of how they engaged with the app. At the outset, participants thought that having the option to sign-up through their email or various social media accounts (eg, Facebook) was the best way to begin use of the app:

> *Some people are sticklers for logging in with their other social media accounts. So, the ability to log in through any platform is definitely, it has to be there....why close the door on somebody ready to start?* [P1, male, 27]

Once they were signed up, participants reported that it was important for them to tailor the app according to their needs. As such, they wanted the app to have an option wherein they can input their e-cigarette behavior including amount consumed per day, level of addiction, situations of temptations, reasons for quitting, and personal goals:

> *I think it's important for a person who wants to quit e-cigarettes to give them the best chance maybe the software has to determine what level of addiction they have. So, you know, inputting the user's typical day and amount they smoke and then you know, calculating a reduction rate and maybe you know the ability to calculate when this person has the most usage maybe, you know asking questions like do you smoke at work? Do you work a stressful job? When do you smoke most?* [P1, male, 27]

Furthermore, to make the app more personalized and stand out from the rest of general intervention apps, they wanted the ability to set and modify their personalized goals.

> *I can personalize my stats, and my goals will motivate me to keep using the app.* [P5, male, 26]

Women were particularly insistent that the personalized content was matched with a personal look and feel. When they were talking about the design of the app, female participants suggested adding options to change the appearance of the app, such as changing the background color or adding pictures.

> *I love color. So, to be able to customize background colors and appearance of your dashboard, that would probably be really cool.....[I] would be more willing to, you know, log in every day and actually give it a shot.* [P6, female, 20]

They also mentioned the desire to have the current day/time portrayed, and a personalized greeting to be displayed when users log in the app.

> *When user logs in, it can say, like, good morning and then your name….to make it more personalized and to make it feel like the app is talking to you.* [P10, female, 24]

e-Cigarette Behavior Tracking

Another feature that the participants wanted in the app was to track their e-cigarette behavior, particularly their progress in staying away from using an e-cigarette and the direct benefits they could expect from this reduction in e-cigarette use. They

wanted information about associated improvements in health and money saved listed as the top 2 items that they would like to be tracked, which directly reflected their top reasons for quitting. Additionally, participants wanted apps to have options to track withdrawal symptoms, progress to desired goals, and situations where they vape the most. The majority of participants wanted a graphical representation (pictures, charts, graphs, etc.) of the data monitored by the tracking feature to make it easier to understand:

> *Like [show] a picture of lungs, and then as the app goes on, and based on your own personal progress, like [show] the change in lungs, that's kind of cool.* [P4, female, 26]

Safely Managed Social Support

To make the app engaging, participants expressed a desire to see a social support or a community feature incorporated in the app. The participants indicated this feature would allow users to view and share their e-cigarette cessation journey, including any difficulties they are facing, as well as progress, making the process of quitting "less lonely." One participant explained:

> *Like [part of the] recovery process is to have some camaraderie with other people that are going through the same thing whether it be drugs or alcohol or smoking. I definitely think that sense of community is really super important.* [P11, female, 29]

A few participants wanted a buddy option added with the community feature to enable others to provide encouragement, increase accountability, and to help them stay motivated. The use of tags was also suggested by participants, such as withdrawal symptoms, tips on setting goals, testimonies/advice from successful quitters, and inspirational messages/positive reinforcement. With these tags, users would have tools to navigate the community and find the support they needed.

Underpinning the desire for social support through an app, participants were adamant that the delivery platform is managed safely. Some suggested that a moderator in the community feature would be needed to prevent users from posting abusive and inappropriate content. Similarly, an age limit added to this feature was suggested to help make the community feature safe from predators.

> *[It] should have a moderator or an admin type so that it does not go out of hands and everyone stays civil.* [P8, female, 27]

Finally, participants showed their interest in sharing posts anonymously to ensure the privacy of app users:

> *A lot of people don't want to talk about why they're quitting. So having it be a bit more anonymous or being able to post anonymously.* [P12, male, 21]
>
> *[I would be] more comfortable using it if there was an anonymous posting feature, or like, it didn't include your name and your profile picture. And you could just choose the option to post anonymously.* [P6, female, 20]

Positively Framed Notifications

Participants suggested that an effective app needs to provide positively framed notifications that consist of motivational messages, encouraging reminders related to personal goals to strengthen and sustain motivation, and notifications that focus more on the benefits of quitting e-cigarettes rather than providing information on harmful effects of e-cigarettes.

> *Notification messages like, congratulations or like, keep going, you're doing great, that type of thing to encourage people. People respond well to acknowledgement, and like instant gratification, positive reinforcement.* [P4, female, 29]

Participants also wanted notifications to give insight into their progress, such as through an end of the day or weekly report:

> *You've gone 24 hours this week without an e-cigarette you know, you've cumulatively given up e-cigarettes for 48 hours, like those kind of milestones. So, I definitely think like those kind of milestone notifications might be helpful.* [P11, female, 29]

Additionally, participants expressed their interest in receiving updates and notifications on e-cigarette research and cessation from reliable sources.

Discussion

Principal Findings

In this study, we examined young adults' perceptions and preferences around receiving e-cigarette cessation support via smartphone technology. The findings reveal that young adults not only want support via smartphone apps, but also that they want this support to be as tailored and as flexible as possible to meet their personal needs. Prior research on app-based health interventions indicates that users prefer customizable features that meet their personalized needs [24-26]. Unfortunately, however, a recent evaluation of health-promoting apps revealed that most apps incorporate a static, one-size-fits-all approach when it comes to personalization [26]. This is likely contributing to the ongoing finding that most app-based interventions have a minimal effect compared with usual care [26], including cessation apps [27]. Enhancing personalization of these interventions would arguably enhance the effect of these interventions. In relation to e-cigarettes, capturing granular information from an end user would ensure that the app learns about the characteristics of the vape user, and uses this information to tailor the type and intensity of intervention and target different aspects of the quitting process on an individual level. Future research on harnessing end user data for improved personalization and the impact it has on outcomes is needed.

We also found that the participants welcomed receiving positive, nonjudgmental notifications and messages versus receiving messages around the negative impacts of e-cigarette during their quit attempt through an app. This finding is in line with previous research findings indicating that young adults who are ready to quit prefer positively framed messaging to support smoking cessation [28,29]. In addition, positive message framing has been found to be more persuasive in prompting smoking cessation compared with negative message framing [30].

However, one must be cautious when considering these findings in light of evidence that message framing should be considered in the context of the cessation trajectory [31], nicotine-dependence levels [32], and user characteristics, such as gender [33]. For example, Cornacchione and Smith [31] found that smokers were more receptive to positive message framing if they were moving from contemplation to preparation to quit. In this regard, positive message framing may be most effective and helpful when a user first signs up and during the early stages of quitting, with negative messaging an effective approach later on once their confidence and motivation are higher (eg, present what they would lose if they started e-cigarettes again). Future research on the preferences of young adults moving through the process of e-cigarette cessation is needed to determine the most effective messaging at different time points for different end users.

Tracking one's behavioral patterns was perceived as a critical component in an e-cigarette cessation app. To track user's behaviors and outcomes more precisely, designers should consider designing smart cases for e-cigarette products that could collect e-cigarette intake and related data and send them to the smartphone app for advanced analysis [34,35]. This could complement the mobile app–based e-cigarette cessation intervention. The VapeTracker, which tracks the number of puffs and puff duration by attaching it to an e-cigarette device, is an example of an external device that vapers perceived positively [35]. Exploring user preferences around how an external device could be engaged to support their e-cigarette cessation needs further study.

This study also indicated a difference in the preference of young men and women in the design of the app, with female participants wanting more tailoring in terms of the appearance of the app (such as background color, font size/color, greetings from the app when logged in) compared with male participants. In addition, according to the demographic questionnaire data, female participants often used e-cigarettes to cope with stress, which holds implications for incorporating stress management strategies (eg, meditation, exercise) into the app. We also observed that male participants preferred quitting cold turkey, whereas women preferred a more gradual approach toward quitting. This is similar to findings from research related to preferences for a smoking cessation app, where young men reported a preference for cold turkey and young women preferred a gradual approach to quitting [36]. It has been suggested that these preferences may tie into heteronormative narratives (eg, men can quit when they want; women are more open to receiving help), and that masculinities (eg, autonomy and ability) and femininities (eg, caring and emotionally attuned) carry potential in being leveraged to support behavior change [36]. These noted differences in preferences suggest that attention to health equity and gender influences is necessary when developing such interventions.

Comparison With Other Work

When examining other app-based interventions, only 3 were found in the iTunes and Apple stores (Quit e-Cigarettes, Escape the Vape, and Quit E-cigarette Addiction) that specifically targeted e-cigarettes (versus smoking or smoking and e-cigarette). None of these apps have been evaluated in the scientific literature to determine the level of personalization, social support, tracking features, and type of messaging. The text-messaging intervention (This is Quitting) [37] to help young people quit e-cigarettes has been evaluated. This program offers young people a minimum of 4 weeks of messages tailored to age and a resettable quit date, which are focused on skills and confidence building [37]. Results from a randomized control trial revealed that this program achieved 30-day point prevalence abstinence of 24.1% at 7 months compared with the control (18.6%) [12], adding support to our findings in relation to the value of personalization and positive-message framing. Our findings also suggest that there is an appeal among users for gamification and behavioral self-monitoring when it comes to e-cigarette interventions. Therefore, future researchers should consider how incorporating such features into a potential app might increase the acceptability of this type of cessation intervention, and explore the longevity of app-based e-cigarette cessation.

Researchers have indicated that there is an urgent need for research to inform vaping cessation programs for young adults and enhance an evidence base [38]. While the findings of our study fill some important content-related gaps, more research is needed to understand how a cessation app might account for the context of young adult vaping, including varying patterns of use, co-use with other products (eg, tobacco and cannabis), various perspectives and experiences with quitting, and various motives for both vaping and cessation [38]. Future research, therefore, not only needs to test features described in this study, but also needs to pay attention to the complexity of young adult vaping in order to successfully advance science in this area.

Limitations and Strengths

A limitation of this study is that it was conducted with 12 participants, and there may be additional views that are not represented in this sample. Further, given our recruitment procedures (online and through a university), we acknowledge that our findings are limited to a sample that has internet access and is likely pursuing a postsecondary education. We are, however, confident that the study provides important insights that can be used as a foundation for guiding the development of novel apps to support e-cigarette cessation. In addition, our findings do not account for new regulatory policies that may impact the way people vape and their needs for support (eg, policies around nicotine concentration, where you can vape, taxation on e-cigarettes). Therefore, our study does not account for the influence of a wide variety of e-cigarette policies and its impact on e-cigarette use. As such, an app would need to be attuned to those policies. Strengths of this study include equal representation of young women and men, providing a more equitable look at what end users would want from a cessation app. Another strength of the study is the use of inductive qualitative methods to identify key themes in relation to app features. This lends to a strong evidence base from which to move forward with recommendations.

Conclusion

In this qualitative study, we took an initial step to explore the preferences and perceptions of young adults on mobile

app–based e-cigarette cessation interventions. Participants provided suggestions on the content and design of the mobile app–based intervention for e-cigarette cessation. These suggestions provide direction for the development and testing of technology-based e-cigarette cessation interventions for young adults.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions.
[DOCX File , 14 KB - formative_v6i4e33640_app1.docx]

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Abbreviations

e-cigarettes: electronic cigarettes

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Original Paper

A Smart Mobile App to Simplify Medical Documents and Improve Health Literacy: System Design and Feasibility Validation

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Abstract

Background: People with low health literacy experience more challenges in understanding instructions given by their health providers, following prescriptions, and understanding their health care system sufficiently to obtain the maximum benefits. People with insufficient health literacy have high risk of making medical mistakes, more chances of experiencing adverse drug effects, and inferior control of chronic diseases.

Objective: This study aims to design, develop, and evaluate a mobile health app, MediReader, to help individuals better understand complex medical materials and improve their health literacy.

Methods: MediReader is designed and implemented through several steps, which are as follows: measure and understand an individual's health literacy level; identify medical terminologies that the individual may not understand based on their health literacy; annotate and interpret the identified medical terminologies tailored to the individual's reading skill levels, with meanings defined in the appropriate external knowledge sources; evaluate MediReader using task-based user study and satisfaction surveys.

Results: On the basis of the comparison with a control group, user study results demonstrate that MediReader can improve users' understanding of medical documents. This improvement is particularly significant for users with low health literacy levels. The satisfaction survey showed that users are satisfied with the tool in general.

Conclusions: MediReader provides an easy-to-use interface for users to read and understand medical documents. It can effectively identify medical terms that a user may not understand, and then, annotate and interpret them with appropriate meanings using languages that the user can understand. Experimental results demonstrate the feasibility of using this tool to improve an individual's understanding of medical materials.

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KEYWORDS

health literacy; knowledge graph; natural language processing; machine learning; medical entity recognition

Introduction

Background

Effective communication in health care has an enormous impact on the health and safety of patients. Limited health literacy is one of the major obstacles to good health care results including health status, health outcomes, health care use, and health costs for patients [1]. Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [2]. In today's health care systems, patients are expected to read long lists of complex health care documents, such as detailed home care guidelines, medication information, consent forms, discharge instructions, insurance summaries, and health educational materials. Misunderstanding of such information can lead to negative results. Unfortunately, many of these materials are difficult to understand. New medical achievements have introduced new jargon, descriptions, and medical terminologies, making it even more difficult to comprehend, even for individuals with sufficient literacy. Studies have shown that people with insufficient health literacy know less about their illness, lack proper health

self-management knowledge, and have few precautionary measures for their health [3].

However, according to the US Department of Health and Human Services, only 12% of adults in the United States have proficient health literacy, whereas more than one-third of adults have low health literacy levels, which make it difficult for them to deal with common health tasks such as following directions for how to use prescription medications [4]. Low health literacy is a serious problem, especially in underrepresented racial or ethnic groups and older adults [4]. For example, the proportion of adults with basic or below basic health literacy ranges from 28% among White adults to 65% among Hispanic adults [5]. Adults aged ≥65 years are more likely to have below basic or basic health literacy skills than those aged <65 years. The proportion of adults at these lower levels of literacy was greatest for those aged >75 years [4]. Centers for Disease Control has been engaged in the plain language effort to encourage communication effectively in culturally appropriate ways. Although using plain language is a promising idea, many organizations do not use it as often as they should [6].

Objectives

Given the aforementioned gap between the current health information and people's poor understanding of this information to make life-altering decisions, many policies and strategies have been proposed by policy makers, administrators, educators, and health care professionals to simplify medical information and improve health literacy. Besides these efforts, there is an increasing need to provide tools to facilitate people to understand medical information. This may enhance the patient-physician relationship and improve health care outcomes by reducing the incidence of morbidity, mortality, and misuse of health care [7]. For this purpose, in this paper, we propose a mobile health (mHealth) app to help users understand complex medical documents and improve their health literacy. On the basis of a user's health literacy level, the tool will translate into or interpret a complex medical document in languages that the user is familiar with and at appropriate reading levels. Evaluation surveys are provided to users to evaluate the effectiveness of this tool and the users' satisfaction. This tool will help to make health information accurate, accessible, and actionable.

Methods

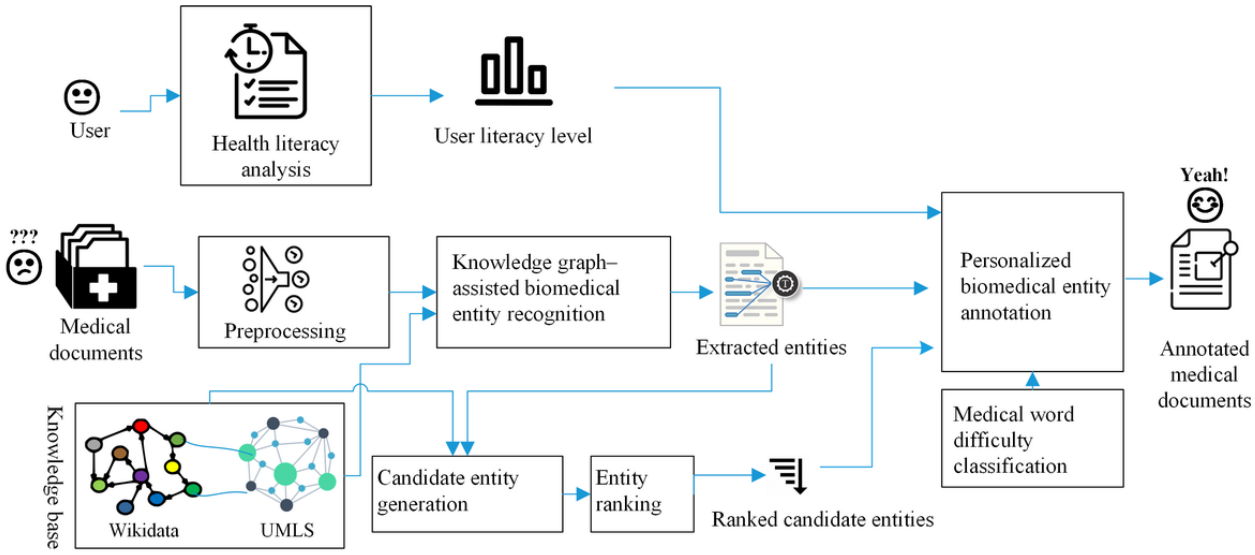
Ethics Approval

This study was approved by the institutional review board of North Dakota State University (IRB0003857).

System Overview

The goal of the system is to design a mobile app to remove people's barriers to understanding difficult medical documents by annotating or interpreting medical terminologies with plain texts, which they can understand easily. The app, MediReader, is built based on comprehensive knowledge sources and artificial intelligence–based processing mechanisms. It annotates a medical document with external knowledge according to each user's health literacy level. Figure 1 illustrates the architecture of the proposed system. First, MediReader identifies a user's health literacy level. Then, it annotates the documents such that it is tailored to the user's skill level. Medical terms will be identified with the help of external medical dictionaries. Then, based on the user's health literacy level, *complex* medical entities will be linked to and explained by entities in the external knowledge base or data set. The complexity of a term is relative to the specific user; therefore, users with different health literacy levels may obtain different annotation results. We present the details of the system components in the following subsections.

Figure 1. The architecture of the system. UMLS: Unified Medical Language System.



Knowledge Base Construction

We created a comprehensive medical knowledge base by integrating multiple publicly available knowledge sources, including Unified Medical Language System (UMLS) [8] and Wikidata [9]. Specifically, we used UMLS's three knowledge resources: Metathesaurus, semantic network, and specialist lexicon and lexical tools. Vocabularies gathered in the UMLS Metathesaurus include the National Center for Biotechnology Information taxonomy [10], gene ontology [11], Medical Subject

Headings [12], Online Mendelian Inheritance in Man [13], Digital Anatomist Symbolic Knowledge Base [14], Systematized Nomenclature of Medicine–Clinical Terms [15], International Classification of Diseases and Health-Related Problems–10th edition [16], Medical Dictionary for Regulatory Activities [17], and others. Wikidata is a multidisciplinary ontological database that encompasses many medicine-related entries such as human genes, human proteins, diseases, drugs, drug classes, therapies, human arteries, human muscles, human nerves, medical specialties, surgical procedures, human veins, pains, human bones, human enzymes, syndromes, human joints, and human ligaments.

User Health Literacy Measurement

The objective of our health literacy measurement was to identify the degree to which individuals can understand health information and services. We studied many health literacy screening and measurement approaches, including the National Assessment of Adult Literacy [4], Rapid Estimate of Adult Literacy in Medicine [18], Test of Functional Health Literacy in Adults [19], Newest Vital Sign [20], Wide Range Achievement Test [21], ComprehENotes [22], and so on. We adopted the recently proposed approach, ComprehENotes, as our literacy screening approach, as its questions are sufficiently general to be applicable to a wide variety of individuals while still being grounded in specific medical concepts. Most of the questions have low difficulty estimates, which makes the test appropriate for screening for low health literacy. We chose questions from the question set of ComprehENotes that is created from real patients' electronic health records (EHRs) [22]. Experts including physicians and medical researchers identified important concepts from the EHR of six common diseases (heart failure, diabetes, cancer, hypertension, chronic obstructive pulmonary disease, and liver failure). Medical experts believe that these concepts are important for patients to understand the EHR materials. The test questions were designed to assess the comprehension of these concepts.

We chose a subset of ComprehENotes' questions to perform user evaluation, as a test with fewer questions can be administered more quickly than the full test. The subset of the questions should be sufficiently informative to identify different health literacy levels. We used the item response theory (IRT) [23] to choose a good subset of questions. IRT models the relationship between latent traits (unobservable characteristics or attributes) and their manifestations (ie, observed outcomes, responses, or performance) [24]. IRT has been widely used to analyze individuals' responses (graded as right or wrong) to a set of questions. IRT predicts the performance of a test by jointly modeling individual ability and item characteristics. Using IRT, we repeatedly removed questions that cannot distinguish between individuals with high ability levels and individuals with low ability levels. Then, we identified n (n<55) questions from the original 55 questions with the largest discrimination capability and highest average information for inclusion in the short form of the test to make it as informative as possible.

ComprehENotes uses the IRT model that is widely used in education to calibrate and evaluate items in tests, questionnaires, and other instruments and to score participants on their abilities, attitudes, or other latent traits. Specifically, we applied the 3-parameter logistic model, in which the item characteristic curves are assumed to follow a logistic function with a nonzero lower asymptote:

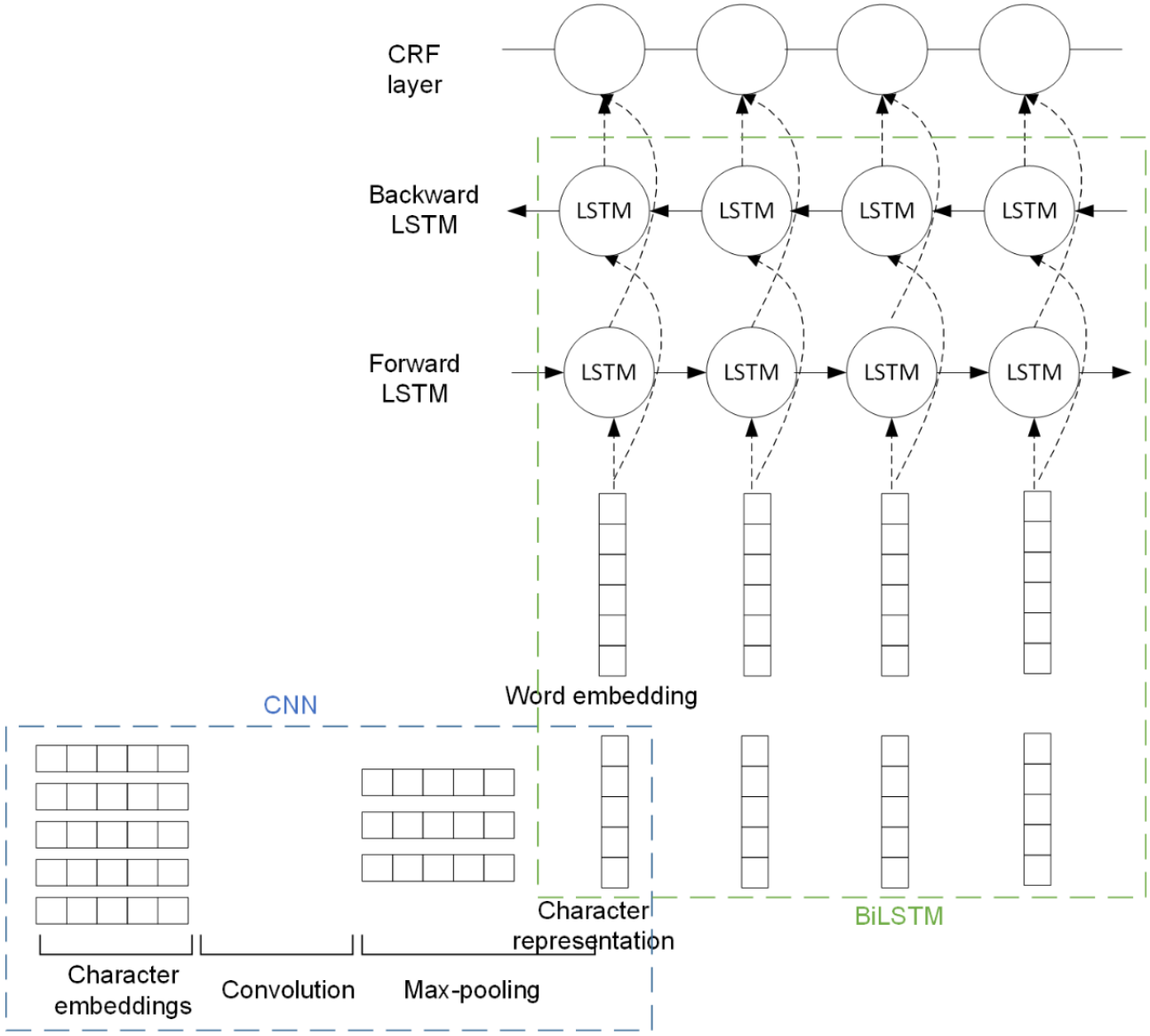
In the above equation, Pij is the probability that person j answers item i correctly, and θj is the ability level of individual j. In our project, θ represents the ability of an individual in the task of medical document comprehension. As individuals are assumed to be sampled from a population, their ability levels are assumed to have a random effect with a standard normal distribution. Therefore, a score of 0 is considered as average (ie, in the 50th percentile), scores >0 are considered as above average, and scores <0 are considered as below average.

Medical Entity Identification

In this task, medical entities in a document, such as diseases, medical problems, drug names, tests, and examinations, will be identified. Existing research on biomedical named entity recognition can be classified into three types: rule-based [25], dictionary-based [26], and machine learning–based approaches [27]. Machine learning–based approaches are more accurate and stable than rule-based and dictionary-based approaches, as machine learning–based approaches have the potential to manage features with high dimensions and find new terms and variants based on the learning trends.

MediReader uses the so-called *BiLSTM-CNN-CRF* deep learning neural tagging network based on works of Lample et al [27] and Ma et al [28]. This network combines bidirectional long short-term memory (BiLSTM) [29], convolutional neural networks (CNNs) [30], and conditional random field (CRF) [31] to enable effective entity recognition. The overall architecture of the proposed neural network is shown in Figure 2.

Figure 2. Bidirectional long short-term memory (BiLSTM), convolutional neural networks (CNNs), and conditional random field (CRF) neural network architecture.



Word embedding [32] is used to transform words into low-dimensional vectors, so that the semantics of words and relationships between them can be captured. In our model, we use publicly available pretrained word embeddings from large medical corpora to accurately represent the meaning of each entity in the medical and health care domain. The word embeddings we used included global vectors embeddings [33] and a new embedding we generated using concepts that we extracted from the MedMentions data set [34]. In addition to word embedding, character-level embedding was used to represent input tokens. A CNN was used to encode the character-level information of a word.

For each word, the character-level representation was computed by the CNN with character embeddings as inputs. Then, the combined character-level and word-level encoding were fed into a BiLSTM to model the context information of each word. LSTMs [29] are variants of recurrent neural network [35], designed to cope with the gradient vanishing problems of recurrent neural network. A total of 2 LSTMs were used so that each sequence can be presented forward and backward to 2 separate hidden states to capture both the past and future information, respectively. Then, the 2 hidden states were concatenated to generate the final output. Finally, the output vectors of BiLSTM were fed into a CRF layer to jointly decode the best labels for the whole sentence.

Medical Entity Linking

After the medical entities (referred to as *mentions* in this section) were identified from a document, they were mapped into appropriate entities defined in the knowledge base that has rich information describing the mentions and their relationships with other entities. Then, the entities defined in the knowledge base can be used to explain the mentions in the document. Owing to of text ambiguity, the same mention can often refer to many different entities depending on the context, as many entity names tend to be polysemous. This task was executed in two steps, namely, candidate generation and candidate ranking.

To link mentions to the right entities defined in a knowledge base, the system needs to generate a manageable candidate list containing possible entities that the mention may refer to. In

our system, the knowledge base entries were retrieved from a subset of the UMLS concepts data set and extended using Wikidata [9]. Wikidata is a multidisciplinary ontological database that encompasses many medicine-related entries, such as human genes, human proteins, diseases, drugs, drug classes, therapies, and so on. All these items are connected to create an extensive biomedical taxonomy using taxonomic Wikidata properties [36]. Wikidata was used as a secondary database, relying mainly on other resources to match its content. Wikidata connects with UMLS through its concept unique identifier. We used the taxonomic properties of Wikidata, such as the instance of (P31), subclass of (P279), part of (P361), and has part (P527), to extend an entity.

Entities (concepts and aliases) in the knowledge base were encoded using term frequency-inverse document frequency scores of character n-grams (n=3 in our implementation) that appears more than a certain number of times in the knowledge base. Then, the k-nearest neighbor search was applied to generate candidate entities for linking a given mention.

Entity linking may encounter the problem of entity ambiguity; that is, 1 mention may be mapped to several candidate entries in the knowledge base. For example, the word *cold* has multiple meanings even in the medical domain including *common cold*, *cold sensation*, and *chronic obstructive airway disease (cold)* [37]. In the candidate ranking phase, we disambiguated the candidate entities using the word sense disambiguation system proposed by Stevenson et al [38]. This system leverages the context in the text and combines various types of information including linguistic features and knowledge sources specific to the biomedical domain. The domain-independent linguistic features include local collocations and salient bigrams and unigrams. For knowledge sources, UMLS concept unique identifier and Medical Subject Headings were considered. Vector space model [39] was used as the learning model.

Personalized Annotation

After mentions in the document and entities in the knowledge sources were linked, annotation was performed. Annotating all medicine-related mentions is unnecessary as readers may know many of them. By contrast, a full annotation may cause discomfort to readers. Therefore, the system needs to determine which mentions should be annotated. MediReader proposes a personalized annotation scheme that annotates a mention based on an individual reader's health literacy level, as discussed in the previous section. For readers with very low literacy levels, more mentions should be annotated, and the annotation should be easy to understand. For readers with high literacy levels, only complex medical terms should be annotated.

Medical term's difficulty and readability assessment was approached as a classification problem. We used a feature set with many features commonly used for standard natural language processing, such as grammatical metrics, semantic metrics, and new composite metrics. We also added new features to the biomedical domain to make the classification specialized in this field. The feature set included the following items:

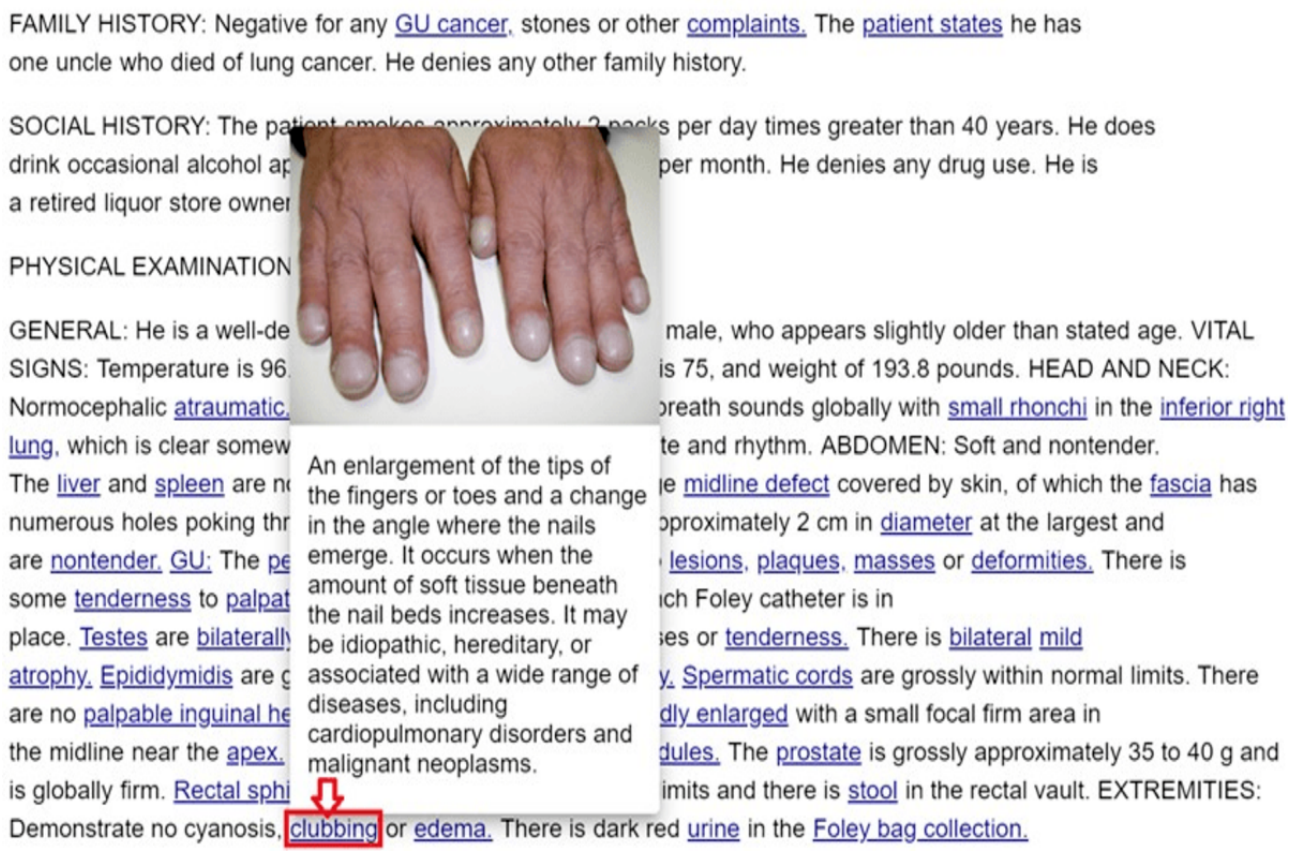
1. Syntactic categories; for example, nouns, adjectives, proper names, verbs, and abbreviations
2. Number of characters and syllables in the word
3. Prefixes and suffixes of the word
4. Number and percentage of consonants, vowels, and other characters (ie, hyphen, apostrophe, and commas)
5. Presence of words in WordNet
6. Word frequency in Google
7. Word frequency in UMLS
8. Word semantic categories in UMLS
9. Pretrained word embeddings using MedMentions

To build our data set, we extracted medical concepts from the website of Medical Transcription Samples [40], which contains a vast collection of transcribed medical transcription sample reports of many specialties. We used the data set to train a prediction model that again used the BiLSTM-CNN model. We extracted 1000 terms from the website. We used 6 graduate students (n=1, 17% native English speaker and n=5, 83% nonnative speakers) to identify whether they can understand the meaning of each of the 1000 words. If a word received 6 positive answers, it was labeled as easy. If it received 5 or 4 positive answers, it was labeled as medium. If it received <4 positive answers, it was labeled as difficult. These labeled terms were used to train the classification system.

On the basis of a reader's health literacy level, medical mentions were annotated. For readers with high health literacy levels, only difficult words were annotated. For readers with low health literacy levels, medium and difficult words were annotated. We did not annotate easy words such as *fever*, *wound*, *operation*, and so on. In addition, medical stop words were removed before the entity linking process.

Each entity was annotated with its definition in the knowledge source. In addition, they were linked by taxonomic relations, such as *instance of*, *subclass of*, and *part of* and major nontaxonomic associative relations (eg, *drug used for treatment* and *risk factor*) to allow a reader to better understand the various aspects about the concept. Figure 3 shows a screenshot of an annotated document for readers with low health literacy levels.

Figure 3. Screenshot of an annotated document.



Results

Test Setup

We implemented the MediReader prototype system as a mobile app. We conducted a set of evaluation tests with representative users to assess the technical viability and effectiveness of this app. To conduct the test, we developed a test plan, recruited participants, and then, analyzed and reported our findings. In our study, we used 2 types of quality metrics that combine to form the big construct we call *usability*. One type of metric was objective criteria, and the other type was subjective criteria.

For the *objective* quality measurement, we invited participants to use MediReader and created a set of tasks for them to complete. Then, we recorded the time they spent on the tasks, their success rates, and errors. For comparison, a control group was also used to perform the same tasks but without the help of MediReader. In our test, we used the same participants to act as both the experimental and control groups. Specifically, the task was to ask users to read 2 sets of medical documents; each set contains 3 physicians' notes on three different diseases, namely, endometrial adenocarcinoma, bladder cancer, and breast calcifications. We tried to choose common and familiar diseases that involve unfamiliar vocabularies. Cancer is a familiar disease. However, many cancer-related documents are difficult to understand. Therefore, we chose two types of cancer: endometrial adenocarcinoma (uterine cancer) and bladder cancer. Breast calcifications are common among women; thus, we chose it as the third disease. One set of documents was annotated using MediReader, and the other set was original medical documents without any annotation. Each set of documents contained 12 questions related to the notes to identify whether the participants can understand the notes. All questions were multiple-choice with 3 answers, and only 1 of them was correct. These notes focused on different diseases and treatments and were randomly selected from real-world web-based physician notes [40]. For a particular participant, one set of documents was randomly selected and annotated using our app, and the other set of documents was shown to the participants without any annotation. In this way, we created a control group that read the same physician notes as the experimental group and answered the same set of questions, but without the help of MediReader. Before the task, health literacy tests were conducted to assess the participants' health literacy skills (high and low only).

We also performed a *subjective* evaluation of the system through a user satisfaction survey. We surveyed participants with 6 satisfactory questions after they used our MediReader prototype system. All the questions were measured using a 4-point Likert scale that ranged from strongly disagree (rating=1) to strongly agree (rating=4).

Before conducting the test, we conducted a pilot study to verify our programming, database, and scoring. We expected that some participants may not read the assigned documents and questions and may choose random answers. To eliminate such responses, we included qualifying questions in different sections. In each multiple-choice section, we added 1 question that could easily be answered correctly if the participant read it. Participants who did not answer these questions correctly were eliminated from the data set.

Test Outcome

Owing to the difficulty in recruiting participants, we had to include as many participants as possible. Therefore, we only required the participants who were aged ≥18 years and knew English. A total of 52 individuals participated in our test. Among the 52 individuals, 13 (25%) individuals did not complete the test and 11 (21%) individuals were disqualified based on our qualifying questions. The remaining 54% (28/52) of the participants completed the test successfully. Table 1 shows the basic demographic information about the participants.

Table 1. Demographic information of the participants (N=28).

Variable	Value, n (%)
Sex	
Men	13 (46)
Women	15 (54)
Age (years)	
40-50	4 (14)
30-39	7 (25)
20-29	17 (61)
Education	
Undergraduate	19 (68)
Postgraduate	9 (32)
Health literacy level	
Low	10 (36)
High	18 (64)

We compared the average scores between the experimental and control groups for all the questions. We noticed that the experimental group significantly exceeded the control group, as they scored 76% compared with 36% for the control group, which means that participants who were provided with medical documents annotated using our tool had a higher score than those who were given documents without annotation.

In terms of the time spent for the reading test, we found that the experimental group spent more time than the control group (29 minutes and 24 minutes, respectively). From the participants' comments, we learned that they spent time in reading more information about the annotated terms and other information related to the term. We believe that this explains why the experimental group spent more time in the test.

Table 2 demonstrates that the contents of the medical documents affect the participants' reading and impact our tool's performance. For example, regarding the first type of document, that is, the document about endometrial adenocarcinoma (disease 1 in Table 2), the control group obtained a score of approximately 60% when they read unannotated documents. However, the score moderately increased to approximately 70% for experimental groups when they read the same document annotated using our tool. For the third type of document, that is, the document about breast calcifications (disease 3 in Table 2), there was great increase (from 27% to 87%) in the scores for the experimental group compared with the control group.

Table 2. Comparison of the average scores of the experimental and control groups on different medical domains or diseases.

Disease and group	Score, mean (SD)
Disease 1	
Experimental	70 (0.35)
Control	60 (0.32)
Disease 2	
Experimental	74 (0.39)
Control	26 (0.29)
Disease 3	
Experimental	87 (0.19)
Control	27 (0.16)

Our tool has a different impact on participants with different health literacy levels. The average score increased from 36% to 88% for participants with high health literacy levels. For participants with low health literacy, the score greatly increased from 17% to 85%.

Table 3 shows the detailed scoring of the experimental and control groups with different health literacy levels for different medical subjects. The scores increased for the participants in the experimental group, who read annotated medical reports regardless of their level of health literacy. For documents on endometrial adenocarcinoma (disease 1), the score for the participants with low literacy in the experimental group showed a moderate increase of approximately 20%; the increase was lower (10%) for participants with high health literacy. The experimental group showed great increase in the average score for the questions related to bladder cancer (disease 2) and breast calcifications (disease 3) for participants with both high and low health literacy levels. The score for participants with low health literacy increased considerably from 12.5% in the control group to approximately 61% in the experimental group for documents related to bladder cancer (disease 2). The score for participants with high health literacy increased from approximately 43% in the control group to approximately 86% in the experimental group for the same type of documents. Similarly, for questions about breast calcifications (disease 3), the average score increased from 36% to 88% for participants with high literacy and from 17% to 85% for participants with low literacy.

We applied the Wilcoxon rank-sum test [41] to determine the differences between the experimental and control groups. *P* value <.05 was considered as significant. Regarding endometrial adenocarcinoma (disease 1) document, the difference between the experimental group and control group was not significant (*P*=.54 for participants with high literacy and *P*=.20 for participants with low literacy). On the other hand, there was significant difference in the score for the participants who solved questions on disease 3 (breast calcifications; *P*=.002 for participants with high literacy and *P*=.002 for participants with low literacy). For participants who dealt with the document about bladder cancer (disease 2), there was significant annotation effect only on users with high health literacy (*P*=.02); for participants with low health literacy, the difference was not significant (*P*=.06).

Table 3 summarizes the detailed scoring of the experimental and control groups and shows the *P* values.

To identify participants' overall satisfaction, they were asked to provide their satisfaction feedback regarding the use of the mobile app. The participant satisfaction analysis showed that, in general, the participants were satisfied with the mobile app. As shown in Table 4, most participants agreed (18/28, 64% strongly agreed, and 6/28, 21% agreed) that the app helped them understand the medical documents better. Only 14% (4/28) of the participants disagreed (1/28, 4% strongly disagreed, and 3/28, 10% disagreed). Similarly, as shown in Table 4, most participants agreed that the app was easy to use and that they would recommend it. Regarding whether appropriate medical terms were annotated, 43% (12/28) of the participants strongly agreed, and 46% (13/28) of the participants agreed that the app annotated medical terms, as shown in Table 4.

Table 3. Comparison of the average score and *P* values of the experimental and control groups with different health literacy levels on different medical domains or diseases.

Disease, health literacy level, and group	Score, mean (SD)	*P* value
Disease 1		
High		.54
Experimental	71 (0.30)	
Control	62 (0.23)	
Low		.20
Experimental	67 (0.42)	
Control	46 (0.25)	
Disease 2		
High		.02
Experimental	86 (0.26)	
Control	43 (0.25)	
Low		.06
Experimental	61 (0.49)	
Control	12.5 (0.25)	
Disease 3		
High		.002
Experimental	88 (0.16)	
Control	36 (0.15)	
Low		.002
Experimental	85 (0.23)	
Control	17 (0.11)	

Table 4. Overall feedback regarding the use of the mobile app (N=28).

Survey question	Strongly agreed, n (%)	Agreed, n (%)	Disagreed, n (%)	Strongly disagreed, n (%)
The application helped me understand medical documents better	18 (64)	6 (21)	3 (10)	1 (4)
The application was easy to use	18 (64)	4 (14)	4 (14)	1 (4)
I will recommend the application to others	18 (64)	6 (21)	3 (11)	1 (4)
The application annotated appropriate medical terms	12 (43)	13 (46)	2 (7)	1 (4)

Discussion

Principal Findings

People need to understand medical information to have the best chance of a good health outcome. However, understanding medical information is more difficult than what most people realize, as it requires a certain degree of health literacy. To assist people in understanding medical documents, we designed, developed, and evaluated a mobile app, MediReader. MediReader uses external knowledge sources to annotate medical documents according to each user's health literacy level. Algorithms based on machine learning and natural language processing have been proposed and implemented to recognize medical entities, identify the complexity of medical terms, and link medical terms to external knowledge that can explain the terms. MediReader was evaluated through task-based user studies with a control group and users' satisfaction survey.

On the basis of the comparison with a control group, the test results demonstrate that MediReader can improve users' understanding of medical documents. This improvement is particularly significant for users with low health literacy levels. The satisfaction survey shows that users are satisfied with the tool in general. The result also shows that some medical information is more difficult to understand than others, even with the help of MediReader. In summary, our study demonstrated that it is feasible and effective to implement an mHealth tool to help people better understand medical documents.

MediReader simplified medical documents for the general public and improved their understanding, whereas most existing annotation tools, such as MetaMap [42] and Clinical Text Analysis and Knowledge Extraction System [43], were designed for medical professionals such as physicians, medical students, and biomedical researchers. It is not clear how these tools will benefit the general users. MediReader adapts its interface based on users' health literacy, whereas most existing tools (eg, National Center for Biomedical Ontology Annotator [44] and BioMedical Concept Annotation System [45]) do not distinguish between users. MediReader uses an effective machine learning mechanism to locate medical terms and subsequently link and explain medical terms that are most appropriate for the given context. Many existing systems (such as National Center for Biomedical Ontology Annotator [44] and ConceptMapper [46]) have adopted the dictionary-based matching that lacks disambiguation ability; they only list all meanings of the annotated entity.

Limitations and Future Work

This study had some limitations. The qualitative evaluation was performed with limited participants and most of them were college students. The results that will be obtained if it is conducted on underrepresented racial or ethnic groups and older adults remains questionable. More comprehensive user studies will be performed on a large population to evaluate the usability, satisfaction rate of users, and health and quality of life-improvement outcomes.

Some medical information is still difficult to understand even after our tool's annotation. Through our test, we found that some medical terms are annotated with annotations and definitions that are difficult to understand, especially when the annotations are retrieved from professional medical resources such as the UMLS vocabularies. We will work on exploiting more information sources (eg, Google Knowledge Graph) to enrich and simplify the annotation.

When a new document is loaded, there is a delay in providing the annotations to the users. We will continue to optimize our algorithms in natural language processing and machine learning to reduce the execution time. In addition, we plan to encode frequently used knowledge and store it in the storage memory of the device to further reduce the delay.

Conclusions

Limited health literacy may restrict an individual's participation in health contexts and activities. To help people improve their health literacy and understand medical documents better, in this study, we proposed and evaluated an mHealth app, MediReader. The app annotates medical documents with information that people can understand. Our experiments demonstrated that this tool can help users better comprehend the contents of medical documents. It is especially useful for people with low health literacy levels. From our test, we found that low health literacy does not necessarily correspond to general low literacy; individuals who may be extremely literate in their areas of expertise (eg, graduate students) may also have a problem in understanding medical terminology. Further research is needed to overcome the limitations of this study.

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Conflicts of Interest

None declared.

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Abbreviations

BiLSTM: bidirectional long short-term memory
CNN: convolutional neural network
CRF: conditional random field
EHR: electronic health record
IRT: item response theory
mHealth: mobile health
UMLS: Unified Medical Language System

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Original Paper

An Evaluation of Real-world Smart Sock–Based Temperature Monitoring Data as a Physiological Indicator of Early Diabetic Foot Injury: Case-Control Study

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Abstract

Background: Lower extremity complications of diabetes represent major health care complications both in terms of cost and impact to quality of life for patients with diabetic peripheral neuropathy. Temperature monitoring has been shown in previous studies to provide a useful signal of inflammation that may indicate the early presence of a foot injury.

Objective: In this study, we evaluated the temperature data for patients that presented with a diabetic foot injury while using a sock-based remote temperature monitoring device.

Methods: The study abstracted data from patients who were enrolled in a remote temperature monitoring program (2020-2021) using a smart sock (Siren Care). In the study cohort, a total of 5 participants with a diabetes-related lower extremity injury during the study period were identified. In the second comparison cohort, a total of 26 patients met the criteria for monitoring by the same methods but did not present with a diabetes-related podiatric lower extremity injury during the same period. The 15-day temperature differential between 6 defined locations on each foot was the primary outcome measure among subjects who presented with a diagnosed foot injury. Paired *t* tests were used to compare the differences between the two groups.

Results: A significant difference in temperature differential (temperature measured in °F) was observed in the group that presented with a podiatric injury over the course of evaluation versus the comparator group that did not present with a podiatric injury. The average difference from all 6 measured points was 1.4 °F between the injury group (mean 3.6, SD 3.0) and the comparator group (mean 2.2, SD 2.5, t=–71.4, df=39; P<.001).

Conclusions: The results of this study suggest temperature monitoring in a sock form factor could be used to predict a developing foot injury. The continuous temperature monitoring system employed has implications for further algorithm development to enable early detection. The study was limited by a nonrandomized, observational design with limited injuries present in the study period. We look forward to further studies that will refine the predictive potential and confirm or refute the current promising data.

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KEYWORDS

diabetes; diabetic foot ulcer; temperature monitoring; Charcot foot; digital health; wearable; neuropathy; remote patient monitoring; foot ulcer; monitoring device; patient monitoring

Introduction

Diabetic foot ulcers (DFUs) represent a major challenge for the health care system as both a major contributor of health care cost and the greatest single contributor to lower limb amputation [1]. DFUs are estimated to cost public and private payers in the United States US $9-13 billion in addition to the costs associated with diabetes itself [2].

To curtail the devastating ramifications of DFUs, greater efforts have been made toward prevention. One method of early detection that has been studied is the use of temperature monitoring, which has been shown to be a surrogate marker. The elevation of temperature is from inflammation that may be potentially due to and a precursor to tissue injury. The predictive potential of temperature monitoring to detect ulceration was first proposed in 1994 by measuring mean plantar foot temperature by Benbow et al [3]. The potential for foot temperature monitoring was further advanced by Armstrong et al [4], who demonstrated the potential of measuring 6 sites on each foot, with a temperature differential of >4 °F signaling an inflammatory response significant enough to either warrant a change in behavior or seek medical attention. The authors concluded high temperature gradients between feet may predict the onset of neuropathic ulceration, and self-monitoring may reduce the risk of ulceration. Their results showed patients using temperature monitoring were one-third less likely to develop an ulcer compared with the standard therapy group. Armstrong's study and others have led to the inclusion of temperature monitoring in the guidelines for management of the diabetic foot [5].

The introduction of new technologies for the remote temperature monitoring of patients with diabetes and neuropathy at risk of ulcer formation suggests more patients may be able to use temperature monitoring in their daily lives. One such technology, Siren Socks (Siren Care), is a smart sock worn by patients; it has a regular connection to the cloud for the capture and sharing of temperature data with health care professionals. Siren Socks are available for patients under the supervision of a physician. Reyzelman et al [6] first evaluated Siren Socks in a 35-patient study and found the temperatures measured by the stand-alone sensors were within 0.36 °F of the reference standard. Patients reported the socks were comfortable and easy to use, ranking them at a median score of 9 and 10 on a 10-point scale for comfort and ease of use, respectively.

In this study, we review the actual temperature recordings and real-world monitoring data from patients using remote temperature monitoring. The purpose of this study is to investigate any significant difference of foot temperature prior to the presentation of a foot injury as confirmed by a medical diagnosis.

Methods

Study Design

Patients were retrospectively reviewed in the Siren Care data registry between December 1, 2020, and April 15, 2021. Inclusion criteria consisted of patients who had greater than 50 days of wear of the Siren Socks temperature monitoring device during the study period. To be eligible to use Siren Socks, patients needed to have a diagnosis of peripheral neuropathy. The study cohort included patients in the database who had a diagnosed lower extremity injury that presented itself during the study period. The 15-day period prior to the diagnosis of an injury was reviewed, and a total of 900 minutes of temperature monitoring were analyzed during the period. For the control cohort, patients meeting the same criteria of wear (ie, diagnosed with peripheral neuropathy) without reported foot injuries in the study period were selected. For the control cohort, the temperature monitoring data for a randomly selected 900 minutes over a randomly selected 15 days were chosen for comparison.

The temperature data were reviewed retrospectively for a 15-day period before the presentation of an injury to a medical professional. For comparison, a similar 15-day period of temperature monitoring was reviewed for other patients who wore the Siren Socks but did not present with an injury in the study period.

Description of Temperature Monitoring Workflow

Patients in both cohorts were prescribed remote patient monitoring socks by their podiatrist. The patients in both cohorts were under the care of a podiatrist who directed a licensed practical nurse (LPN) to regularly monitor these patients based on temperature monitoring data, and to escalate any identified issues to their attention for possible clinical follow-up and intervention. Each patient had continuous measurements of temperature taken at 6 points on each foot (hallux, heel, arch, metatarsal 1, metatarsal 3, and metatarsal 5). The temperature is measured automatically throughout the day. The socks turn on when worn and turn off automatically when no longer worn. No charging is required, and data transmission does not require a smartphone. A hub is plugged into the wall for data transmission, and monitoring data is also stored on the socks to allow for monitoring when away from home.

Data are collected at each point in the foot, and the temperature differential between each right and left point is computed each minute. Finally, the daily average temperature differential is computed for each area on the foot and each patient. Figure 1 and Figure 2 are examples of the data capture for study patients.

Figure 1. The temperature difference of a patient who developed a foot ulcer. The green plot reveals the baseline measurements, the red plot shows the 15 days before the ulcer was diagnosed, and the grey plot shows the active ulcer period.

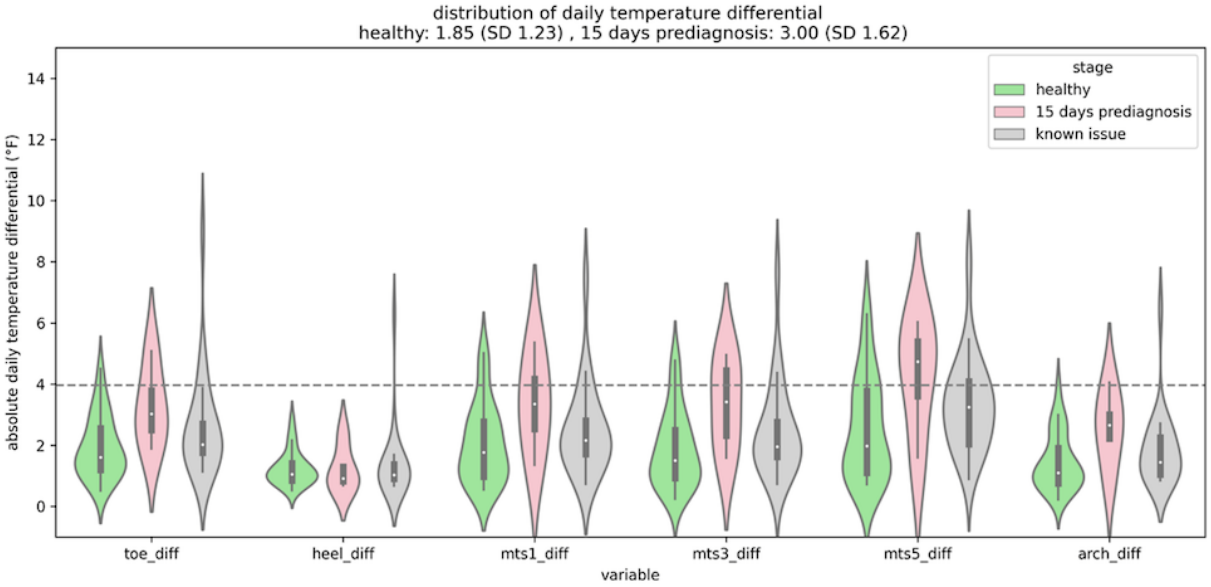
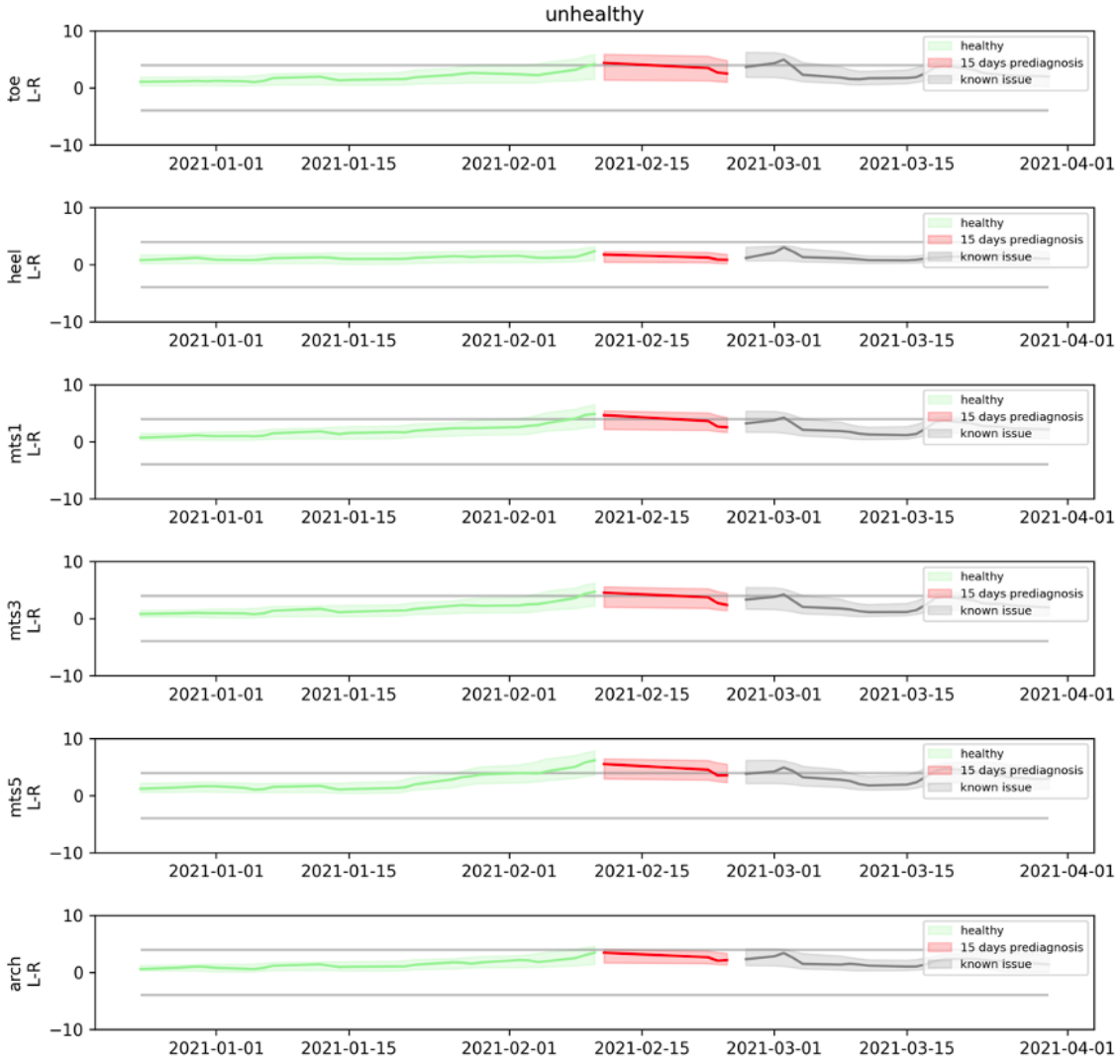


Figure 2. The temperature differentials measured over the study period for a patient who developed an ulcer at the right fifth metatarsal (mts) location. The green plot represents the baseline period, the red plot is the period 15 days prior to the ulcer presenting, and the grey plot is the period after the issue was diagnosed by a medical professional. Changes in temperature trends are noticeable even before the 15-day period, suggesting earlier detection of foot ulcers might be possible.



Description of Follow-up Routine

The data from the remote patient monitoring device were reviewed by LPNs under the supervision of a podiatrist. Any temperature differentials greater than 4 °F sent an alert to the LPN that required follow-up via a phone call to the patient. In each case, the sustained level of temperature rise with the possible presentation of an injury caused the patient to be referred to the clinic for evaluation. In the case of the control cohort, the temperature was monitored using the same method used for the study cohort, and the same alert criteria for temperature differential and follow-up routine were used.

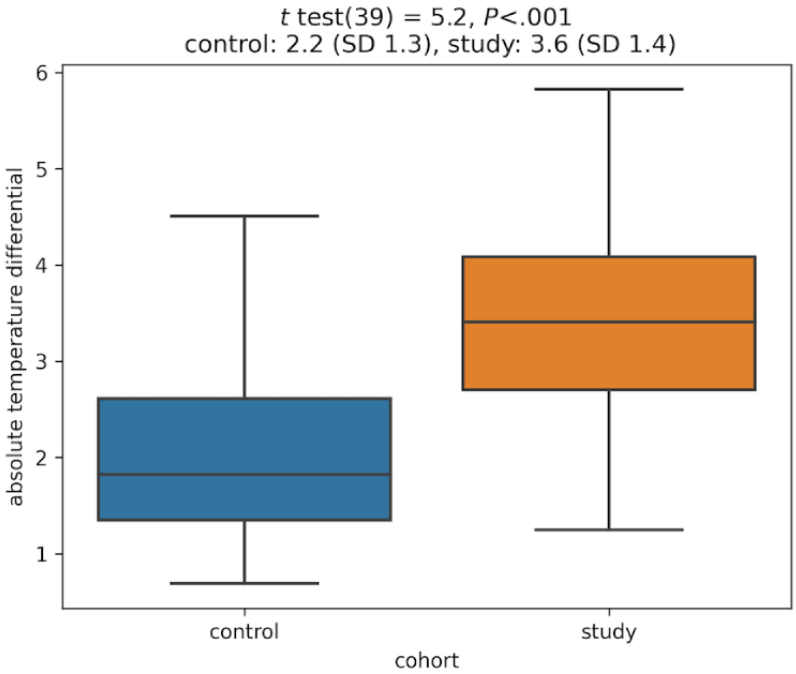
Description of Outcome Measures

The primary outcome measure is the difference in temperature between two points on the feet of a patient.

Statistical Analysis

A Welch *t* test was applied to determine that the mean temperature deviation in the study cohort was significantly higher than the control cohort (Figure 3) ($P<.001$). The analysis was performed using SciPy v1.6.3 programmed in Python (Python Software Foundation).

Figure 3. Comparison of the average temperature differential between two cohorts.



Ethics Approval

This study was approved by the WCG IRB (study number 12843666). If an individual wished to participate in the study, they were informed about the study objectives, and they could consent through a mobile app or over the phone after having started using the socks.

Results

A review of the relevant patient demographics is presented in Table 1. None of these differences are considered clinically relevant in terms of temperature data observations. During the observation period, a total of 5 patients presented with lower extremity injury with a temperature differential of 4 °F compared to the contralateral foot. The profile of each injury is listed in Table 2.

Table 1. Patient demographics.

Criteria	Study cohort (N=5)	Control cohort (N=26)
Average age (years)	66.0	70.4
Sex, n		
Female	1	9
Male	4	17
Additional diagnosis, n (%)		
Diabetes	3 (60)	24 (92)
Peripheral artery disease	2 (40)	5 (19)

Table 2. Study cohort.

Injury type	Age (years)	Patient history	Clinical notes
Charcot arthropathy	68	Neuropathy, type 1 diabetes	5-6 days of hotspots. Patient saw provider in clinic for diagnosis of early onset Charcot. Treatment: stay off of foot, use CAM[a] walker, x-rays of right foot.
Ulcer	75	Type 2 diabetes	New diagnosis added: traumatic blister of right hallux—right blister (nonthermal), right lesser toe(s), initial encounter. Crest pads added to shoes.
Osteomyelitis	61	Peripheral artery disease	Persistent hotspots at all 6 foot locations, patient hospitalized for infection symptoms. Osteomyelitis diagnosed with subsequent angioplasty and stent placement.
Fifth metatarsal head ulcer	48	Type 2 diabetes, history of ulcers	Right fifth metatarsal diagnosis changed to ulcer during provider visit. Ulcer was debrided. Go to his cast boot. Continue Siren Socks. Antibiotic ointment to the wound.
Blood clot	76	Peripheral artery disease	Patient began alerting with temperature differential in entire right foot. Patient reported thigh, knee, calf, and foot are swollen. Provider discussed and advised to go to emergency room where deep vein thrombosis was diagnosed and treated.

[a]CAM: controlled ankle movement.

A mean significant temperature increase of 3.59 °F (SD 1.42) was observed in the study cohort in the 15 days preceding an injury confirmed by physical medical examination. The control cohort had a mean temperature differential of 2.20 °F (SD 1.31) during a 15-day comparative period. The difference in means between the two cohorts was 1.4 °F (95% CI 0.859-1.20). Of note, the *P* value between the two cohorts was <.001, demonstrating statistical significance between the two cohorts as to the level of temperature differential.

Discussion

Principal Findings

The prevalence of DFUs and the extent of the clinical complications suggest new methods must be explored. Though temperature monitoring on an episodic basis has been previously described in the literature, this study appears to be the first to use a continuous temperature monitoring device in a real-world environment. The goal of this evaluation was to determine how temperature data would be different, particularly as an early warning indicator, for those patients presenting with a diagnosed foot injury. Previous studies have demonstrated the inflammatory response to injury does lead to a measurable increase in temperature [7,8].

The results of this study suggest that an inflammatory signal is seen with temperature monitoring when there is an injury. Of note, the presence of the temperature difference in the 15-day period prior to the patient presenting and the injury being assessed by a clinician is of particular interest in terms of potential impact on clinical practice. If at-risk patients routinely used a remote temperature monitoring device, it might be possible to identify risks and intervene sooner than standard practice currently allows. In addition to observing the absolute temperature differential, the creation of a continuous temperature monitoring device offers new possibilities to establish a baseline level of variation for a particular patient. The potential exists for significant temperature data to be used to create algorithms to better predict the early formation of podiatric injuries.

Study Limitations

The study has several limitations. There was a small number of injuries, which limited the study population. As the overall number of patients using a remote patient monitoring solution grows, there will likely be a much larger number of cases where a foot injury diagnosis is made. The study was limited to observations made in a 135-day period. The 15-day period was chosen for evaluation, but data certainly suggested temperature differentials of longer periods are of interest. Further study is needed with greater numbers of patients to establish the optimal early detection period.

Comparison With Prior Work

Several studies have been published that evaluate the role of temperature monitoring in the detection or possible prevention of DFUs. Of note, this study appears to be the first to evaluate a continuous temperature monitoring device in patients who did and did not experience a podiatric injury, with both groups providing continuous temperature monitoring data. In an evaluation of an episodic temperature monitoring device, the threshold of 4 °F was used to predict 97% of observed ulcers in a study of patients at risk of recurrent DFUs, but the false-positive rate was 57% [9]. Raising the temperature differential threshold reduced sensitivity but also reduced the false-positive rate. Another study looked at the validity of a specific 4 °F threshold for ulceration detection and postulated daily variations could influence outcomes [10]. The authors suggested future research should identify ways to use continuous monitoring sensors to further define individual thresholds.

Conclusion

The results of this study suggest temperature monitoring using a sock form factor may be a predictor of a developing foot injury. The study cohort had a mean foot temperature differential that was significantly different from that of the control cohort. The ability to review continuous temperature data in a 15-day period prior to a recognized problem showed that temperature differences beyond expected baseline variation were observed. The predictive value of these temperature data suggests patients and providers may become aware and engage earlier to address an issue before it progresses to a more serious level.

The value of temperature monitoring has been demonstrated in controlled studies in the past, but limited real-world data exist of its use in clinical practice. This study showed a statistically significant difference in the continuous temperature monitoring differential of patients who presented with a podiatric injury in the 15-day period prior to seeing a health care professional. Further study is warranted in larger patient groups over a longer follow-up period to better understand the predictive power of temperature monitoring for earlier detection of foot injury in patients with neuropathy and diabetes.

Conflicts of Interest

HJS, RM, KM, and MN are employees and shareholders of Siren Care, Inc. AMR and DGA are advisors to Siren Care, Inc. CDS is a prescriber of Siren socks. GT declares no conflict of interest.

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Abbreviations

DFU: diabetic foot ulcer
LPN: licensed practical nurse

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Original Paper

Development and Application of an Open Tool for Sharing and Analyzing Integrated Clinical and Environmental Exposures Data: Asthma Use Case

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Abstract

Background: The Integrated Clinical and Environmental Exposures Service (ICEES) serves as an open-source, disease-agnostic, regulatory-compliant framework and approach for openly exposing and exploring clinical data that have been integrated at the patient level with a variety of environmental exposures data. ICEES is equipped with tools to support basic statistical exploration of the integrated data in a completely open manner.

Objective: This study aims to further develop and apply ICEES as a novel tool for openly exposing and exploring integrated clinical and environmental data. We focus on an asthma use case.

Methods: We queried the ICEES open application programming interface (OpenAPI) using a functionality that supports chi-square tests between feature variables and a primary outcome measure, with a Bonferroni correction for multiple comparisons (α=.001). We focused on 2 primary outcomes that are indicative of asthma exacerbations: annual emergency department (ED) or inpatient visits for respiratory issues; and annual prescriptions for prednisone.

Results: Of the 157,410 patients within the asthma cohort, 26,332 (16.73%) had 1 or more annual ED or inpatient visits for respiratory issues, and 17,056 (10.84%) had 1 or more annual prescriptions for prednisone. We found that close proximity to a major roadway or highway, exposure to high levels of particulate matter ≤2.5 μm ($PM_{2.5}$) or ozone, female sex, Caucasian race, low residential density, lack of health insurance, and low household income were significantly associated with asthma exacerbations (P<.001). Asthma exacerbations did not vary by rural versus urban residence. Moreover, the results were largely consistent across outcome measures.

Conclusions: Our results demonstrate that the open-source ICEES can be used to replicate and extend published findings on factors that influence asthma exacerbations. As a disease-agnostic, open-source approach for integrating, exposing, and exploring patient-level clinical and environmental exposures data, we believe that ICEES will have broad adoption by other institutions and application in environmental health and other biomedical fields.

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KEYWORDS

open patient data; electronic health records; airborne pollutant exposures; socioeconomic exposures; medication exposures; asthma exacerbation

Introduction

Several large-scale initiatives are advancing efforts to reduce barriers surrounding access to patient data maintained in electronic health record (EHR) systems. Relevant initiatives include Columbia Open Health Data [1] and Medical Information Mart for Intensive Care [2]. The common goal is to promote open access to and sharing of patient data for research purposes, while respecting and preserving patient privacy and institutional assurances.

As part of the Biomedical Data Translator program (Translator) [3,4], supported by the National Center for Advancing Translational Sciences, we have developed a disease-agnostic, regulatory-compliant framework and approach for openly exposing and exploring patient data: the Integrated Clinical and Environmental Exposures Service (ICEES) [5]. ICEES was designed to overcome the regulatory, cultural, and technical challenges that hinder efforts to openly share and explore patient data [6,7]. ICEES is unique from similar efforts toward open patient data in that the service provides access to clinical data that have been integrated at the patient level with environmental exposures data derived from a variety of public sources. Thus, ICEES allows for patient-level research in environmental health and related fields.

Herein, we describe the further development and application of ICEES to data on a large cohort of patients with a diagnosis of asthma or a related condition. We examine the impact of select airborne pollutant exposures, demographic factors, and socioeconomic exposures on asthma exacerbations, which we define using 2 primary outcome measures: annual emergency department (ED) or inpatient visits for respiratory issues and annual prescriptions for prednisone. We present our findings and compare results for the 2 outcome measures.

Methods

Study Approval

All study procedures were approved by the Institutional Review Board at the University of North Carolina at Chapel Hill (protocol #16-2978). Informed consent was not required as the study involved existing biomedical data only and patient contact was not involved.

Asthma Cohort

ICEES was designed as a disease-agnostic, regulatory-compliant, open platform. For the work described here, we focused on 157,410 patients with asthma or a related pulmonary condition at UNC Health (all available sites). The specific criteria used to select patients for inclusion in the ICEES asthma cohort were adapted from [8] and included a combination of diagnoses, medications, and laboratory measures. (Details can be found in [5].) Briefly, we captured data on (1) patients with a diagnostic code for "asthma" and prescribed or administered medications that are typically used to treat asthma; (2) patients with a diagnostic code for a respiratory condition other than asthma and prescribed or administered medications that are typically used to treat asthma; (3) patients with a diagnostic code for a pulmonary condition other than asthma but prescribed tests or procedures that are typically used to manage asthma; and (4) patients with a diagnostic code for a respiratory condition other than asthma but with frequent ED visits in which albuterol nebulizer treatments were administered.

ICEES Integrated Feature Tables

"ICEES integrated feature tables" are key to the open design of ICEES. These tables were created using a complex custom software pipeline within a secure environment and under a protocol (#16-2978) approved by the Institutional Review Board at the University of North Carolina at Chapel Hill. For data extraction, Clinical Asset Mapping Program for Health Level 7 Fast Healthcare Interoperability Resource (CAMP FHIR) converted patient data from the PCORnet common data model to FHIR files [9]. FHIR Patient data Integration Tool (FHIR PIT) then ingested the FHIR files and integrated the patient data with multiple sources of environmental exposures data, using patient geocodes as reported in the EHR and dates [10]. The exposures data were derived from public sources and included airborne pollutant exposures data from the United States (US) Environmental Protection Agency Fused Air Quality Surface Using Downscaling repository; major roadway or highway exposures data (a proxy for airborne pollutant exposures) from the US Department of Transportation; and socioeconomic exposures data from the US Census Bureau American Community Survey. (Additional information on the sources of environmental exposures data can be found in [11].) After the data were integrated, the resultant ICEES integrated feature tables were stripped of identifiers per the Safe Harbor method outlined in the Health Insurance Portability and Accountability Act (HIPAA) before being exposed with an open application programming interface (OpenAPI).

ICEES integrated feature tables were created with respect to 1-year "study" periods, that is, calendar years, to provide a reference point for date-based calculations such as age and estimated exposure. Rows contained binned or recoded data on individual patients, with column headers representing data fields for each of the integrated feature variables. Of note, our institution classifies exposure estimates as "secondary protected health information" because the estimates are derived using primary protected health information (PHI; namely, geocodes and dates) to account for the fact that exposure estimates vary across space and time. We addressed this concern by binning all exposure estimates.

The binning strategy that was applied to each feature variable was based on a combination of expert opinion, published literature, and mathematical approaches. Age on day 1 of the 1-year study period was binned using our prior approach [5,12,13]: <5, 5-17, 18-44, 45-64, and 65-89 years (89 years being the oldest permissible age per HIPAA). Sex was treated

as male or female as coded in the EHR. Multiple race categories were available in ICEES; we focused on Caucasian and African American, as each of the other categories encompassed ≤1% of the total patients. Rural versus urban residence was examined using the US Census Bureau classifications based on American Community Survey–estimated residential density: rural area (<2500 persons per Census block group); urban cluster (between 2500 and 50,000 persons per Census block group); and urbanized area (>50,000 persons per Census block group). Estimated probability of no health insurance and estimated median household income were binned using the pandas.qcut function, which bins according to frequencies: [0, 0.637], [0.0637, 0.1121], [0.1121, 0.1644], [0.1644, 0.5548] estimated probability of no health insurance; [7,470, 36,635], [36,635, 46,750], [46,750, 59,566], [59,566, 78,355], [78,355, 250,001] estimated median household income (US $). Proximity to a major roadway or highway was binned based on published work [14]: 0-49, 50-99, 100-149, 150-199, 200-249, ≥250 m). Average daily particulate matter ≤2.5 μm ($PM_{2.5}$) and maximum daily ozone exposure were averaged over the 1-year study period and binned using the pandas.cut function, which bins patients according to the distribution of value estimates: [3.27, 6.30], (6.30, 7.81], (7.81, 10.83] μg/m^3 $PM_{2.5}$; [27.80, 39.00], (39.00, 42.73], (42.73, 46.45] ppb ozone. Importantly, bins were determined in our prior work to be sufficiently granular for statistical analysis [5].

ICEES OpenAPI

We accessed the ICEES OpenAPI through the ICEES Swagger OpenAPI interface and by command-line requests. An ICEES user interface was also available. ICEES was designed to support several functionalities for exploring and displaying the data, including chi-square tests, with counts of patients, chi-square statistics, and probabilities returned to users. In this study, we applied an ICEES functionality that allows users to run multiple chi-square comparisons based on available features and a primary outcome measure, with options to include a correction metric for multiple comparisons or collapse contiguous bins. In all cases, missing data were excluded from analysis. We queried the ICEES OpenAPI for data on all patients included in the asthma cohort and focused on outcomes in year 2016, which was the most recent year available with complete exposures data. We ran separate queries for each of the following primary outcome measures: (1) 1 or more annual ED or inpatient visits for respiratory issues; and (2) 1 or more annual prescriptions for prednisone. Specifically, we asked the following natural language question: “Among all patients within the ICEES asthma cohort, what airborne pollutant exposures, demographic features, and socioeconomic exposures differ significantly between patients with 0 versus 1 or more annual ED or inpatient visits for respiratory issues in year 2016?” The corresponding command-line API request was:

curl -X POST “https://icees.renci.org:16340/patient/2016/cohort/COHORT%3A12/associations_to_all_features” -H “accept: text/tabular” -H “Content-Type: application/json” -d “{\”feature\“:{\”TotalEDInpatientVisits\“:{\”operator\“:\”=\“, \”value\“:0}},\”maximum_p_value\“:1}”

A similar query was used to examine the primary outcome of 1 or more annual prescriptions for prednisone.

Statistical Analysis

The exploratory 1 × N feature association functionality available via the ICEES OpenAPI automatically invoked a chi-square test of the association between available features and our user-defined primary outcome measure, significance level, and multiple-comparison correction. We considered the primary outcomes of 1 or more annual ED or inpatient visits for respiratory issues and 1 or more annual prescriptions for prednisone. We focused our analysis on select feature variables that were considered a priori to have a potential impact on asthma exacerbations and were available for patients within the asthma cohort: demographic factors (age, sex, and race); socioeconomic exposures (residential density, health insurance access, and median household income); and airborne pollutant exposures (proximity to major roadway or highway, and exposure to $PM_{2.5}$ and ozone). We set the significance level at α=.05, which was adjusted by Bonferroni correction to α=.001. A power calculation was not conducted, as this was an observational, exploratory study focused on existing biomedical data.

Results

We successfully queried the ICEES OpenAPI for outcomes data on year 2016. Of the 157,410 patients who met the criteria used to define the asthma cohort, 26,332 patients (16.73%) had 1 or more annual ED or inpatient visits for respiratory issues, and 17,056 patients (10.84%) had 1 or more annual prescriptions for prednisone. Table 1 provides additional details on the cohort, including demographic and clinical profile and environmental exposures.

Table 1. Patient characteristics: demographic factors, environmental exposures, and clinical outcomes (N=157,410).

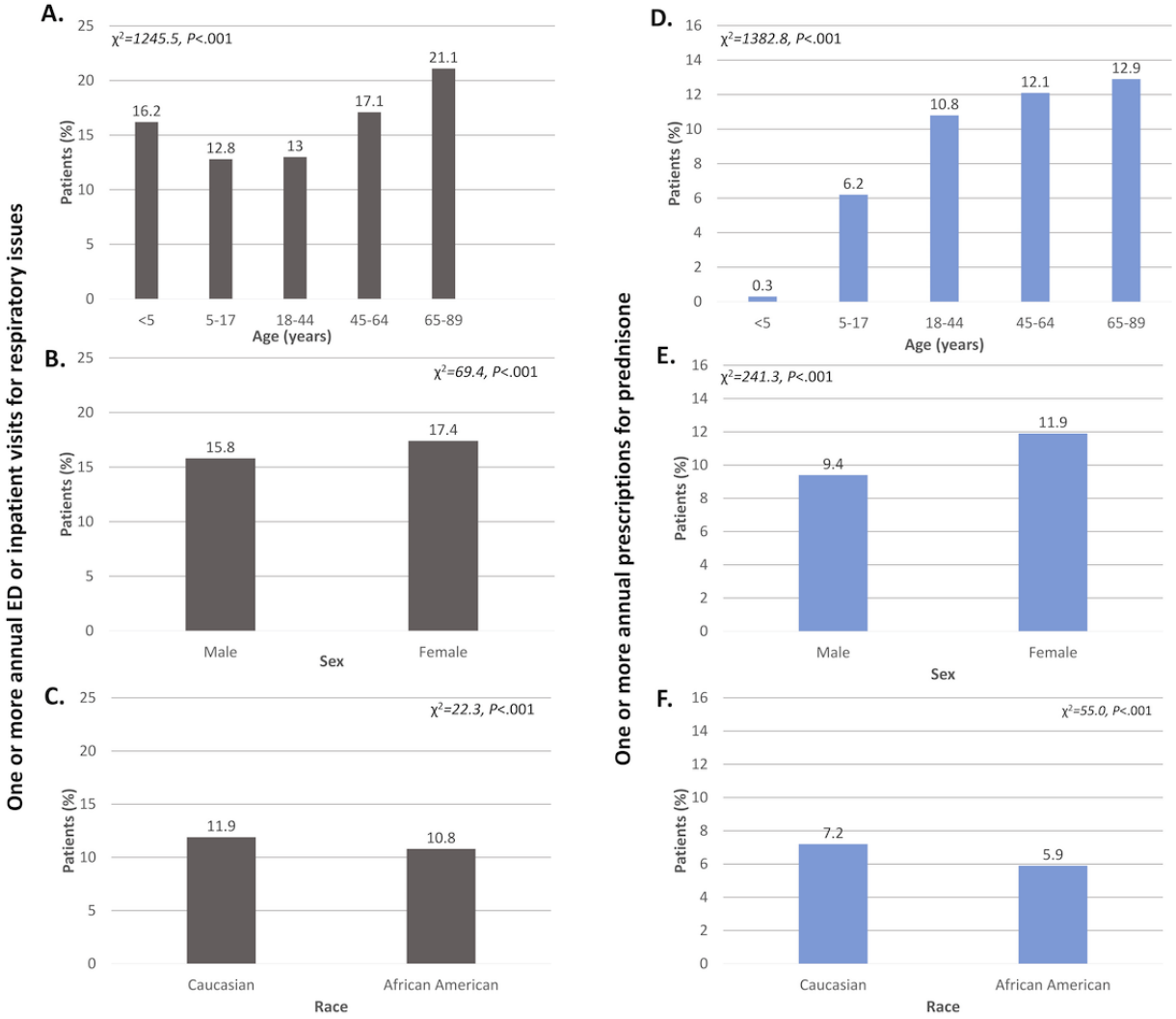
Feature variable	Values, n (%)
Age at study start (years)	
<5	5638 (3.58)
5-17	20,071 (12.75)
18-44	35,777 (22.73)
45-64	51,495 (32.71)
65-89	44,429 (28.23)
Sex	
Male	67,875 (43.12)
Female	89,531 (56.88)
Missing[a]/other	4 (<.0001)
Race	
Caucasian	78,418 (49.82)
African American	28,977 (18.41)
Asian	1608 (1.02)
American/Alaskan Native	902 (0.57)
Native Hawaiian/Pacific Islander	67 (0.04)
Unknown/other/missing	47,438 (30.14)
Ethnicity	
Hispanic	7488 (4.76)
Not Hispanic	105,925 (67.29)
Unknown/missing	43,997 (27.95)
Estimated residential density	
Rural area	95,632 (60.75)
Urban cluster	41,798 (26.55)
Urbanized area	0 (0)
Missing	19,980 (12.69)
Estimated probability of no health insurance	
[0, 0.0637]	34,500 (21.92)
(0.0637, 0.1121]	34,313 (21.80)
(0.1121, 0.1644]	34,340 (21.82)
(0.1644, 0.5548]	34,201 (21.73)
Missing	20,056 (12.74)
Estimated median household income (US $)	
(7470, 36,635)	26,967 (17.13)
(3663, 46,750]	27,081 (17.20)
(46,750, 59,566]	26,843 (17.05)
(59,566, 78,355]	26,968 (17.13)
(78,355, 250,001]	26,955 (17.12)
Missing	22,596 (14.35)
Proximity to major roadway/highway (m)	
0-49	17,485 (11.11)
50-99	9754 (6.20)

Feature variable	Values, n (%)
100-149	10,244 (6.51)
150-199	9398 (5.97)
200-249	8477 (5.39)
≥250	85,989 (54.63)
Missing	46,694 (29.66)
Average daily exposure to $PM_{2.5}$ ($\mu g/m^3$)[b]	
[3.27, 6.30]	8806 (5.59)
(6.30, 7.81]	108,847 (69.15)
(7.81. 10.83]	23,359 (14.84)
Missing	16,398 (10.42)
Maximum daily exposure to ozone (ppb)[b]	
[27.80, 39.00]	11,608 (7.37)
(39.00, 42.73]	127,202 (80.81)
(42.73, 46.45]	2202 (1.40)
Missing	16,398 (10.42)
Annual ED or inpatient visits for respiratory issues	
0	131,078 (83.27)
≥1	26,332 (16.73)
Annual prednisone prescriptions/administrations	
0	140,354 (89.16)
≥1	17,056 (10.84)

[a]Missing data reflect gaps in the electronic health record data, particularly missing geocodes that prevented the determination of exposure estimates.
[b]Averaged over the 1-year study period.

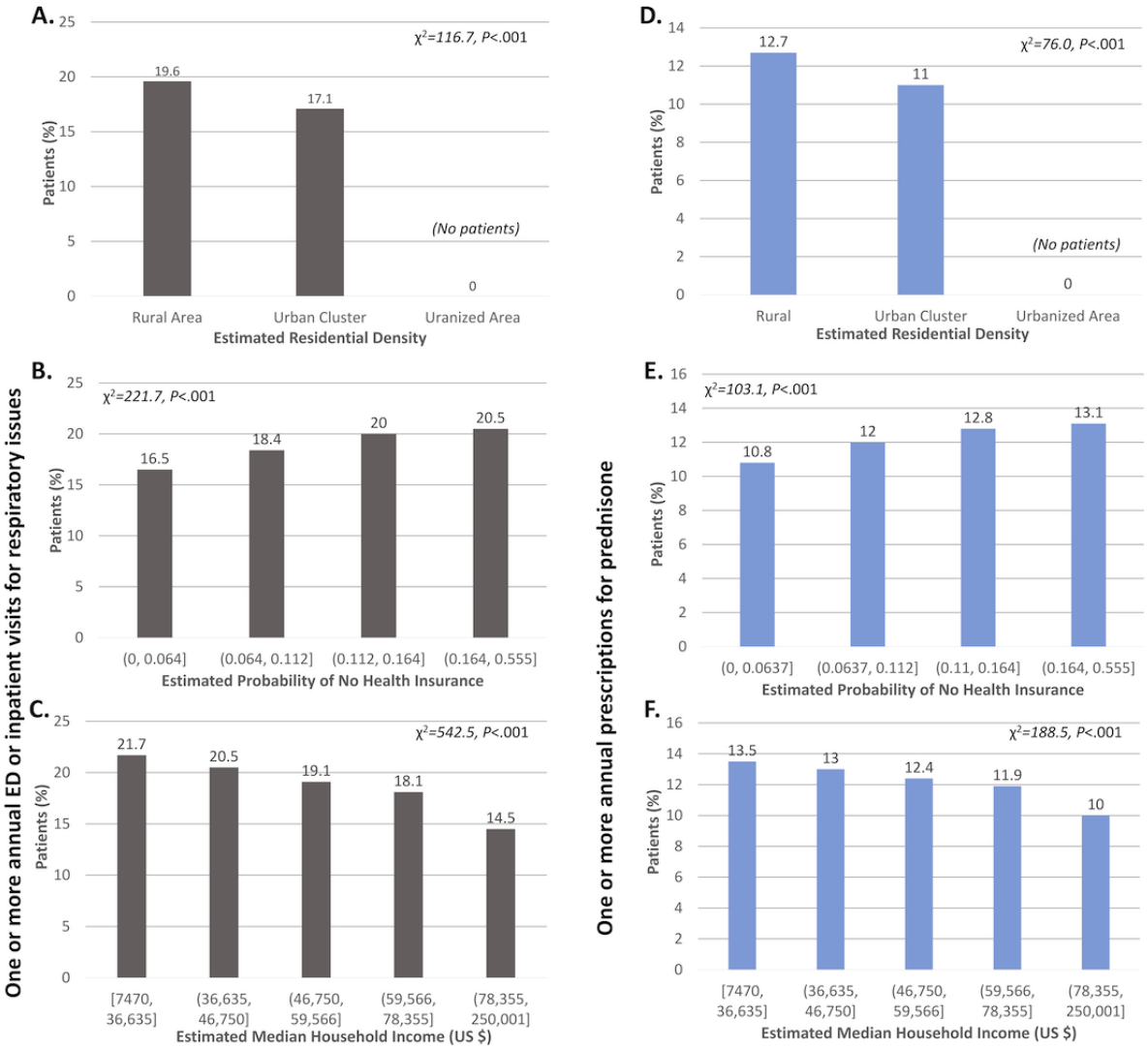
We then examined associations between select feature variables and annual ED or inpatient visits for respiratory issues, focusing initially on demographic factors (Figure 1A-C). We found that the percentage of patients with asthma exacerbations was higher among females than males (17.41% [15,587/89,531] vs 15.83% [10,743/67,875]; χ^2=69.4; *P*<.001) and among Caucasians than African Americans (11.86% [9304/78,418] vs 10.83% [3137/28,977]; χ^2=22.3; *P*<.001). A U-shaped relationship was found between age and the percentage of patients with 1 or more ED or inpatient visits for respiratory issues (<5 years, 16.21% [914/5638]; 5-17 years, 12.83% [2576/20,071]; 18-44 years, 13.01% [4655/35,777]; 45-64 years, 17.13% [8822/51,495]; 65-89 years, 21.08% [9365/44,429]; χ^2=1245.5; *P*<.001). (Degrees of freedom are not returned by ICEES and thus are not reported here.)

Figure 1. Associations between age (A,D), sex (B,E), race (C,F) and asthma exacerbations, defined as one or more annual emergency department (ED) or inpatient visits for respiratory issues (A-C) or one or more annual prescriptions for prednisone (D-F) (N = 157,410).



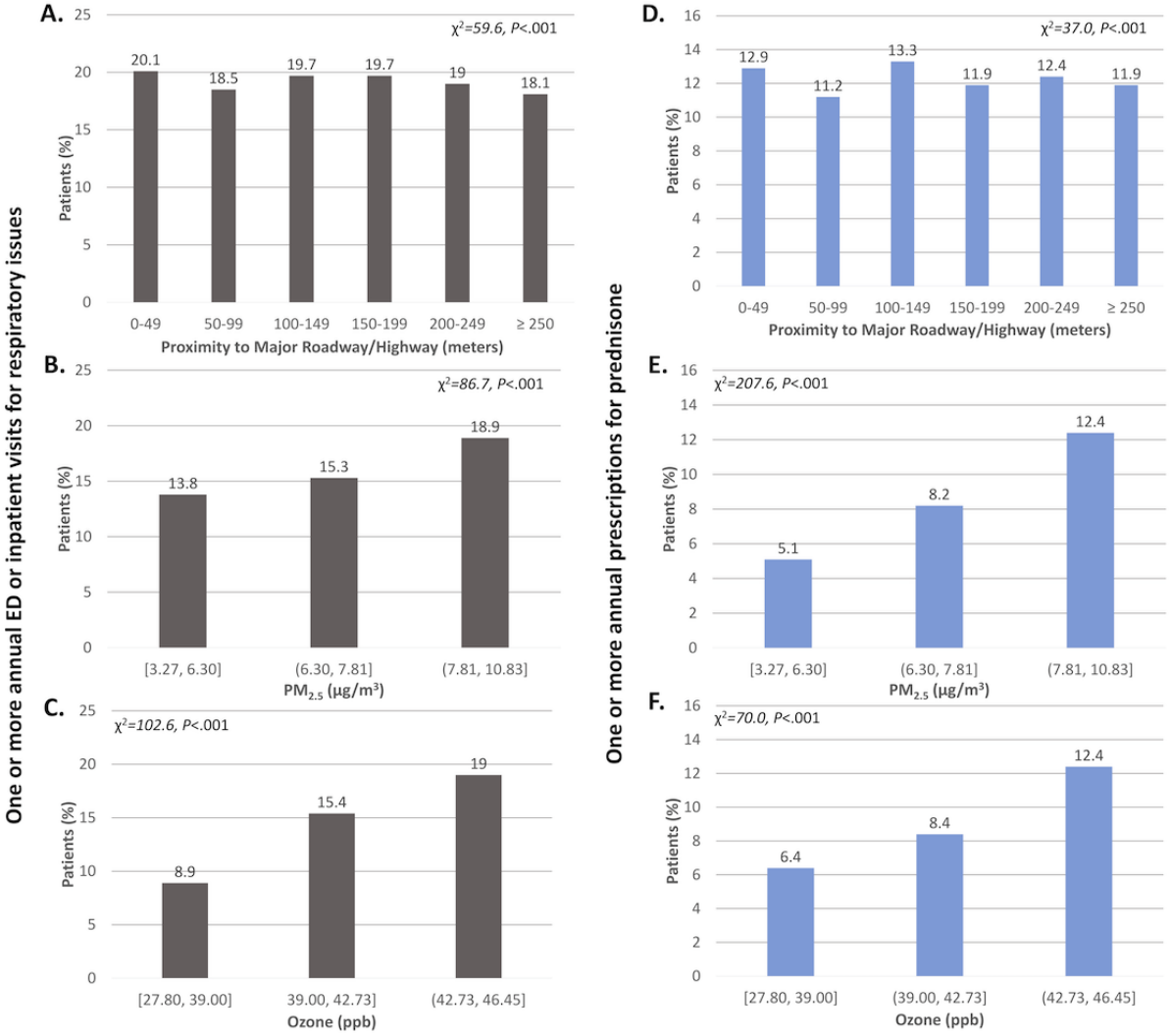
We also examined associations between socioeconomic exposures and annual ED or inpatient visits for respiratory issues (Figure 2A-C). We found that the percentage of patients with 1 or more annual ED or inpatient visits for respiratory issues was higher among patients residing in low-density rural areas than among those residing in higher-density urban clusters (19.59% [18,739/95,632] vs 17.12% [7155/41,798]; χ^2=116.7; *P*<.001). No patients were identified as residing in urbanized areas, as estimated by the American Community Survey and classified by the US Census Bureau. Asthma exacerbations increased with increasing probability of no health insurance (bin 1, 16.47% [5681/34,500]; bin 2, 18.43% [6325/34,313]; bin 3, 20.03% [6878/34,340]; bin 4, 20.47% [7000/34,201]; χ^2=221.7; *P*<.001) and decreased with increasing median household income (bin 1, 21.68% [5847/26,967]; bin 2, 20.51% [5553/27,081]; bin 3, 19.10% [5127/26,843]; bin 4, 18.07% [4872/26,968]; bin 5, 14.46% [3898/26,955]; χ^2=542.5; *P*<.001). (Bin values are provided in Table 1.)

Figure 2. Associations between residential density (A,D), probability of no health insurance (B,E), and median household income (C,F) and asthma exacerbations, defined as one or more annual emergency department (ED) or inpatient visits for respiratory issues (A-C) or one or more annual prescriptions for prednisone (D-F) (N = 157,410).



We then examined associations between airborne pollutant exposures and annual ED or inpatient visits for respiratory issues (Figure 3A-C). Asthma exacerbations decreased with increasing household distance from a major roadway or highway (0-49 m, 20.11% [3516/17,485]; 50-99 m, 18.45% [1800/9754]; 100-149 m, 19.73% [2021/10,244]; 150-199 m, 19.69% [1850/9398]; 200-249 m, 18.96% [1607/8477]; ≥250 m, 18.06% [15,529/85,989]; χ^2=59.6; *P*<.001) and increased with exposure to increasing levels of $PM_{2.5}$ (bin 1, 13.82% [300/2170]; bin 2, 15.33% [1017/6636]; bin 3, 18.89% [24,975/132,206]; χ^2=86.7; *P*<.001) and ozone (bin 1, 8.90% [21/236]; bin 2, 15.38% [1749/11,372]; bin 3, 18.95% [24,522/129,404]; χ^2=102.6; *P*<.001).

Figure 3. Associations between proximity to a major roadway or highway (A,D), exposure to particulate matter ≤ 2.5-μm (PM2.5) (B,E), exposure to ozone (C,F) and asthma exacerbations, defined as one or more annual emergency department (ED) or inpatient visits for respiratory issues (A-C) or one or more annual prescriptions for prednisone (D-F). (N = 157,410).



Results for the primary outcome of annual prescriptions for prednisone (Figures 1D-F, 2D-F, and 3D-F) were similar to those for annual ED or inpatient visits for respiratory issues, with 1 exception. Specifically, a linear relationship was found between age and prednisone prescriptions, with the percentage of patients with 1 or more annual prednisone prescription increasing with age (<5 years, 0.27% [15/5638]; 5-17 years, 6.1% [1235/20,071]; 18-44 years, 10.79% [3861/35,777]; 45-64 years, 12.08% [6222/51,495]; 65-89 years, 12.88% [5723/44,429]; χ^2=1382.8; *P*<.001).

Discussion

Principal Findings

We describe the further development and application of ICEES+ to explore select feature variables associated with asthma exacerbations in a large cohort of patients with asthma or a related condition. We focused on select demographic factors, socioeconomic exposures, and airborne pollutant exposures. We compared results for 2 outcome measures that are indicative of asthma exacerbations: annual ED or inpatient visits for respiratory issues and annual prescriptions for prednisone. We found that female sex, Caucasian race, rural residential density, high probability of no health insurance, low estimated median household income, close residential proximity to a major roadway or highway, and exposure to relatively high levels of $PM_{2.5}$ or ozone were significantly associated with asthma exacerbations. Moreover, the results were largely consistent across outcome measures, even though rates of annual ED/inpatient visits for respiratory issues were higher than those for annual prednisone prescriptions.

Limitations

Our study has several limitations that should be considered when interpreting the results. Specifically, as an open service that exposes EHR data, ICEES must abide by stringent regulatory and institutional regulations that limit the granularity of data that can be exposed and the statistical capabilities that are supported. For instance, ICEES exposes binned or recoded data, not raw data. In addition, our institution treats exposure estimates as secondary PHI because they are derived from primary PHI (ie, geocodes and dates); as such, we are unable to reveal the estimated values themselves, only the bins, thus

preventing a determination of mean exposures and other statistics based on continuous values. Finally, ICEES currently only supports basic bivariate statistical capabilities. However, we are developing approaches to adapt ICEES to support, in a regulatory-compliant manner, more sophisticated multivariate statistical approaches and machine learning algorithms [15,16].

Comparison With Prior Work

We highlight several scientific findings and discuss unexpected findings. First, we observed an increase in the proportion of asthma exacerbations among females versus males. Asthma and acute exacerbations of asthma are more common in males than females in childhood. However, in adulthood, the effect of sex shifts, with females accounting for the majority of asthma and asthma exacerbations. As the majority of patients in our cohort were adults, this observation is consistent with what has been reported in the literature [17-19]. In addition, the increase in asthma exacerbations among patients with lower median household income and those lacking health insurance reflects established disparities in asthma management, particularly among minorities [20]. However, the increase in the proportion of asthma exacerbations among Caucasians versus African Americans was unexpected and contradicts both our findings [10] and those of other investigators [21]. While the reason for this apparent discrepancy is unclear, several possible explanations exist, including the fact that our institution's racial category of "Caucasian" does not definitively distinguish Hispanic Caucasians from non-Hispanic Caucasians, which may have introduced variability. We are currently exploring approaches that may allow us to clearly distinguish Hispanic and non-Hispanic Caucasians and thus refine our racial and ethnic categorization. Another possible explanation is that our prior study focused on year 2010 [10], whereas this study focused on year 2016, and our institution's demographics and patient catchment area have changed significantly over that period [22].

Second, the relationship between age and asthma exacerbations was U-shaped when based on annual ED or inpatient visits for respiratory issues and linear when based on annual prescriptions for prednisone. We suspect that this difference is due to the heterogeneity of wheezing phenotypes in the younger age range, which can be associated with different long-term prognoses for the development of asthma and variance in the use of oral corticosteroids for disease exacerbation [23-26].

Third, one of the key features of ICEES is that it supports research on the impact of environmental exposures such as airborne pollutants on health and disease. Indeed, we identified that asthma exacerbations increased with increasing exposure to $PM_{2.5}$ and ozone, as we and others have shown [5,27]. We also found an increase in asthma exacerbations among patients residing in close proximity to a major roadway or highway, as others have found when using roadway exposure as a proxy for airborne pollutant exposure [14,28,29], although the effect in this study was modest. While one might have expected an increase in asthma exacerbations among persons living in densely populated areas, we found the opposite to be true, with increased asthma exacerbations among persons residing in low-density regions classified by the US Census Bureau as rural areas versus higher-density regions classified as urban clusters. We suspect that several factors might explain these findings. For instance, UNC Health's patient catchment area draws heavily from rural regions of North Carolina, with multiple clinics and small hospitals located across the state and many patients relying on the state hospital system for health care services. Indeed, not a single patient in the cohort described in this study resided in a region classified by the US Census Bureau as an urbanized area. This may have introduced bias into the results. In addition, we note that many major roadways and highways run through rural parts of our patient catchment area, and so any presumption that close proximity to a major roadway or highway is more common in urban versus rural regions may not be valid. A related point is that rural exposures carry risks that may differ from urban exposures. For instance, we are expanding ICEES to include data on concentrated animal farming operations and landfills so that we can begin to examine exposures that may uniquely impact persons residing in rural regions.

We also highlight key technical aspects of this study and discuss limitations. First, the data reported herein are openly available via the ICEES OpenAPI, without any regulatory restrictions or login credentials. This allowed us to rapidly execute the queries and analyze the results, thereby accelerating the speed of discovery. Because ICEES is designed to be disease agnostic and is not restricted to patients with asthma and related conditions, we can adapt our approach and the service itself to support any number of use cases and explore environmental influences on virtually any disease. Indeed, we have deployed additional ICEES instances that expose data on patients with drug-induced liver injury and patients with coronavirus infection. In addition, we are adapting ICEES to support a use case on primary ciliary dyskinesia and related rare pulmonary disorders.

Second, by using health care system EHR data, a large and clinically relevant patient sample can be identified. In this study, our sample size was approximately 160,000 patients, thus supporting rigorous open statistical analysis. While the statistical tests available via the ICEES+ OpenAPI are currently limited to bivariate analyses, we are developing approaches to support multivariate analyses such as generalized linear models, random forest trees, and causal inference models, with options to control for potential covariates, account for missing data, and examine only those patients who are active in a given year, meaning that they were seen at 1 or more clinics within UNC Health. One significant challenge is the binning approach that is adopted for variables. For instance, automated binning algorithms typically bin data by value or by frequency. The former supports the study of extreme values, but at the expense of evenly distributed bin sizes; the latter supports an even distribution of observations among cells, but at the expense of overlap in patients with equal exposures between bins and bin cutoff points that may not be scientifically meaningful. We are systematically exploring this issue.

Conclusions

Our results demonstrate that the open-source ICEES can be used to replicate and extend published findings on factors that

influence asthma exacerbations. While we are actively researching the limitations of the service and developing ways to improve it, we believe that ICEES will greatly speed and democratize the use of EHR data to support research and discovery. Moreover, to the best of our knowledge, ICEES is the only open source of clinical data that have been integrated at the patient level with multiple sources of public environmental exposures data. While we have described an application use case focused on asthma, ICEES is disease agnostic. We expect the service to advance research in environmental health and related fields and continue to grow as we expand both our user base and the service itself to support new clinical use cases, additional EHR elements (eg, laboratory measures), and new data sources (eg, survey data). Moreover, because ICEES is open source, the model and software code [30,31] can be adopted by other institutions as a novel approach for openly exposing and sharing sensitive data. Indeed, ICEES may have application as an open, privacy-preserving approach to inform decision making by the US Environmental Protection Agency and other federal agencies regarding the patient-level impact of environmental exposures on risk of disease. Finally, we are assessing regulatory-compliant options for applying ICEES as a tool for clinical decision support by identifying patients with asthma (and eventually patients with other chronic diseases) or geographical regions at high risk for poor health outcomes based on their exposures profile and then flagging those patients in their EHR to inform patient care.

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Authors' Contributions

KF, SCA, and EP conceived the general design of the Integrated Clinical and Environmental Exposures Service (ICEES); KF led the scientific implementation of ICEES; HX led the technical implementation of ICEES; KF and HX developed and implemented the binning strategy and statistical functionalities and also performed quality control testing; KF analyzed the data, prepared the figures and table, and drafted the first version of the manuscript; S Appold contributed the US Census Bureau American Community Survey data; S Arunachalam contributed the US Environmental Protection Agency Fused Air Quality Surface Using Downscaling airborne pollutant data; LS and AV contributed the US Department of Transportation roadway data; EP contributed the UNC Health patient data; LS performed all geocoding; SCA provided project leadership; DBP led the study design and asthma use case, provided scientific rationale, and served as the subject matter expert. All authors reviewed and approved the manuscript for journal submission.

Conflicts of Interest

DBP receives funding from the National Institute of Environmental Health Sciences; the National Institute of Allergy and Infectious Diseases; the National Heart, Lung, and Blood Institute; the US Environmental Protection Agency; and the US Department of Defense. He has been a consultant for GlaxoSmithKline, Teva, and Sanofi. All other authors declare no potential conflicts of interest.

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Abbreviations

CAMP FHIR: Clinical Asset Mapping Program for Health Level 7 Fast Healthcare Interoperability Resource
ED: emergency department
EHR: electronic health record
FHIR PIT: Fast Healthcare Interoperability Resource Patient data Integration Tool
HIPAA: Health Insurance Portability and Accountability Act
ICEES: Integrated Clinical and Environmental Exposures Service
OPENAPI: open application programming interface
PHI: protected health information
PM: particulate matter ≤2.5 μm

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Original Paper

The Impact of Web-Based Physical Activity Interventions on Depression and Anxiety Among College Students: Randomized Experimental Trial

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Abstract

Background: Depression and anxiety are growing issues for college students, with both aerobic resistance training and mindfulness yoga exercises known to be effective in reducing symptoms and severity. However, no known research is available comparing these 2 depression and anxiety interventions simultaneously and in a web-based environment.

Objective: This study aims to determine the effects of a web-based aerobic resistance exercise intervention (WeActive) and a web-based yoga mindfulness exercise intervention (WeMindful) on depression and anxiety symptoms in college students.

Methods: The participants were 77 college students who anonymously completed a Qualtrics survey, including the Generalized Anxiety Disorder Scale and the Major Depression Inventory at baseline and after the intervention. Participants were randomly assigned to either the WeActive or WeMindful group and underwent two 30-minute web-based aerobic resistance exercise lessons or yoga mindfulness lessons per week for 8 weeks.

Results: The results of analysis of covariance with repeated measures indicated that although not statistically significant, both groups showed a notable decrease in anxiety with a marginally significant main effect of time (F_1=3.485; P=.07; η^2=0.047) but no significant main effect of group and no significant interaction effect of time with group. The 2 intervention groups experienced a significant decrease in depression with the main effect of time (F=3.892; P=.05; η^2=0.052). There was no significant main effect of group or interaction effect of time with group for depression.

Conclusions: College students in both WeActive and WeMindful groups experienced a significant decrease in depression symptoms and a decrease, although not significant, in anxiety as well. The study suggests that web-based WeActive and WeMindful interventions are effective approaches to managing US college students' depression and anxiety during a pandemic.

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KEYWORDS

depression; anxiety; college students; mindfulness; aerobic exercise; resistance training; web-based intervention

Introduction

Background

It has been well-documented that mental health issues are increasing within a college student population [1,2]. This increase in mental health problems, such as anxiety and depression, seems to have been exacerbated by the onset of the COVID-19 pandemic [3-6], making the task of determining effective reduction strategies more pressing. Examining for potential increases in depression and anxiety issues due to the COVID-19 pandemic, global research has found that mental health problems have increased both in prevalence and severity in several countries. In China, 31% and 41.8% of 1396 surveyed college students experienced depression and anxiety, respectively [5]. Corroborating these findings, a separate longitudinal study on 66 Chinese college students found that qualities of mental health, including anxiety, were negatively affected by the pandemic [6]. In Italy, research has found that 27.8% of 400 analyzed college students and employees displayed notable depressive symptoms and 34.3% displayed notable anxiety symptoms [3]. In the United States, 44% of 195 interviewed college students reported an increase in depressive symptoms, whereas 71% of the same sample of students reported an increase in stress and anxiety symptoms [4]. In a meta-analysis examining the percentage increases in self-reported anxiety and depression worldwide, researchers found an increase in anxiety from 19% to 37% and an increase in depression from 21% to 54% after March 1, 2020, the time at which the SARS-CoV-2 virus started to rapidly spread worldwide [7]. Many colleges and mental health researchers have focused on finding ways to prevent or treat this rising rate of anxiety and depression [4,8,9], as these mental health problems are thought to have been aggravated by the onset of the global COVID-19 pandemic. Recently, attention has been given to potential lifestyle-based anxiety and depression prevention and treatment strategies, such as through the use of physical activity and mindfulness exercise interventions.

The 2018 Physical Activity Guidelines for Americans recommends that adults participate in 150 minutes of moderate-intensity aerobic activity per week or 75 minutes of vigorous-intensity aerobic activity per week or a combination of the 2 intensities [10]. Research has shown that engaging in physical activity, even in amounts that are less than those recommended by the aforementioned guidelines, can lessen the severity of mental health disorder symptoms, including anxiety and depression [5,11-15]. Depression, in particular, seems to experience the greatest benefits from increased physical activity time, including through group exercises and sports play [16] and through outdoor activities [17]. Anxiety has also been shown to decrease with participation in either individual or group sport–based exercises, with a higher frequency of physical activity correlated with lower levels of both anxiety and depression [13].

Web-based physical activity interventions have also been shown to be associated with reductions in depression and anxiety symptoms in a collegiate population [18]. Recent research on physical activity and mental health has found that more than half of all college students have not participated in an adequate amount of physical activity during the COVID-19 pandemic [5]. Researchers have discovered that individuals who have participated in high-volume and high-frequency structured exercise during the pandemic showed a decrease in depression and anxiety compared with inactive individuals [19]. At the time of study completion, the COVID-19 pandemic had not yet ended, and the lasting effects of this lack of activity in most college students were not yet known. However, as physical activity has been established to have a clear negative correlation with anxiety and depression symptoms, it can be reasonably predicted that inactive students may have more severe long-term mental health effects in the near future.

College students' mental health has also been found to improve with the practice of mindfulness activities, which are designed to allow participants to practice self-awareness of sensation and feeling [12,20-22]. In particular, mindfulness practices of meditation [21-23] and awareness and breathing exercises [21] have been shown to be correlated with improvements in college students' anxiety and depression issues. Yoga exercises, which combine aspects of mindfulness practices and physical activity, have also been shown to be effective in reducing depression, anxiety, and overall stress [21,23]. In addition, research has found a connection between mindfulness exercise practice and other positive psychological constructs, such as psychological flexibility [24] and nonreactivity [25], which, in turn, further decreases mental distress. Similarly, practicing mindfulness has been shown to mediate negative psychological factors, such as intolerance of uncertainty [26], and reduce anxiety symptoms that occur in connection to these negative factors.

In a web-based setting, the use of mindfulness-based interventions to reduce anxiety and depression symptoms in college students has demonstrated similar results to those of in-person interventions [27,28]. An experimental trial with 72 participants on mobile game–based meditation found a significant decrease in depression scores in the intervention group [28]. An 8-week web-based mindfulness study by Ahmad et al [27] with 113 student participants compared a full-time mindfulness virtual community (MVC) group, a part-time MVC group, a cognitive behavioral therapy group, and a waitlist control group. The study by Ahmad et al [27] found statistically significant reductions in depression scores in the full- and part-time MVC groups as well as statistically significant reductions in anxiety scores for the part-time MVC group [27]. However, not all studies on mindfulness-promotion interventions have produced significant positive changes in anxiety and depression. For example, a study examined the changes in perceived stress, anxiety, and depression in students over the course of a semester and found no statistically significant differences among the control group, mindfulness and yoga group, and stress management class group [29]. Similarly, a study examining college students' anxiety and depression after using a mindfulness smartphone app for 5 weeks did not find significant changes from the baseline test to the postintervention test [30]. Despite the few studies that have not shown a correlation between mental health problems and mindfulness practices, most studies examining this topic have found a positive connection [12,20-28].

Overall, there is clear and repeated evidence showing that practicing mindfulness activities or physical activities can positively affect mental health problems. One study compared the influence of mindfulness exercises with that of physical activity on stress, anxiety, and depression in the adult population and found significant reductions in the severity of mental health symptoms across both interventions [31]. Another study examined the impact of physical education activities and mindfulness activities on reducing the severity of anxiety and depression in 125 university students [32]. The results indicated significant reductions in these variables in the mindfulness group, with nonsignificant but observable reductions in the physical activity group, suggesting that mindfulness practices may be more effective in combating anxiety and depression symptoms [32]. In contrast, a recent systematic review comparing the mental health effects of mindfulness-based interventions with exercise interventions in collegiate populations found that the effect size on depression and anxiety was greater with exercise interventions than with mindfulness interventions [12]. To date, few studies have examined the influence of the web-based application of these 2 intervention strategies. Furthermore, there are no intervention studies that have directly compared mindfulness exercises with physical activity using a web-based format during the pandemic. In addition, with contradictory information on intervention effects on reducing mental health problems, there is a critical need to explore the effects of web-based or Zoom-based physical activity and mindfulness exercise in counteracting mental illness symptoms. In addition, the impact of the COVID-19 pandemic on the average mental health status of college students may have complicated the ways in which mindfulness and physical activity interventions interact with anxiety and depression symptoms, furthering the need to understand the utility of these interventions. To the best of our knowledge, there is a lack of research on the effects of web-based aerobic and resistance exercises or yoga with mindfulness on college student depression and anxiety in a midpandemic environment.

Purpose and Hypothesis

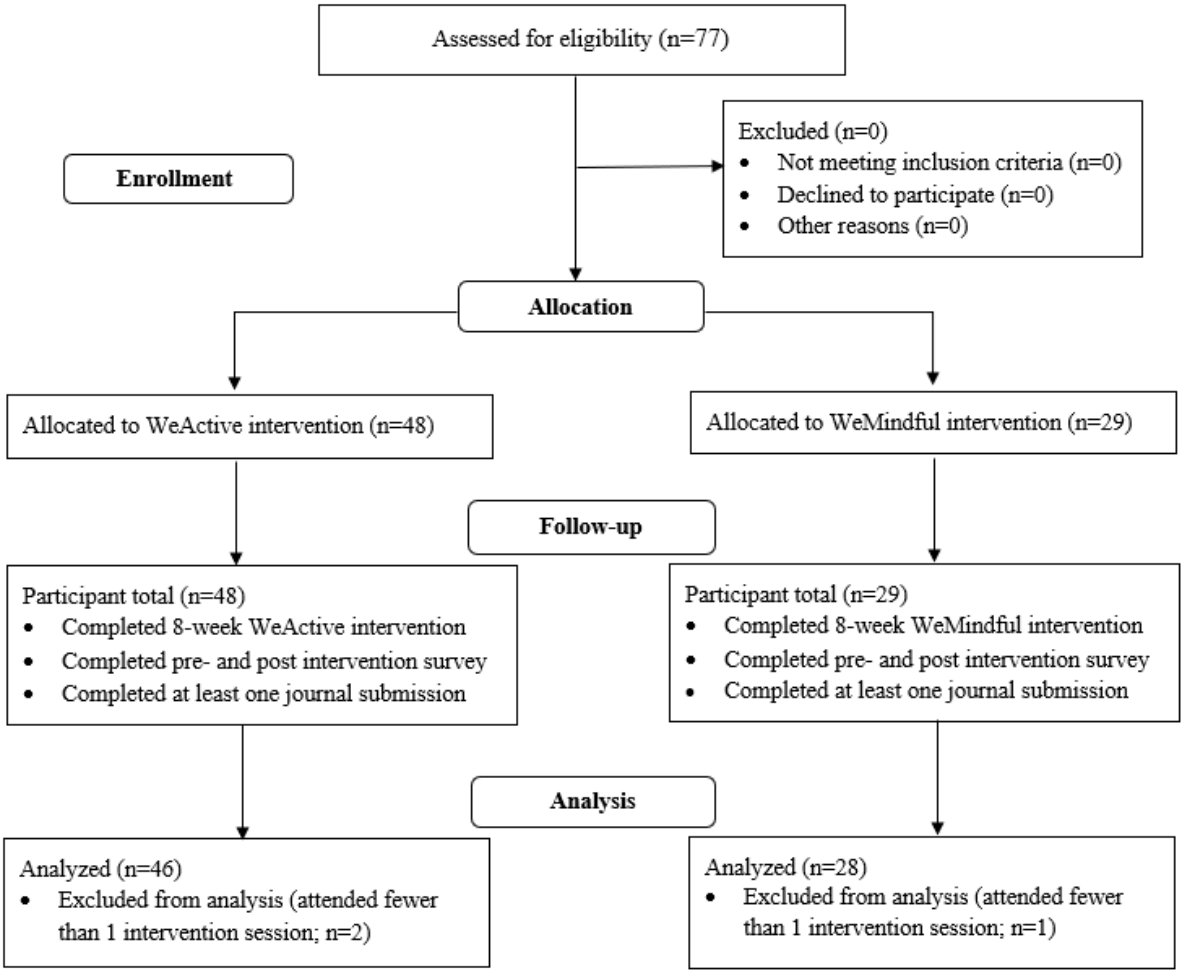
Therefore, this study aims to compare the effects of a web-based aerobic resistance exercise intervention (WeActive) and a web-based yoga mindfulness intervention (WeMindful) on depression and anxiety in college students during the winter semester of 2021. It was hypothesized that both intervention groups would produce improvements in depression and anxiety but that the fitness intervention would show slightly higher positive improvements in both measures. As fitness and mindful exercise interventions have been shown to assist with depression and anxiety improvement, the significance of this study is in determining the effectiveness of web-based fitness exercise and mindfulness exercise interventions on improving student mental health in the midst of a pandemic.

Methods

Participants and Study Design

We recruited college students from a large public university in the Midwestern region of the United States to participate in a randomized quasi-experimental study during the spring semester of 2021. We used several recruiting strategies, including the targeted email response system, the university's canvas learning management platform, undergraduate and graduate bulletins, and university social media pages. The eligibility criteria included being at least 18 years of age, having current status as a student at the university, and having consistent access to the internet and to the web-based conferencing app Zoom (Zoom Video Communications). Participant enrollment information is available in Figure 1.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) recruitment and study design diagram.



As seen in Figure 1, after the pre-evaluation, 77 participants attended the 8-week intervention components and completed the postintervention test. We calculated the study sample size with an effect size, Cohen *d*=0.80, on college students' anxiety [33], 2-tailed with an α level of .05 and a power of 0.80 using G*Power 3.1.9.7 software. The results showed that the total required sample size of the study was 52, with 26 students in each intervention group. On the basis of our previous study's adherence rate of >90% and an estimated program dropout rate of 10%, we needed to recruit a targeted sample size of 57 college students. Our sample size of 77 participants exceeded the required sample size of 57.

Intervention Conditions

Overview

Both intervention groups were asked to attend two 30-minute group exercise classes via Zoom twice per week. Participants opted to attend 1 synchronized Zoom exercise lesson and 1 asynchronized lesson or 2 asynchronized lessons that were Zoom-recorded and uploaded to the University Canvas study-related website. The asynchronous recording contained the same lesson content from the synchronous live session, meaning content was repeated for the second session each week. In addition, all participants were asked to attend synchronous, researcher-led peer coaching sessions that took place once every 2 weeks for 30 minutes.

The intervention lasted for 8 weeks over the course of the winter 2021 semester. Before the intervention started, participants were given 1 week to complete a preintervention Qualtrics survey that included anxiety and depression measures. Immediately after the intervention period, the participants were again given 1 week to complete a postintervention Qualtrics survey that included the same anxiety and depression measures used in the preintervention survey.

WeActive Intervention

The objectives of the WeActive intervention were to help the participants engage in at least 150 minutes of moderate to vigorous physical activity per week and improve their abilities to achieve the recommended amount of weekly moderate to vigorous physical activity minutes throughout the intervention. The participants were instructed to attend two 30-minute exercise classes via Zoom per week for 8 weeks. The class duration was set to 30 minutes to maximize participant retention while still allowing participants to achieve an amount of exercise that has been shown to be beneficial [17]. The lessons were taught by a student instructor who had previously taken the University of Michigan classes *Methods of Instruction for Exercises* and *Fundamentals of Strength and Conditioning*. In

addition, the WeActive student instructor was a certified strength and conditioning specialist and a graduate student with ≥5 years of experience in personal training. Each exercise lesson used a structured format, consisting of 5 minutes of warm-up (eg, marching in place and dynamic stretching), 20 minutes of both aerobic and resistance exercises (eg, squats and pushups and high knees and jumps), and 5 minutes of cooldown with static stretching exercises (eg, hamstring and quadriceps static stretching when lower body exercises were used in the session). For the first 4 weeks of the intervention, the lesson focused on introducing participants to low to moderate impact resistance and cardio exercises. As lessons continued, exercise difficulty progressed (eg, from a 2-leg bodyweight squat to a moving lunge). The last 4 weeks of the intervention included high-intensity exercise with a greater cardiovascular focus.

WeMindful Intervention

The WeMindful group was instructed to participate in two 30-minute web-based yoga mindfulness classes per week for 8 weeks. The use of yoga, which incorporates movement with breathing and self-awareness, as a primary mindfulness exercise has been supported by previous research [21,23]. The lessons were taught by a student instructor who had previously taken the University of Michigan classes *Methods of Instruction for Exercises* and *Fundamentals of Strength and Conditioning*. In addition, the WeMindful student instructor was a junior undergraduate student studying movement science with 3 years of experience teaching yoga and dance classes. Class content consisted of a 5- to 7-minute–long movement and breathing-based warm-up (eg, focusing on space and deep breathing), followed by 15 to 20 minutes of learning and practicing sequences of basic yoga poses (eg, cat-cow and triangle pose) and ending with a 3 to 5 minutes of mindfulness relaxation (eg, reading meditation scripts). Yoga poses used in the classes often included accommodations for more difficult positions if participants needed to decrease difficulty. The lessons progressed by adding 1-3 new yoga poses per week for the first 3 weeks of lessons, followed by the fourth week that consisted of an overview of all poses learned up to that point. The fifth through eighth weeks followed a similar format, with weeks 5, 6, and 7 consisting of new poses that were reviewed during week 8.

Intervention Implementation Strategies

To facilitate the participants to attend the WeActive or WeMindful exercise lessons and to provide ongoing emotional, informational, and appraisal support for them, we offered all participants in both groups with four 30-minute peer coaching sessions conducted via Zoom, with 1 session every 2 weeks. Each peer coaching session included experience and feedback sharing from participants, barrier or challenge reflections, and participant suggestions for class content. The focus of the first peer coaching session was on orienting and introducing participants to the session formatting, which included goal-setting prompts, self-regulation prompts, self-monitoring reflection, and time for social support. The second, third, and fourth peer coaching sessions delved deeper into obtaining participant feedback on any challenges or preferences they had during the main intervention group components, along with continued goal-setting, self-regulation, and self-monitoring exercises. The peer coaching sessions were led by 1 doctoral student and 1 other undergraduate student of the research team. In addition to peer coaching sessions, all participants were instructed to complete weekly journals that asked participants to provide their weekly attendance for both synchronous and asynchronous classes. In addition, participants received encouraging messages on the web from the research team every Thursday, with content including praise and motivational phrasing.

Intervention Outcome Measures

Anxiety Measure

This study used the 7-item Generalized Anxiety Disorder (GAD-7) scale by Spitzer et al [34] for participants to self-rate their anxiety symptoms. The GAD-7 questionnaire measures anxiety symptoms occurring within the past 2 weeks on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day). The 7 items were added together to provide a total anxiety score. The scores for the questionnaire ranged from 0 to 21. A score between 5 and 9 indicated mild anxiety, a score between 10 and 14 indicated moderate anxiety, and a score above 15 indicated severe anxiety [34]. In this study, the Cronbach α coefficients of the GAD-7 scale at baseline test and after the test were .794 and .795, respectively, indicating acceptable internal consistency.

Depressive Symptoms Measures

This study used the 10-item Major Depression Inventory (MDI) developed and validated by Bech et al [35] for participants to self-rate their depression symptoms. The MDI questionnaire measures depression symptoms occurring within the past 2 weeks on a 6-point rating scale ranging from 0 (no time) to 5 (all the time). Items 8 and 10 consist of 2-part questions (a and b), where the highest score between the 2 subquestions is used as the item score. The scores for this questionnaire ranged from 0 to 50. A score <20 indicates no or doubtful depression, a score between 21 and 25 indicates mild depression, a score between 26 and 30 indicates moderate depression, and a score >30 indicates severe depression [35]. In this study, the baseline test of the MDI had a Cronbach α of .770, whereas the posttest evaluation of the MDI had a Cronbach α of .773, indicating both having an acceptable internal consistency level.

Data Analysis

Of the 77 participants who completed the preintervention and postintervention surveys, 3 were excluded from the final data analysis because of poor participation. The final data set included 46 participants from the WeActive intervention and 28 participants from the WeMindful intervention, for a total of 74 participants.

The preintervention and postintervention data were analyzed using SPSS 26 software (IBM Corporation), with statistical significance set at $P<.05$ for the tests. Of the 77 students who completed both the preintervention and postintervention surveys, 74 were included in the final analysis (46 from WeActive and 28 from WeMindful). Overall, three participants (2 from WeActive and 1 from WeMindful) were excluded from the final

analysis because of a lack of adequate participation. The mean scores of the GAD-7 and MDI tests were compiled and used for dependent variable analysis. Descriptive statistics of each intervention at baseline were calculated, and 2-tailed independent *t* tests were used to determine any significant differences in the dependent variables of each intervention group. A mixed-design analysis of variance repeated measure was used to examine the effect of either intervention group on depression and anxiety measures. Depression and anxiety scores were the main dependent variables in this study, with univariate tests separately for each variable. In this study, the between-factor was the analysis of the WeActive intervention group against the WeMindful intervention group. The within-subject factor was the comparison of the preintervention test against the postintervention test. In the analysis of covariance (ANCOVA) tests, if sphericity was violated, the Greenhouse-Geisser correction was applied. The results showed no significant differences in the preintervention mean scores for X3month_exercise, X3month_yoga, MDI score, GAD-7 score, education, race, and age, with the only significant difference between groups coming from the X3month_therapist variable (F_1=15.083; P=.01). Therefore, ANCOVA was used to determine the intervention effects on anxiety and depression while controlling for covariates. The between-subject factor for analysis was the intervention group, comparing the WeActive group with the WeMindful group, and the within-subject factor was time, comparing the baseline test scores with the posttest scores.

Ethics Statement

This study was reviewed and approved by the University Institutional Review Board-Health Sciences and Behavioral Sciences (IRB-HSBS) (HUM00189120). We conducted this study in accordance with the principles of the Declaration of Helsinki. All participants in the study have provided written informed consent to participate in the study.

Results

Overview

The results showed significant decreases in depression symptoms in both intervention groups as a main effect of time. Anxiety symptoms decreased marginally in both groups. There were no significant effects of group or of time and group in affecting anxiety or depression symptoms.

Baseline Characteristics

The final WeActive group consisted of 48 participants, with a mean age of 23.02 (SD 4.83) years. The final WeMindful group consisted of 29 participants, with a mean age of 24.31 (SD 7.48) years. Both groups had similar educational and racial distributions. A summary of the descriptive statistics is presented in Table 1**.**

Table 2 displays the baseline score difference between the 2 intervention groups.

Table 1. Descriptive statistics of baseline characteristics of all participants.

Characteristics	Values
Sex, n (%)	
Female	63 (85.1)
Male	7 (9.5)
Nonbinary	4 (5.4)
Education, n (%)	
Freshman	8 (10.7)
Sophomore	9 (12)
Junior	15 (20)
Senior	14 (18.7)
Masters	13 (17.3)
Doctoral	14 (18.7)
Professional	2 (2.7)
Race, n (%)	
African American	4 (5.4)
Asian	15 (20.3)
White	48 (64.9)
White, Asian	3 (4.1)
White, native	1 (1.4)
White, other	1 (1.4)
Other	2 (2.7)
Age (years), mean (SD; mean of SD)	
WeActive (n=46)	23.02 (4.833; 0.713)
WeMindful (n=29)	24.31 (7.479; 1.389)
X3month_exercise[a], mean (SD; mean of SD)	
WeActive (n=46)	0.47 (0.504; 0.072)
WeMindful (n=29)	0.38 (0.494; 0.092)
X3month_yoga[b], mean (SD; mean of SD)	
WeActive (n=46)	0.16 (0.373; 0.053)
WeMindful (n=29)	0.24 (0.435; 0.081)
X3month_therapist[c], mean (SD; mean of SD)	
WeActive (n=46)	0.20 (0.407; 0.058)
WeMindful (n=29)	0.48 (0.509; 0.094)

[a]X3month_exercise: number of exercise sessions in the previous 3 months.[b]X3month_yoga: number of yoga sessions in the previous 3 months.[c]X3month_therapist: number of therapist visits in the previous 3 months.

Table 2. Independent t tests of baseline difference between the WeActive and the WeMindful groups.

Equal variances assumed	*t* test (*df*)	*P* value (2-tailed)
Age (years)	−0.908 (73)	.37
Race	−1.077 (72)	.29
Education	0.299 (73)	.77
X3month_exercise[a]	0.768 (76)	.45
X3month_yoga[b]	−0.839 (76)	.40
X3month_therapist[c]	−2.660 (76)	.01[d]
Health_rating	−0.610 (76)	.54
PreGADtotal[e]	−0.941 (76)	.35
PreMDItotal[f]	−0.509 (76)	.61

[a]X3month_exercise=number of exercise sessions in the previous 3 months.

[b]X3month_yoga=number of yoga sessions in the previous 3 months.

[c]X3month_therapist=number of therapist visits in the previous 3 months.

[d]*P*<.01.

[e]PreGADtotal=baseline total Generalized Anxiety Disorder.

[f]PreMDItotal=baseline total Major Depression Inventory.

As seen in Table 2, the mean scores of depression in both groups were similar, with the WeActive mean scores of 16.89 falling slightly lower than that of WeMindful at 17.75. Both scores are in the nondepressed classification range through the MDI, which is classified as a score under 20. According to the MDI criteria, both groups' scores indicated *no or doubtful* levels of depression at baseline. Both groups presented similar scores in the anxiety measure, with WeActive at 7.15 and WeMindful at 7.79. These scores placed both groups within the *mild* anxiety range (score between 5 and 9) through the GAD-7. The mean scores of an overall health rating, 3-month history of exercise, and 3-month history of yoga were similar across both groups. Only the measure of the past 3-month therapist visits differed to a notable extent, with WeMindful averaging a higher score at 0.48 compared with the 0.2 therapist visit average for WeActive.

The independent sample *t* tests revealed no significant baseline differences in the outcome variables and demographic variables between the 2 groups (age: *P*=.41; race: *P*=.29; education: *P*=.77; physical activity: *P*=.36; anxiety: *P*=.32; depression: *P*=.60). With regard to the past 3-month therapist visit measure, the WeMindful group had a significantly higher mean average visit number than the WeActive group (t_1=−2.660; *P*=.01). This baseline difference was controlled for when conducting repeated measures ANCOVA.

Intervention Effects on Anxiety and Depression

Table 3 presents the baseline and posttest scores of anxiety and depression by group, whereas Table 4 displays the ANCOVA repeated measure results for anxiety and depression.

Table 3. Baseline and posttest scores of anxiety and depression.

	Values, mean (SD)
Baseline anxiety	
WeActive	7.152 (5.517)
WeMindful	7.786 (4.475)
Posttest anxiety	
WeActive	6.652 (5.225)
WeMindful	6.429 (4.710)
Baseline depression	
WeActive	16.89 (12.97)
WeMindful	17.75 (10.77)
Posttest depression	
WeActive	13.57 (10.98)
WeMindful	16.89 (12.61)

Table 4. Results of analyses of variance with repeated measures for anxiety and depression.

Effects	Anxiety			Depression		
	F test (*df*)	*P* value	η^2	*F* test (*df*)	*P* value	η^2
Time	0.485(1)	.07	0.047	0.892 (1)	.05[a]	0.052
Time×group	0.989 (1)	.32	0.014	0.914 (1)	.34	0.013
Group	0.423 (1)	.52	0.006	0.001 (1)	.98	0.000
X3_month_therapist	8.63 (1)	.004[b]	0.108	7.007 (1)	.01[b]	0.090

[a]*P*<.05.

[b]*P*<.01.

For the anxiety measure, while controlling for the past 3-month therapist visit, the results of ANCOVA with repeated measures indicated no significant main effect of time and group and no significant interaction between time and group. However, the main effect of time was close to a significant level (F=3.485; P=.07; η^2=0.047), indicating that the 2 groups had a marginally significant decrease in anxiety over time. The resulting GAD-7 classification for both groups after the intervention was still considered within the *mild* range for anxiety severity. The results also showed that the past 3-month therapist visit was a significant covariate of anxiety (F=8.629; P=.004; η^2=0.108).

With regard to the depression measure, the results of ANCOVA with repeated measures yielded a significant main effect of time (F=3.892; P=.05; η^2=0.052), while controlling for the past 3-month therapist visit. The results indicated that the 2 groups showed a significant reduction in depressive symptoms from baseline to after the intervention. In contrast, the ANCOVA with repeated measures revealed no significant main effect of group and no significant interaction effect of time with group. The resulting MDI classification for both groups after the intervention was still considered within the *no or doubtful* range for depression severity. Similarly, the 3-month therapist visit was a significant covariate for depression (F=7.007; P=.01; η^2=0.090).

Discussion

Principal Findings

This study aims to examine the effects of a web-based aerobic resistance exercise (WeActive) intervention and web-based yoga mindfulness (WeMindful) intervention on college students' anxiety and depression levels. Both the 8-week interventions were hypothesized to have positive effects on anxiety and depression, with greater positive effects predicted in the WeActive group. As expected, the participants in the 2 groups experienced a significant decrease in depression scores over the 8-week period. Although not statistically significant, the participants experienced a decrease in anxiety scores as well. Contrary to our second hypothesis, there were no significant interactions between group and time, indicating that the WeActive group did not experience greater improvements in mental health scores than the WeMindful group over time.

The decrease in depression scores across both intervention groups in our study aligns with results from previous mindfulness interventions [12,20-23] and physical activity interventions [5,11-18]. The connection behind depression reduction and mindfulness exercises is thought to be caused by a variety of factors. With regard to emotional regulation, mindfulness activities interact directly and indirectly with mechanisms such as rumination and suppression, which act as mediators in the development of both depression and anxiety [36]. At the biological level, cortisol levels have been found to be higher in depressed individuals than in nondepressed individuals, with mindfulness activities such as yoga showing positive effects in reducing cortisol and improving depression measures [37]. Similar to the cortisol-related depression reduction mechanism seen with the use of mindfulness interventions, a reduction in depression due to increased physical activity has been linked to biological factors, such as neurogenesis in the hippocampus, acting similarly to antidepressant drugs [38], and through the regulation of stress hormone release through the hypothalamic-pituitary-adrenal axis [39]. With the implementation of both aerobic and resistance training interventions, some psychosocial symptoms of depression, such as negative thinking and self-efficacy, have been found to directly decrease, which in turn reduces depression severity [39]. It is likely that our WeActive and WeMindful interventions acted across a multitude of depression-meditating mechanisms, although the intervention sessions or length of intervention did not measure for biological changes in participants in either intervention group.

It is important to note that the participants in both groups experienced a marginally significant decrease in anxiety, a result that mostly supported our original hypothesis. Previous research that has examined the relationship between anxiety and either mindfulness or aerobic resistance exercise has displayed mixed results. Although most studies reveal a significant positive relationship [12-14,21-23], some studies show no significant interaction between the intervention and anxiety measure [16,20,29]. In a study by Bosso [30], inadequate participant adherence rates likely caused this lack of significance, with the anxiety measure in this study displaying a dose-dependent response to mindfulness activities. In addition, both the Bosso [30] and Conder [29] studies discovered that shortened intervention duration or low frequency likely limited the intervention effectiveness in reducing anxiety symptoms. Johnston et al [16] suggested that the anxiety levels in their study were likely influenced by external variables, such as increasing college demand over the course of a semester [16].

It is possible that our study had an insufficient frequency to produce significant anxiety changes. It is also likely that the onset of the college final examination period toward the end of the study greatly affected the overall anxiety levels of the participants. Although the results of our study do not indicate statistical significance, the mean anxiety scores across both interventions still notably decreased over time, showing the potential benefit of both the WeActive and WeMindful interventions.

Contrary to our expectations, there was no statistical significance in the group and time interactions, meaning neither the WeActive nor WeMindful group showed significant differences in depression or anxiety changes over time. Of the few studies that have compared the mental health effects of mindfulness exercises with aerobic or resistance exercises, only van der Zwan et al [31] showed similar results across both intervention groups, as in our study [31]. In the study by van der Zwan et al [31], both mindfulness exercise and aerobic exercise interventions showed significant reductions in anxiety and depression scores. As no research on this topic has been conducted in a pandemic environment, there are no definitive reasons yet established on why both intervention types displayed similar results. It is possible that the recent and collective changes in lifestyle may have contributed to the statistically equal impact of both the mindfulness exercise and aerobic resistance exercise interventions, suggesting that both interventions are effective in combating pandemic lifestyle–related depression symptoms. It is necessary to note that despite the presence of academic stressors such as final examinations and learning-related issues on the web, the students in both intervention groups showed a significant reduction in depression scores. This finding suggests that both aerobic and resistance training exercises as well as mindful exercises may be beneficial in buffering academic stress–related depression.

Limitations

This study has several limitations. First, although initial participant interest was high, most interested potential participants decided not to proceed with the study. This limitation was likely caused by the completely web-based nature of this study, which prevented opportunities to connect more directly with participants and by the increasingly busy period of the school semester during which this study was conducted. The stressful nature of college classes, where stress often builds as the semester goes on, may have greatly hindered some of the students' participation, as higher levels of stress related to schoolwork could have reduced the free time these participants had to complete the study. Second, the demographics of participants may have interfered with obtaining widely applicable findings, as most participants identified as female. Previous research has shown that females tend to report higher rates and severity of anxiety and depression symptoms than males [1,2]. Third, there may have been a ceiling effect present in the improvements of each group's anxiety and depression scores, as both groups scored in the lowest severity categories of each disorder at baseline evaluation (*no or doubtful* for depression and *mild* for anxiety). These low baseline scores, indicating a low prevalence of anxiety and depression, may have prevented both the WeActive and WeMindful groups from showing larger improvements. A future study that screens more selectively for individuals experiencing higher levels of symptoms may show a greater effect. Finally, as this study was conducted during the midpandemic in a completely web-based environment, it is possible that some participants may have experienced *Zoom fatigue*, a state of exhaustion from overuse of internet web-based conferencing [40]. As school, work, and social settings had shifted to a primarily web-based setting for many students, the use of web-based interventions may have had effects opposite to what had been intended; instead of providing an accessible mindfulness exercise or physical activity option, the intervention setting could have been perceived as a deterrent or a reason for participant dropout. Future research on the topic of web-based mental health interventions would benefit from more gender-equal participant recruitment and distribution, possibly by comparing an in-person intervention setting with a web-based setting. In addition, future studies of mental health interventions in students could use different strategies to motivate and communicate with participants to reduce the participant attrition rate.

Conclusions

Our study showed that the participants in both the WeActive and WeMindful groups experienced significantly decreased depression symptoms over time. This decrease in depression occurred despite the stressors of upcoming final examinations for all participants. Anxiety symptoms decreased but did not reach a statistically significant level. Both web-based aerobic resistance training and web-based yoga mindfulness exercises seem to be effective in buffering mental health distress, especially with depression. Future research should focus on examining the effects of web-based environments against in-person environments for reducing mental health disorder severity or symptoms in college students. In addition, as this study used multiple modalities in both aerobic resistance training and yoga mindfulness exercise interventions, future research could benefit from exploring single modality interventions, such as aerobic exercise compared with resistance training or yoga compared with meditation. This study suggests that both the combination of aerobic resistance training and the combination of yoga mindfulness exercises are associated with a reduction in college student depression scores over an 8-week period. As the findings from our study indicate the potential efficacy of WeActive and WeMindful interventions in improving student mental health measures, this study design could be a useful resource for colleges and mental health treatment providers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT eHealth Checklist (V 1.6.1).
[PDF File (Adobe PDF File), 848 KB - formative_v6i4e31839_app1.pdf]

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Abbreviations

ANCOVA: analysis of covariance
CONSORT: Consolidated Standards of Reporting Trials

MDI: Major Depression Inventory
MVC: mindfulness virtual community

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Original Paper

Reducing Inappropriate Urinary Catheter Use by Involving Patients Through the Participatient App: Before-and-After Study

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Abstract

Background: The risk of urinary tract infections is increased by the inappropriate placement and unnecessary prolongation of the use of indwelling urinary catheters. Sustained behavior change in infection prevention could be promoted by empowering patients through a smartphone app.

Objective: The aim of this study is to assess the feasibility and efficacy of implementation actions on patients' use of the Participatient app on a clinical ward and to compare 3 survey methods for urinary catheter use.

Methods: Participatient was introduced for all admitted patients at the surgical nursing ward in a university hospital in the Netherlands. Over a period of 3 months, the number of new app users, days of use, and sessions were recorded. In a comparison of urinary catheter use before and after the implementation of the app, 3 methods for point prevalence surveys of catheter use were tested. Surveys were conducted through manual parsing of the text in patients' electronic medical records, parsing a survey of checkbox items, and parsing nursing notes.

Results: In all, 475 patients were admitted to the ward, 42 (8.8%) installed the app, with 1 to 5 new users per week. The actions with the most ensuing app use were the kick-off with the clinical lesson and recruiting of the intake nurse. Between the survey methods, there was considerable variation in catheter use prevalence. Therefore, we used the standard method of manual parsing in further analyses. Catheter use prevalence decreased from 38% (36/96) to 27% (23/86) after app introduction (OR 0.61, 95% CI 0.32-1.14).

Conclusions: The clinical application of Participatient, the infection prevention app for patients, could be feasible when implementation actions are also used. For surveying indwelling urinary catheter use prevalence, manual parsing is the best approach.

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KEYWORDS

infection control; catheter-associated urinary tract infections; urinary catheter; patient empowerment; catheter; urology; infection; urinary tract infection; smartphone app; surgical nursing

Introduction

The risk of urinary tract infections increases with the inappropriate placement and unnecessary prolonged use of indwelling urinary catheters. As a result, catheter-associated urinary tract infections (CAUTIs) are a leading cause of health care–associated infections (HAIs). In Europe, CAUTIs account for 152 (95% CI 145-161) cases of HAIs and 81.2 (95% CI 69.0-94.2) disability-adjusted life years per 100,000 population per year. CAUTIs cause excess morbidity, increased length of hospital stays, and increased use of antibiotics [1,2].

Current infection control programs for CAUTI prevention increase health care worker knowledge and awareness of inappropriate catheter use with varying success. Best practices for preventing CAUTIs in acute care hospitals include providing guidelines, supplies, and documentation; performing CAUTI surveillance; educating and training staff; ensuring the use of appropriate technique for aseptic insertion; and ensuring appropriate management [3,4]. Sustained behavior change in appropriate catheter use is often arduous [5]. However, although challenging to implement and compare, we hypothesize that patient participation in infection prevention could be an effective sustainable strategy [6].

Together with patients, nurses, and physicians, we initially developed the smartphone app Participatient for patients. It contains details on practical matters related to the hospital stay, such as visiting hours, and a catheter check function aiming to promote communication on catheter use [7]. The catheter check helps patients assess the indication for their catheter. If no appropriate indication is found, the app advises the user to ask their nurse or physician for the indication. This way, the app helps create awareness and reduce the unnecessary (long-term) use of catheters, thereby aiming to reduce CAUTIs on the entire ward. Surveys of catheter use will be essential for testing the eHealth intervention Participatient in the future. Therefore, in addition to the standard manual survey, 2 alternative methods for surveying catheters will also be evaluated. If accurate enough compared to the standard method, parsing of checkboxes or nurses' notes parsing methods could be a more efficient alternative to manual text parsing.

This study is embedded in the National eHealth Living Lab (NeLL). Through interdisciplinary collaboration, eHealth studies conducted in partnership with the NeLL will create new and innovative solutions that improve health and wellbeing by using suitable eHealth tools for each specific research question.

In this study, the main objective was to assess the feasibility of implementing the Participatient app and the efficacy of sequential stimulating actions on patients' use of the app. The secondary objective was to compare the accuracy of 3 survey methods for urinary catheter use.

Methods

Study Design and Setting

In this study, a before-and-after design was used; surveys were conducted on indwelling urinary catheter use before (T0) and after (T1) the app was introduced. Usage data were continuously collected from the app after introduction.

Adult patients were eligible for inclusion in the surveys if admitted to the 36-bed nursing ward for general, gastrointestinal, and oncological surgery at the Leiden University Medical Center in the Netherlands. Patients were excluded from the point prevalence surveys (PPS) if they were not present on the ward at the time of the survey or if they were admitted on the day of the survey. Patients in T1 were invited to use the app during their stay.

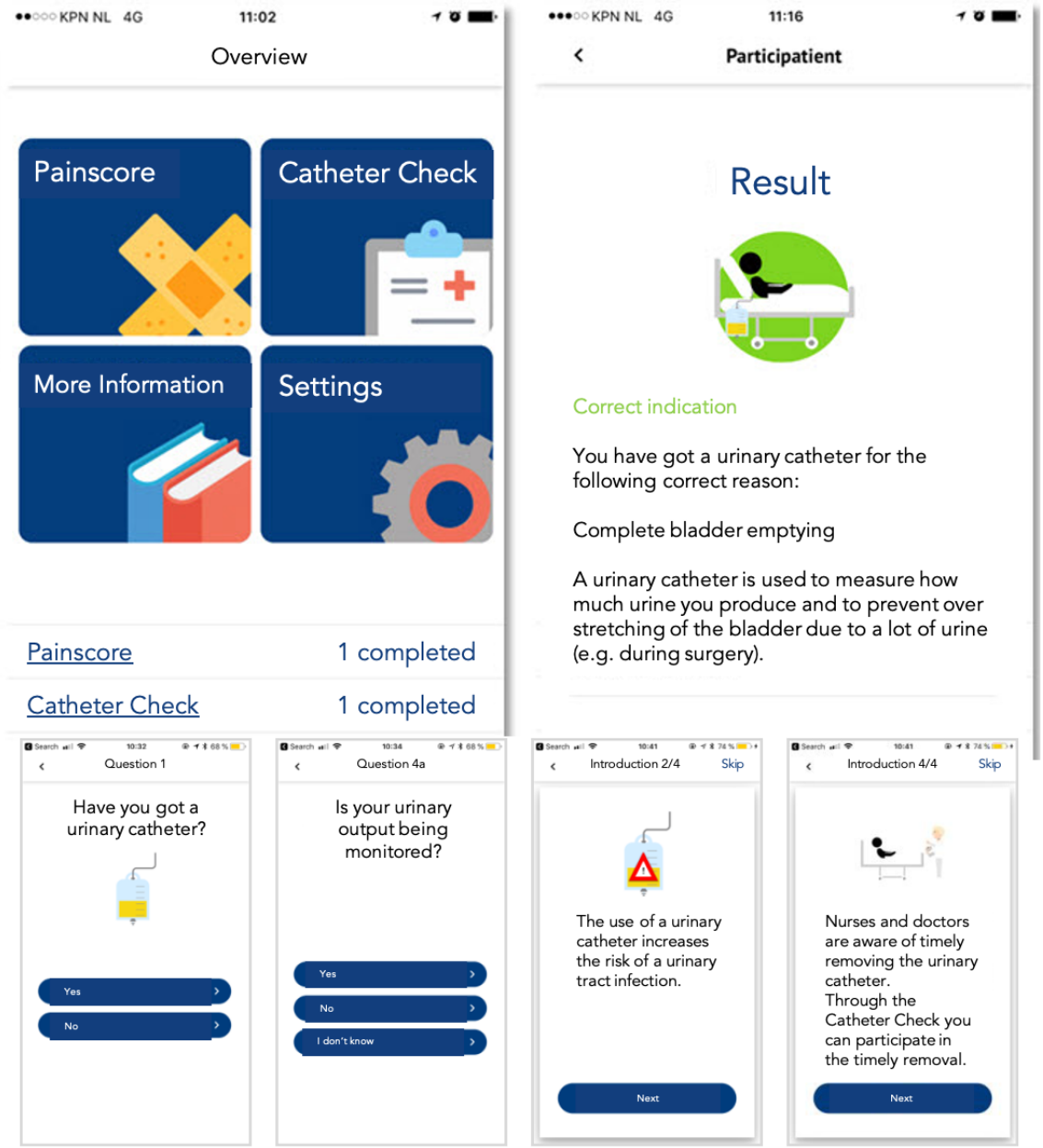
Ethics Approval

This trial was approved by the Medical Ethics Research Committee of the Leiden University Medical Center, with a waiver for individual informed consent (protocol C17.075). Local feasibility was approved by the ward.

Participatient App

The top left panel of Figure 1 shows the Participatient app menu with links to the following pages: painscore (added to help with pain management during admission), catheter check, more information, and settings. The top right panel of Figure 1 shows the result screen for the catheter check function with, depending on the outcome of the questionnaire, an appropriate indication for catheter use (measuring urinary output) with background information. The bottom row of Figure 1 shows screenshots of the questions in the catheter check function with an explanation and a prompt for the patient to discuss their catheter use with their nurse or physician. App development and the final product were previously described in full [7].

Figure 1. The Participatient app with the catheter check function.



Feasibility Testing of the Implementation Actions

In preparation for putting this previously developed app (Figure 1) into practice, the nursing team was given a clinical lesson on urinary tract infections, catheter indications, patient involvement, and the functions of the Participatient app (this implementation action is hereby referred to as the kick-off with the clinical lesson). The nurses were asked to provide input for updating the app and for adjusting it to the ward. Adjustments included the addition of visiting hours, staff, and medical information. After updating the app with these adjustments, nurses merely invited patients to download the app upon admission to the ward. As an implementation action during the course of the study, the intake nurse was recruited and trained to invite patients early in the patients' admission to the ward to further stimulate app use. Additionally, the researchers scheduled reminders of the project for the nurses to promote app use (stimulant reminder given to nurses).

The efficacy of the implementation actions on app use was evaluated by calculating the number of new users, sessions, and days of active use. A new user was registered when the catheter check was used on a unique mobile device. Every instance of opening the app was counted as a session. The days of active use were calculated as the days with one or more sessions per user. Access to the app was restricted to the ward through a 4-digit code.

Feasibility Testing of the 3 Survey Methods

The PPS were conducted using 3 methods and the accuracy of these methods was compared. Data were collected on the prevalence, indication, and duration of urinary catheter use. The PPS were carried out according to national and international guidelines [8,9], as was the scoring of the appropriateness of the catheter indication (Multimedia Appendix 1).

The prevalence and indication of catheter use were manually scored as documented in-text on the date of the survey in the

electronic medical record (EMR). This method was compared with the sensitivity and specificity of surveys of checkboxes (which could be automated) and with parsing nursing notes surveys (Table 1 and Multimedia Appendices 2-4). In the event of missing data on the catheter indication, the reason for catheter use was scored as "not registered" and thus, inappropriate. A total of 2 trained observers (MLB and RGB) independently surveyed catheter use to reduce bias in the measurement of the outcome [10]. We compared the results and discussed discrepancies with a senior observer (KEV).

Data were analyzed using descriptive statistics with the statistical package SPSS (version 26.0; IBM Corp). Between categorical variables, associations were tested with the Pearson chi-squared test, calculating odds ratios with confidence intervals and *P* values. Two-sided *P* values less than .05 were considered significant.

Table 1. A comparison of the 3 survey methods for urinary catheter use before (T0) and after (T1) the implementation of the Participatient app.

Survey methods	Urinary catheter prevalence at T0 (n=96), n (%)	Urinary catheter prevalence at T1 (n=86), n (%)	Odds ratio (95% CI)	*P* value[a]
Manual text parsing	36 (38)	23 (27)	0.61 (0.32-1.14)	.12
Checkbox survey parsing	37 (39)	29 (34)	0.81 (0.44-1.49)	.50
Nurses' notes parsing	28 (29)	18 (21)	0.64 (0.33-1.27)	.20

[a]Two-sided *P* values less than .05 were considered significant.

Results

App Use

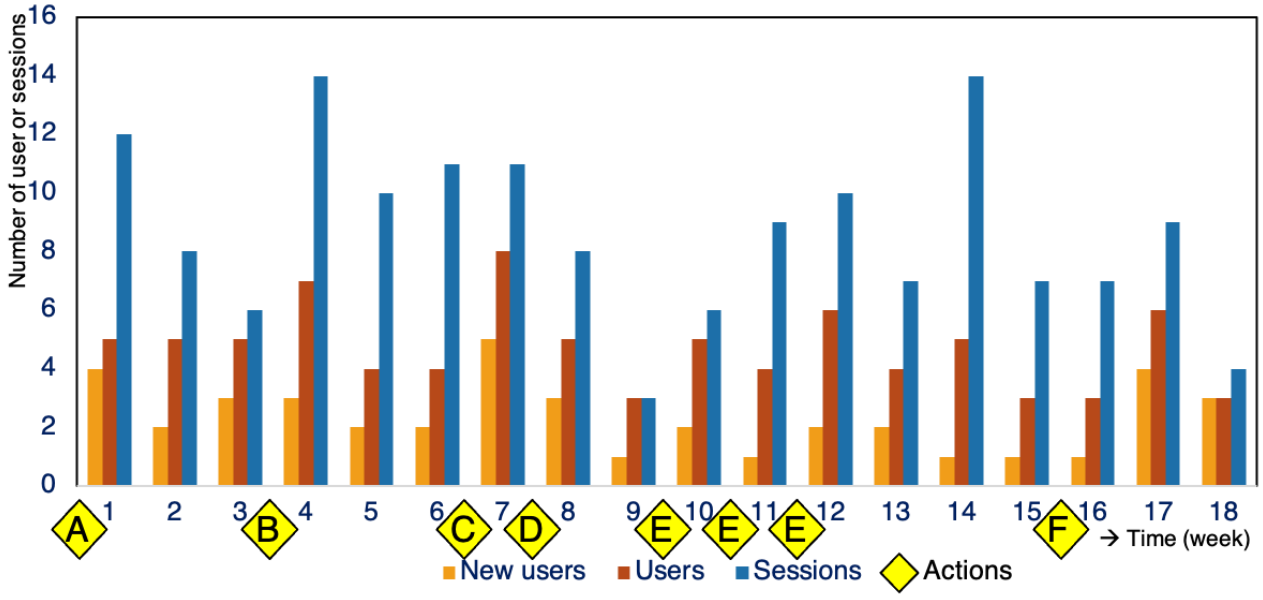
The Participatient app was introduced between October 2017 and January 2018 (T1). Of the 475 patients admitted to the ward, 42 (8.8%) new users installed and used the catheter check function. We registered 85 days of active use and 156 sessions, with an average use of 3.7 sessions per individual user (Multimedia Appendix 5). Since the app is meant to be privacy-friendly, we did not collect demographic data on users.

The highest number of new users was seen following the kick-off with the clinical lesson for nurses and after recruiting the intake nurse to promote app use for the project. The infographic posters and the stimulant reminder given to nurses resulted in the fewest new users among the implementation actions used (Figure 2). The app users reported to be very satisfied with their involvement and the personalized advice they received, rating the app 4.7 out of 5 stars.

The efficacy of the implementation actions for promoting app use was registered as the number of new users, users, and sessions.

A new user was measured as a new installation on a unique mobile device. The number of users referred to the total number of unique users per 24 hours, and a session was counted for every instance of use. Within Figure 2, the following implementation actions are marked at the time point when they began: (A) kick-off with the clinical lesson, (B) infographic posters, (C) recruiting the intake nurse, (D) stimulant reminder given to the nursing team, (E) support rounds with technical assistance performed by the research team, and (F) feedback given to the nursing team on app use and catheter use prevalence. Actions C and D were added to the scheduled actions after interim analyses and feedback from the ward.

Figure 2. Results of implementation actions to increase patients' app use. The efficacy of the implementation actions was registered as the number of new users, users, and sessions.



Catheter Use Surveys

Of the 182 patients included in the PPS, 96 patient records were surveyed in T0 and 86 were surveyed in T1. Baseline characteristics (sex and age) were similar between the groups (Multimedia Appendix 6). The mean age was 63 years, and 41% (75/182) of patients were female.

The prevalence of indwelling urinary catheter use differed considerably between survey methods (Table 1 and Multimedia Appendices 2-4). Compared to the customary method of manual parsing of the text in the EMR, parsing a survey of checkbox items in the EMR had a sensitivity of 96.6% and a specificity of 92.7%. Paring nurses' had a sensitivity of 64.4% and a specificity of 93.5%. Therefore, we decided to continue to use manual parsing in further analyses.

Catheter use prevalence on the ward decreased from 38% (36/96) of patients to 27% (23/86) of patients after app introduction (OR 0.61, 95% CI 0.32-1.14). The average duration of catheterization dropped from 6.9 days to 2.3 days, while the median remained 2 days. We found a 39% (from 56% to 17%) decrease in the number of inappropriate indications for catheter use after the introduction of the app (OR 0.17, 95% CI 0.05-0.60). A total of 56% (20/36) of patients had an inappropriate indication before the introduction of the app, and 17% (4/23) had an inappropriate indication after the introduction of the app. This is shown in Table 2.

Table 2. The number of incorrect indications for catheter use before (T0) and after (T1) the implementation of the Participatient app.

Time point of inappropriate indication	Urinary catheter prevalence at T0 (n=36), n (%)	Urinary catheter prevalence at T1 (n=23), n (%)	Odds ratio (95% CI)	*P* value[a]
At catheter insertion	10 (28)	0 (0)	N/A[b]	.006
At catheter survey	20 (56)	4 (17)	0.17 (0.05-0.60)	.004

[a]Two-sided *P* values less than .05 were considered significant.

[b]Not applicable due to an inappropriate urinary catheter prevalence of 0% at T1.

Discussion

The Participatient app aims to reduce the inappropriate (long-term) use of indwelling urinary catheters through patient involvement. The primary objective of this study, to assess the feasibility of the implementation and efficacy of implementation stimulating actions on the use of the Participatient app, was achieved by registering new users each week. Additionally, we were able to compare the 3 survey methods for catheter use.

A total of 1 in 11 patients admitted to the ward used the app. The highest number of new app users per week was registered following the kick-off with the clinical lesson and after recruiting the ward's intake nurse. The peak in downloads in weeks 17 and 18 could be a delayed result of the feedback given to nurses in week 16. We hypothesize that actively engaging the nurses increases their motivation to promote the app. This is largely consistent with patient involvement in infection prevention, which increases with explicit permission to use the app and participate in their care by staff. As in the other HAI prevention studies, we found that involving nursing staff and keeping them engaged through multifaceted stimulant actions is essential for patient empowerment [4,6,11,12].

Parsing the survey of checkbox items or parsing nursing notes for indwelling urinary catheter use prevalence was inadequate compared to manual text parsing. Manual EMR parsing is laborious; however, this method is most in line with guidelines and previous studies [4,8,9] and is needed for the assessment of the catheter indication. Additionally, the results of the alternative survey methods (parsing checkboxes or nursing notes) are too far removed from the standard method. This could be due to a failure to register the catheter removal date in the proper EMR entry field or updating the daily nursing note too late.

A strength of this study is that it assesses the innovative approach of using eHealth to reduce CAUTIs. Additionally, engaging with physicians, nurses, and patients provides a relevant new perspective. A possible limitation of this study is the manual survey method with the registration of indications for catheter use is limited to parsing of the text in the EMR. Indications not described could have been missed. Additionally, the results could be biased by the introduction of the app to a specific department and/or the small sample size. Registered use of the catheter check function was only 8.8% (42/475), with the target group being elderly hospitalized patients. This was not unexpected as the app should be seen as part of a bundle of interventions to create awareness on the ward as a whole. Encouraging patients to use the app and employing nurse ambassadors who can promote the app could help improve app use. Furthermore, CAUTIs, which are also a relevant outcome, were not scored as this was not the objective due to the short duration of this feasibility study. Remarkably, the prevalence of urinary catheter use was high, with a decreasing trend after the introduction of the app. Additionally, the fraction of inappropriately used catheters decreased significantly.

Jones et al [13] found interventions aimed at the prevention of CAUTIs and *Escherichia coli* bacteremia often did not use behavioral theory or frameworks, and research is required using robust methodologies to evaluate these interventions. The Participatient intervention is designed and built according to the CeHRES (Centre for eHealth and Wellbeing Research) framework, with the involvement of all stakeholders in the development [7]. The before-and-after study design used for this feasibility study could be improved to decisively conclude on the intervention's effectiveness. In mHealth interventions, economic evaluations are limited. In future assessments, this should be included in the analysis [14].

The clinical application of Participatient, the infection prevention app for patients, could be feasible when

implementation actions are combined. Engaging physicians and nurses could help because additional users are observed after the implementation stimulating actions, particularly when actively involving nursing staff. Manual parsing is the preferred method for surveying the effect on urinary catheter use. A larger study spanning various populations could further evaluate the app's effectiveness with the outcomes of catheter use appropriateness and infections.

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Authors' Contributions

The conception and design of the study were done by RGB, MLB, NHC, and KEV. RGB and MLB collected the data. The formal analysis of the data was done by RGB. RGB and KEV wrote the original draft of the manuscript. All authors contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Urinary catheter indications.
[PDF File (Adobe PDF File), 55 KB - formative_v6i4e28983_app1.pdf]

Multimedia Appendix 2
A detailed comparison of 3 survey methods for urinary catheter use before (T0) and after (T1) implementation of the Participatient app.
[PDF File (Adobe PDF File), 82 KB - formative_v6i4e28983_app2.pdf]

Multimedia Appendix 3
A comparison of the following survey methods for urinary catheter use: manual parsing versus checkboxes.
[PDF File (Adobe PDF File), 56 KB - formative_v6i4e28983_app3.pdf]

Multimedia Appendix 4
A comparison of the following survey methods for urinary catheter use: manual parsing versus nursing notes.
[PDF File (Adobe PDF File), 58 KB - formative_v6i4e28983_app4.pdf]

Multimedia Appendix 5
Results of implementation actions to increase patients' app use.
[PDF File (Adobe PDF File), 97 KB - formative_v6i4e28983_app5.pdf]

Multimedia Appendix 6
Baseline characteristics of the point prevalence surveys.
[PDF File (Adobe PDF File), 65 KB - formative_v6i4e28983_app6.pdf]

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Abbreviations

CAUTI: catheter-associated urinary tract infection
EMR: electronic medical record
HAI: health care–associated infection
NeLL: National eHealth Living Lab
PPS: point prevalence surveys

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Early Reports

Satisfaction and Acceptability Ratings of a Web-Based Self-help Intervention for Depression: Retrospective Cross-sectional Study From a Resource-Limited Country

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Abstract

Background: Web-based interventions are at an early stage in non–English-speaking low- and middle-income countries, where they remain scarce. Help for Depression (HDep) is one of the few unguided web-based interventions available in Latin America. The results of a use/usability analysis of the original version served as the basis for generating a more user-friendly second version.

Objective: The aim of this study is to explore participants' satisfaction and acceptability for the second version of HDep.

Methods: A retrospective cross-sectional design was used. An email invitation to complete a web-based survey was sent to all people who accessed HDep in 2018. The questionnaire included satisfaction and acceptability scales and open-ended questions. Complete questionnaires were retrieved from 191 participants: 35.1% (67/191) from those who visited only the home page (home page users [HPUs]) and 6.47% (124/1916) from those who registered to use the program (program users [PUs]).

Results: In all groups, users experienced high levels of depressive symptoms (189/191, 98.9%; Center for Epidemiological Studies Scale-Depression >16). Moderate levels of satisfaction (HPUs: mean 21.9, SD 6.7; PUs: mean 21.1, SD 5.8; range: 8-32) and acceptability (HPUs: mean 13.8, SD 3.9; PUs: mean 13.9, SD 3.2; range: 5-20) were found in both groups. Logistic regression analyses showed that among HPUs, women were more satisfied with HDep (odds ratio [OR] 3.4, 95% CI 1.1-10.0), whereas among PUs, older respondents (OR 1.04, 95% CI 1.01-1.08), those with paid work (OR 3.1, 95% CI 2.4-7.6), those who had not been in therapy (OR 2.42, 95% CI 1.09-5.98), and those who had not attempted suicide (OR 3.4, 95% CI 1.1-11.1) showed higher satisfaction. None of the sociodemographic/mental health variables distinguished the acceptability ratings among HPUs. Among PUs, those with paid work (OR 2.5, 95% CI 1.1-5.5), those who had not been in therapy (OR 3.1, 95% CI 1.3-7.3), those without disability (OR 2.9, 95% CI 1.3-6.6), and those who had not attempted suicide (OR 2.6, 95% CI 1.0-6.6) showed higher acceptability.

Conclusions: HDep has good levels of satisfaction and acceptability for approximately half of its users, and the information provided by respondents suggested feasible ways to remedy some of the deficiencies. This qualitative–quantitative study from a low- to middle-income, non–English-speaking country adds to existing knowledge regarding acceptance and satisfaction with web-based interventions for depression in resource-limited countries. This information is important for the creation and adaptation of web-based interventions in low- and middle-income countries, where access to treatment is a major concern, and web-based prevention and treatment programs can help deliver evidence-based alternatives. It is necessary to document the pitfalls, strengths,

and challenges of such interventions in this context. Understanding how users perceive an intervention might suggest modifications to increase adherence.

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KEYWORDS

depression; web-based intervention; unguided intervention; acceptability; satisfaction; resource-limited country

Introduction

Background

The World Health Organization [1] has ranked depression as the single largest contributor to global disability, accounting for 7.5% of all years lived with disability. More than 80% of this nonfatal disease burden occurs in low- and middle-income countries (LMICs). In Mexico, depressive disorders account for 8.6% of the years lived with disability [1]. Prevention and treatment interventions can reduce the burden associated with depression and other mental health disorders. However, mental disorders remain untreated in many nations; in Latin America, only 5% of people with affective disorders receive adequate treatment [2]. In Mexico, only 6.4% of those diagnosed with major depressive disorder receive minimally adequate treatment [3].

Internet- or web-based interventions represent effective, accessible, and low-cost means to treat and prevent depressive disorders, and they can be broadly disseminated [4,5]. Unguided interventions, based purely on self-help with no human support, can reach large numbers of people at low cost, and there is evidence that even those who experience enough symptoms to screen positive for a major depressive episode use preventive interventions [5]. Meta-analytic studies show that these interventions have benefits but exhibit low adherence rates [6]. The average rate of adherence in unguided interventions is estimated at 26%, compared with 72% in guided interventions [7]. Despite the high attrition rates and lesser effectiveness of unguided programs, these low-cost, low-intensity, web-based interventions are suitable from a public health perspective as early intervention in a stepped-care process [8] and are thus of particular benefit in LMICs [9].

Web-based interventions for common mental health problems, such as depression, have a long history and have evolved rapidly in high-income countries, but they are at an earlier stage of development and are less common in LMICs [10-12]. Web-based interventions to prevent depression are associated with small but positive effects on the symptoms [13]. Help for Depression (HDep; Ayuda para Depresión) [14], in Mexico, was the first such web-based intervention in Latin America [15].

The initial version of HDep (2009-2013) was modeled after a face-to-face psychoeducational intervention in Mexico to prevent depression in women, based on multimodal and cognitive behavioral principles (Table 1) [16]. This initial intervention was modeled after that of Muñoz and Ying [17] in California, designed for the ethnic minority groups, including the Latino population. The content of the program that we developed went through a step-by-step process including focus groups and open-ended questionnaires to verify that language, illustrations, and content were sensitive to the target population [18].

Table 1. Help for Depression content.

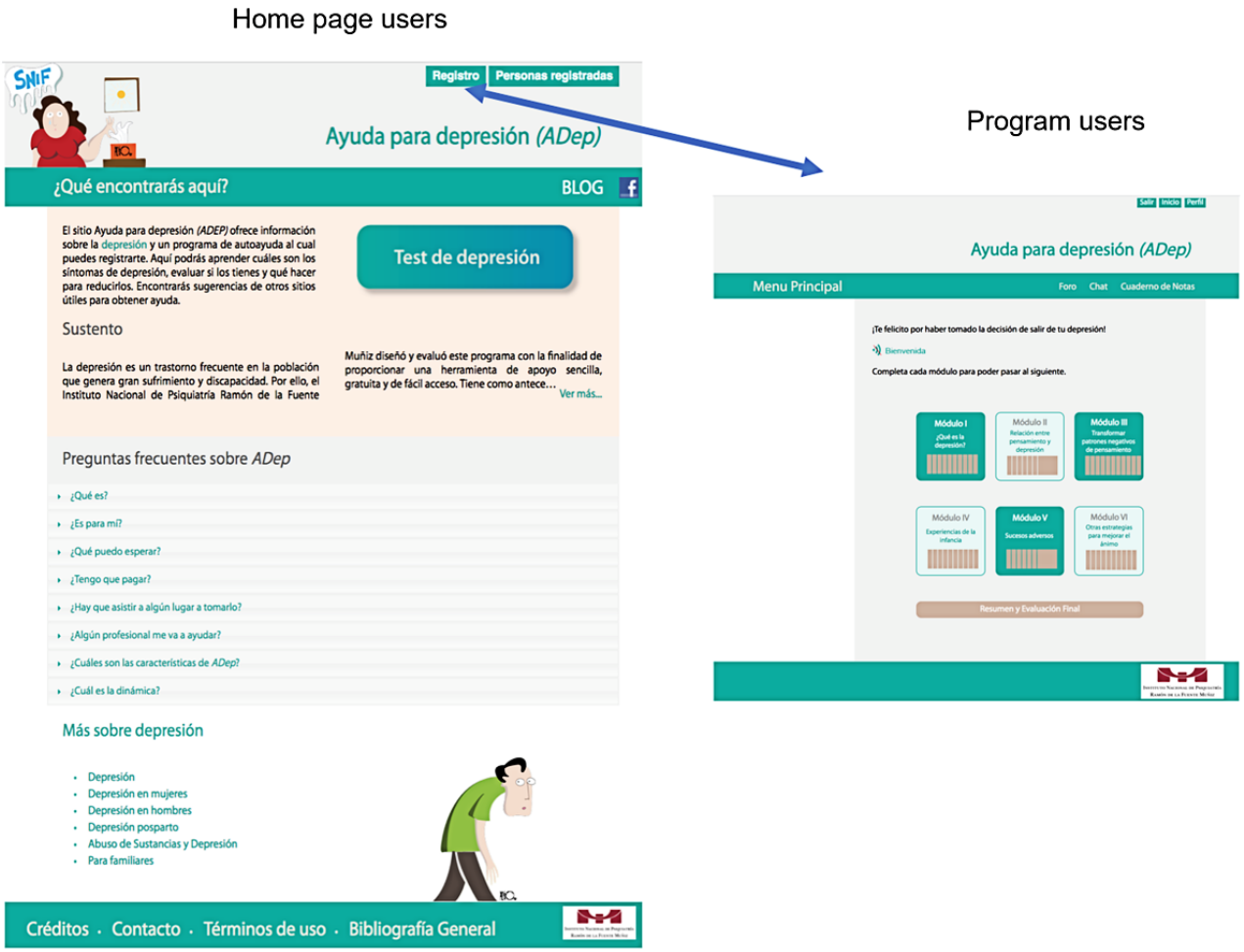
Module	Content
1. What is depression?	• Diagnosis • Symptoms • Risk factors
2. Identify negative thoughts	• Relationship between ways of thinking and depression • Identifying your ways of thinking
3. How to transform negative thoughts	• Changing negative thought patterns • Questioning your negative thoughts • Transforming your negative thoughts
4. Childhood experiences	• Your thought patterns derived from your childhood experiences • Transforming your negative thoughts • Reinforcing your positive thoughts in daily life
5. Adverse events	• Adverse life events • Stressful events in everyday life • Adverse events and negative thoughts • Relaxation exercise
6. Other strategies to improve mood	• Increasing social support • Behavioral activation

A use/usability analysis of the first version of HDep showed that 15.6% of the users were men [15]. Two psychologists with experience working with men reviewed the language and vignettes for cultural sensitivity to male users. The analysis of that version also suggested the need for a shorter and more user-friendly version [15], which was produced by reducing the number of modules. In the new version, users need to provide minimal information (sex, age, and email) to access home page content. The home page includes (1) a self-assessment scale for depressive symptoms (Center for Epidemiological Studies Scale-Depression [CES-D]), with feedback provided via email; (2) extensive information on depression and places to receive help; (3) a description of the aims and content of the intervention; and (4) a link to register to use the program modules. This arrangement allows for two types of users: home page users (HPUs), who are those who prefer to visit only the home page or landing page and program users (PUs), who decide to register for the program modules after exploring the home page (Figure 1). PUs are asked to provide additional information (marital status, education, psychological or psychiatric treatment for depression, suicide attempts, alcohol and drug use, and medication for mental health problems). HPUs and PUs who answer the CES-D and other health measures are given feedback on their responses; those who may be at risk for clinical depression or mental health disorders are advised to find additional psychological or psychiatric help. HDep is freely accessible, with no inclusion criteria for registration; it is thus available not only for people who meet a clinical diagnosis of depression but also to those with other mental health problems, such as substance abuse [15].

The lack of adequate mental health services for most of the population of Mexico and other Latin American countries means that very few people receive even minimally adequate treatment for depression [3]. In this context, internet-based interventions play an important role in the prevention and treatment of depression; however, they are still at an early stage of development in these countries.

Since 2014, the revised version of HDep has had around 2956 visits each month from individuals who answered the depression scale (CES-D) and received feedback based on their scores. At the same time, there is a high rate of attrition, which is consistent with data from a scoping review in Latin America [19]. To improve adherence, it is important to analyze users' experience, perception, and satisfaction with HDep to find ways to encourage people to complete the intervention [5].

Figure 1. Help for depression home page: types of users of the intervention.



Objectives

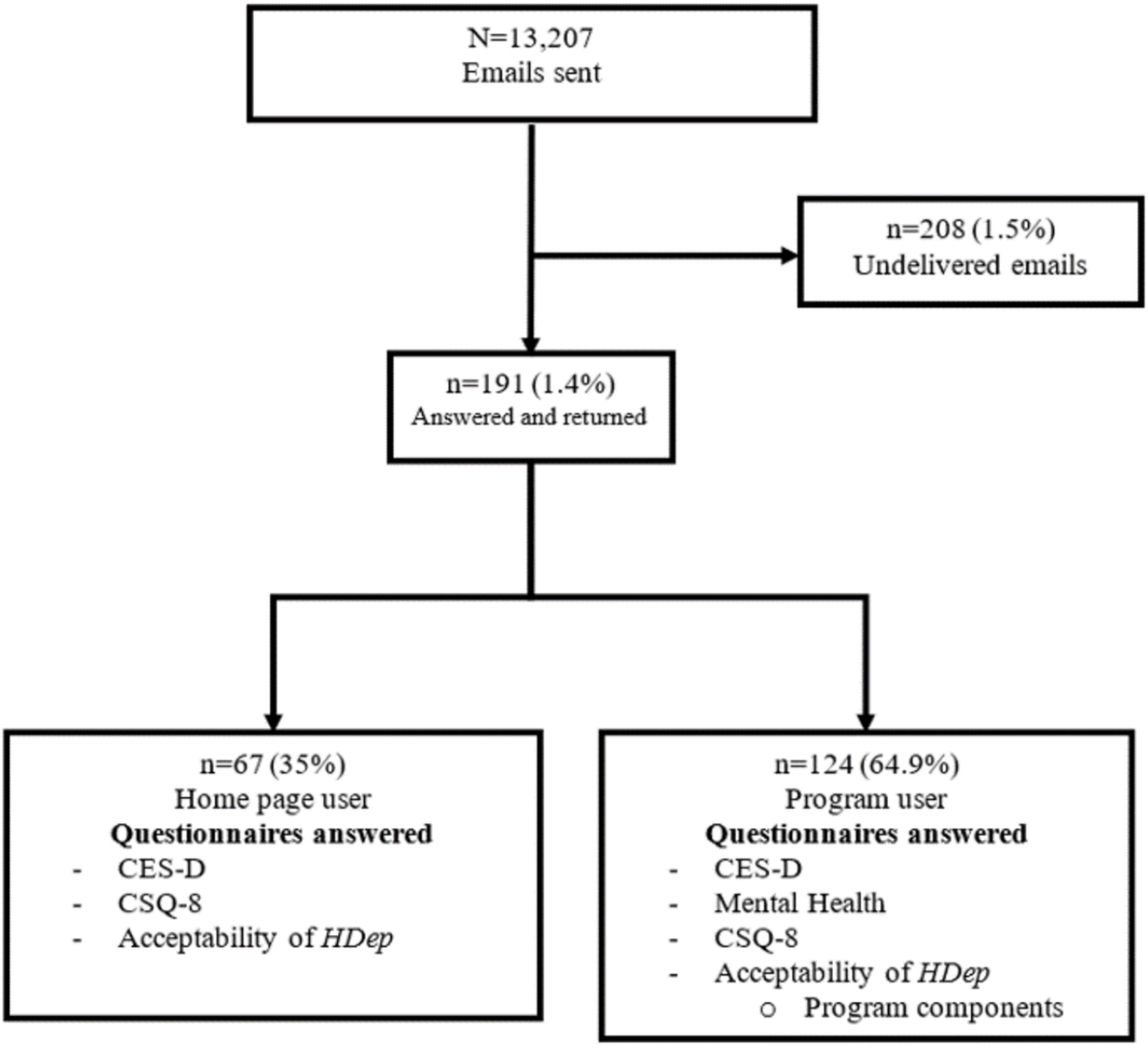
The aim of this study is to assess the acceptability of and satisfaction with the updated version of HDep, considering both types of users separately: HPUs and PUs. This was an exploratory study, with the underlying hypothesis that PUs would show greater acceptance and satisfaction than HPUs, as they were receiving a higher dose of the intervention.

Methods

Study Design and Participants

A retrospective cross-sectional design was used in this study. The population corresponds to people who visited HDep: HPUs and PUs from January to December 2018 (N=13,207) and answered the initial depressive symptoms questionnaire (CES-D), which is accessible on the home page. The sample size was determined according to the procedure of Lemeshow et al [20] for the following parameters: a finite population with a CI of 95% and a margin of error of 10%. This margin of error was chosen because web surveys have response rates approximately 12% points lower than other survey modes [21]. The minimum number of responses required was 96. Of the 13,207 emailed questionnaires, 191 (191/13,207, 1.45%) were answered and returned. A total of 208 (208/13,207, 1.57%) were undelivered (indicated by automatic replies). There is no information on whether the rest reached the target users (Figure 2). The CI for the response rate was 95%, with a margin of error of 7%.

Figure 2. Participant flowchart. CES-D: Center for Epidemiological Studies Scale-Depression; CSQ-8: Client Satisfaction Questionnaire-8; HDep: Help for Depression.



Instruments

Data retrieved from HDep databases: email, sex, age, marital status, occupation, education, depressive symptoms (CES-D), disability during the previous month owing to depressive symptoms, psychological or psychiatric treatment for depression, suicide attempt in the last 6 months, alcohol and drug use, and medication [15].

Depressive Symptoms

Depressive symptoms are assessed with the CES-D [22], which has 20 items with Likert response options (0=rarely or never to 3=most of the time). The cutoff point indicating the presence of depressive symptoms was ≥16. The CES-D has been validated in Mexico [23].

Satisfaction With HDep

Satisfaction with HDep is measured with the short version of the Client Satisfaction Questionnaire-8 (CSQ-8) [24] (Spanish version [25]), which includes 8 questions on a Likert scale of 1 to 4, with higher scores indicating greater satisfaction. A change was made in the wording of the questions to align it with the purpose of the study: *HDep* was used instead of *service*. The CSQ-8 is reliable across a variety of ethnic contexts, including Hispanic groups, and the Spanish version is as reliable as the English version (Cronbach α=.90) [26]. The Cronbach coefficient for the scale in the sample was a Cronbach α of .95.

Acceptability of HDep

As in many studies [27,28], an ad hoc questionnaire was developed to evaluate this construct. It consisted of 17 questions, of which only 15 quantitative questions were analyzed (the other two were open-ended questions that received few responses; thus, they were not included: *Is there something additional that helped you that is not listed here?* and *Are there any additional comments you would like to add?*). The first five questions were related to general acceptability: *Is the home page persuasive? Is the page layout of the modules inviting? Does HDep seem useful for managing depression? Did HDep meet your expectations?* and *Is the website user friendly?* Respondents were asked to answer the questions on a 4-point Likert scale (1=low to 4=high acceptability). The Cronbach coefficient for these 5 questions in the sample was a Cronbach α of .89. In all, 2 questions rated the HDep content and design on a scale of 1 to 10, with a space to provide open-ended elaboration. The final eight questions scored the following elements of HDep on a scale of 1 to 10: module information, sample cases, activities, forums, chats, thought charts, audio, and depressive symptom assessment and feedback. The Cronbach coefficient for the scale in the sample was a Cronbach α of .95. Except for the depressive symptoms assessment and feedback, these questions were analyzed only for users who registered for the program (PUs), as these elements are part of the program modules.

Procedure

The link to the web survey was delivered via email (using the Mail Chimp and Google Forms platforms), including a cover letter explaining the objectives of the study and why users were being contacted. A follow-up email was sent 1 month later to those who had not answered. As a token of appreciation, those who responded to the survey were sent a list of 10 positive thoughts to reinforce HDep activities and improve mood.

The survey was designed to be user friendly; it was configured to prevent users from leaving questions unanswered.

Ethical Considerations

The study was approved by the Ethics Committee of the National Institute of Psychiatry, Mexico (CEI/C/050/2018). The terms of use on the HDep home page explain that some of the data provided by users may be used for scientific reports and publications but that participant confidentiality will be maintained. An informed consent letter was included with the survey, underscoring the guarantee of confidentiality.

Data Analyses

The percentages of sociodemographic characteristics and the means and SDs of the overall satisfaction scale and for individual items were obtained for HPUs and PUs and compared using chi-square and 2-tailed *t* tests. The same procedure was followed to evaluate the elements of acceptability (user friendly, scope, usefulness, motivation to register and carry out the activities, and expectations) of HDep overall and for each component. Logistic regression analyses were conducted to assess the characteristics of users who were satisfied with the HDep program among the HPUs and PUs. For these analyses, the acceptability and satisfaction scales were dichotomized: the cutoff points were defined at the 75th percentile for each scale (for the CSQ-8, it was ≥26 and for the scale of acceptability, ≥16). Finally, a qualitative thematic analysis was conducted on the responses to the 2 open-ended questions regarding design and content.

Results

Demographic and Psychological Characteristics

Of the 13,207 emailed invitations, 191 (1.45%) were completed questionnaires; 67 (67/191, 35.1%) were from HPUs and 124 (124/191, 64.9%) from PUs. Most were women (141/191, 73.8%; HPUs: 42/67, 63%; PUs: 99/124, 79.8%; χ^2_1=6.22; *P*=.01) and aged 20 years (57/191, 29.8%; HPUs: 24/67, 36%; PUs: 33/124, 26.6%) or aged 21-30 years (68/191, 35.6%; HPUs: 24/67, 36%; PUs: 44/124, 35.5%; χ^2_1=6.22; *P*=.01).

Nearly all users (189/191, 98.9%) experienced high levels of depressive symptoms (CES-D>16), with no significant difference between PUs (124/124, 100%) and HPUs (65/67, 97%; χ^2_1=3.74; *P*=.12). Questions on mental health problems were answered only by PUs; 70 (70/124, 56.4%) PUs reported disability associated with depressive symptoms, 20 (20/124, 16.1%) PUs reported psychological or psychiatric treatment for depression, 21 (21/124, 16.9%) PUs reported a previous suicide attempt, 27 (27/124, 21.8%) PUs reported excessive alcohol use, 15 (15/124, 12.1%) PUs reported excessive drug use, and 39 (39/124, 31.5%) PUs had received drug treatment (Table 2).

Table 2. Demographic and psychological characteristics.

Characteristics	All (N=191), n (%)	Home page user (n=67), n (%)	Program user (n=124), n (%)	Values	
				Chi-square (*df*)	*P* value
Demographic characteristics					
Sex				6.22 (1)	.01
Male	50 (26.2)	25 (37.3)	25 (20.2)		
Female	141 (72.8)	42 (62.7)	99 (79.8)		
Age (years)				3.23 (3)	.35
20	57 (29.8)	24 (35.8)	33 (26.6)		
21-30	68 (35.6)	24 (35.8)	44 (35.5)		
31-40	34 (17.8)	8 (11.9)	26 (21)		
41	32 (16.7)	11 (16.4)	21 (16.9)		
Marital status				N/A[a]	N/A
Single	N/A	N/A	87 (70.2)		
With partner	N/A	N/A	37 (29.8)		
Occupation				N/A	N/A
Employed	N/A	N/A	57 (46)		
Unemployed	N/A	N/A	67 (54)		
Education				N/A	N/A
Junior high school or less	N/A	N/A	10 (5.2)		
High school or more	N/A	N/A	181 (94.8)		
Psychological characteristics					
Depressive symptoms (CES-D[b]>16)	189 (98.9)	65 (97)	124 (100)	3.74 (1)	.12
Disability the previous month owing to depressive symptoms	N/A	N/A	70 (56.5)	N/A	N/A
Psychological or psychiatric treatment for depression				N/A	N/A
Yes, currently	N/A	N/A	20 (16.1)		
Not currently but in the past	N/A	N/A	32 (25.5)		
No	N/A	N/A	72 (58.1)		
Suicide attempt in the last 6 months	N/A	N/A	21 (16.9)	N/A	N/A
Alcohol use	N/A	N/A	27 (21.8)	N/A	N/A
Drug use	N/A	N/A	15 (12.1)	N/A	N/A
Medication (for feeling nervous, anxious, or excessively energetic)	N/A	N/A	39 (31.5)	N/A	N/A

[a]N/A: not applicable.

[b]CES-D: Center for Epidemiological Studies Scale-Depression.

Satisfaction With HDep

The mean satisfaction with HDep was 21.9 (SD 6.7; range 8-32) for HPUs and 21.1 (SD 5.8; range 8-32) for PUs. No significant difference was found in the overall level of satisfaction among types of users (t_{189}=0.845; *P*=.39; Table 3) or on individual items. The highest scores were given to *If a friend needed help, would you recommend HDep?* and *If you were to seek help again, would you come back to HDep*? The item with the lowest score was *To what extent did HDep meet your needs?* (Table 3). No significant differences were found between HPUs and PUs on individual items.

Table 3. Satisfaction with Help for Depression (N=191).

Item	Home page user (n=67), mean (SD)	Program user (n=124), mean (SD)	Values	
			t test (*df*)	*P* value
Scale mean	21.90 (6.74)	21.10 (5.83)	0.84 (189)	.39
1. How would you rate the quality of help you have received?	2.87 (0.88)	2.73 (0.79)	1.04 (189)	.29
2. Did you get the kind of help you wanted?	2.58 (1.00)	2.51 (0.87)	0.53 (189)	.95
3. To what extent has the program helped to solve your problems?	2.21 (0.89)	2.07 (0.77)	1.05 (189)	.27
4. If a friend were in need of similar help, would you recommend our program to them?	3.04 (0.89)	3.00 (0.79)	0.35 (189)	.72
5. How satisfied are you with the amount of help you have received?	2.84 (0.97)	2.64 (0.82)	1.49 (189)	.13
6. Has the help you received helped you to deal better with your problems?	2.60 (0.90)	2.60 (0.79)	0.06 (189)	.95
7. Overall, how satisfied are you with the service you have received?	2.72 (1.05)	2.65 (0.94)	0.47 (189)	.63
8. If you needed to seek help again, would you come back to this program?	3.04 (1.03)	2.90 (0.89)	0.98 (189)	.32

HDep Acceptability

The mean of general acceptability of HDep was 13.84 (SD 3.97; range 5-20) for HPUs and 13.97 (SD 3.29; range 5-20) for PUs, with no significant difference among types of users (t_{189}=0.24; *P*=.80; Table 4). The item with the highest rating was *HDep, a user-friendly program*, and the item with the lowest rating was *HDep, which met my expectations*.

Table 4. Help for Depression (HDep) acceptability (N=191).

Item	Home page users (n=67), mean (SD)	Program users (n=124), mean (SD)	Values	
			t test (*df*)	*P* value
Scale mean	13.84 (3.97)	13.97 (3.29)	0.24 (189)	.80
1. Home page specifies what I can find in HDep and persuades me to register.	2.81 (0.89)	2.92 (0.78)	0.91 (189)	.36
2. Once I am registered, the layout of the module page motivates me to go into each module.	2.72 (0.91)	2.69 (0.77)	0.24 (189)	.80
3. HDep seems like a useful tool to manage depression on my own.	2.70 (0.87)	2.73 (0.88)	0.24 (189)	.80
4. Participating in HDep has met my expectations.	2.72 (0.90)	2.58 (0.85)	1.02 (189)	.30
5. HDep is a user-friendly program.	2.90 (0.97)	3.05 (0.80)	1.23 (189)	.21

Profiles of Users' Satisfaction and Acceptability With HDep

Logistic regression analyses showed that among HPUs, women (odds ratio [OR] 3.44, 95% CI 1.16-10.0) were more satisfied with HDep, whereas among PUs, older participants (OR 1.04, 95% CI 1.01-1.08), those with paid work (OR 3.12, 95% CI 2.40-7.69), those who had not been in therapy (OR 2.42, 95% CI 1.09-5.98), and those who had not attempted suicide (OR 3.44, 95% CI 1.08-11.11) showed higher satisfaction (Table 5). There were no significant differences in acceptability ratings among HPUs by sex, age, or the presence or absence of depressive symptoms. Among PUs, those with paid work (OR 2.50, 95% CI 1.16-5.55), those who had not been in therapy (OR 3.17, 95% CI 1.38-7.30), those without disability associated with depression (OR 2.94, 95% CI 1.35-6.66), and those who had not attempted suicide (OR 2.63, 95% CI 1.03-6.66) gave higher acceptability ratings (Table 6).

Table 5. Profile of home page users (HPUs) and program users (PUs) satisfied with Help for Depression.

Characteristics	CSQ-8[a]≥26			
	HPUs		PUs	
	OR[b] (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.01 (0.97-1.05)	.46	1.04 (1.01-1.08)	.01
Female	3.44 (1.16-10.0)	.02	1.01 (0.36-2.89)	.98
Has partner	N/A[c]	N/A	1.51 (0.63-3.70)	.35
Employed	N/A	N/A	3.12 (2.40-7.69)	.01
High school or more	N/A	N/A	3.12 (0.38-2.5)	.29
Has not been in therapy	N/A	N/A	2.42 (1.09-5.98)	.04
Depressive symptoms	0.98 (0.94-1.03)	.37	0.97 (0.93-1.01)	.28
Without disability the previous month owing to depressive symptoms	N/A	N/A	1.85 (0.26-2.35)	.21
Without previous depression	N/A	N/A	2.5 (0.08-3.89)	.24
Medication (for feeling nervous, anxious, or excessively energetic)	N/A	N/A	2.00 (0.85-4.68)	.11
No suicide attempts	N/A	N/A	3.44 (1.08-11.11)	.03
Alcohol use	N/A	N/A	1.43 (0.55-3.72)	.45
Drug use	N/A	N/A	1.33 (0.19-2.89)	.68

[a]CSQ-8: Client Satisfaction Questionnaire-8.

[b]OR: odds ratio.

[c]N/A: not applicable.

Table 6. Profile of home page users (HPUs) and program users (PUs) who accepted Help for Depression (HDep).

Characteristics	Acceptability of HDep ≥16			
	HPUs		PUs	
	OR[a] (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.01 (0.97-1.05)	.49	1.03 (0.99-1.07)	.63
Female	2.43 (0.90-7.14)	.09	3.13 (0.99-9.83)	.60
Has partner	N/A[b]	N/A	1.92 (0.85-4.34)	.11
Employed	N/A	N/A	2.50 (1.16-5.55)	.20
High school or more	N/A	N/A	2.08 (0.42-2.37)	.36
Has not been in therapy	N/A	N/A	3.17 (1.38-7.30)	.01
Depressive symptoms	0.97 (0.93-1.02)	.65	0.96 (0.93-1.00)	.26
Without disability the previous month owing to depressive symptoms	N/A	N/A	2.94 (1.35-6.66)	.01
Without previous depression	N/A	N/A	0.34 (0.74-1.62)	.18
Medication (for feeling nervous, anxious, or excessively energetic)	N/A	N/A	1.20 (0.54-2.67)	.65
No suicide attempts	N/A	N/A	2.63 (1.03-6.66)	.04
Alcohol use	N/A	N/A	1.25 (0.51-3.05)	.62
Drug use	N/A	N/A	2.17 (0.57- 8.33)	.26

[a]OR: odds ratio.

[b]N/A: not applicable.

Acceptability of Content, Design, and Tools of the Program

Content was assessed similarly for HPUs and PUs (HPUs: mean 7.1, SD 2.9; PUs: mean 7.0, SD 2.5; range 0-10; t_{189}=0.16; *P*=.87). The design was also evaluated positively, with means of 7 and 7.5 (HPUs: mean 7.5, SD 2.6; PUs: mean 7.0, SD 2.5), with no significant difference among types of users (t_{189}=1.33; *P*=.18; Table 7).

HDep individual components, evaluated only by PUs, were scored from 5.19 (SD 3.31) to 6.88 (SD 3.14). Forums (mean 5.62, 3.24) and chats (mean 5.19, SD 3.31) had the lowest acceptability. Depressive symptom assessment and feedback, evaluated by both types of users, had the highest acceptability (PUs: mean 6.88, SD 3.14; HPUs: mean 6.73, SD 3.79), with no significant difference between the 2 user types (Table 7).

Table 7. Users' evaluation of Help for Depression (HDep) content, design, and tools.

Item (rate from 0 to 10 how much each of the following has helped you to manage depression)	Home page users (n=67), mean (SD)	Program users (n=124), mean (SD)	Values	
			t test (*df*)	*P* value
HDep content	7.1 (2.93)	7.00 (2.52)	0.16 (189)	.87
HDep design	7.52 (2.60)	7.00 (2.55)	1.33 (189)	.18
HDep components			N/A[a]	N/A
Module information	N/A	6.52 (3.10)		
Case samples	N/A	6.52 (3.01)		
Activities (scales, thought charts, etc)	N/A	6.46 (3.08)		
Forums	N/A	5.62 (3.24)		
Chat	N/A	5.19 (3.31)		
Thought exercises	N/A	6.35 (3.33)		
Audio	N/A	6.09 (3.26)		
Depressive symptom assessment and feedback	6.73 (3.79)	6.88 (3.14)	0.27 (189)	.79

[a]N/A: not applicable.

Analysis of Open-ended Questions

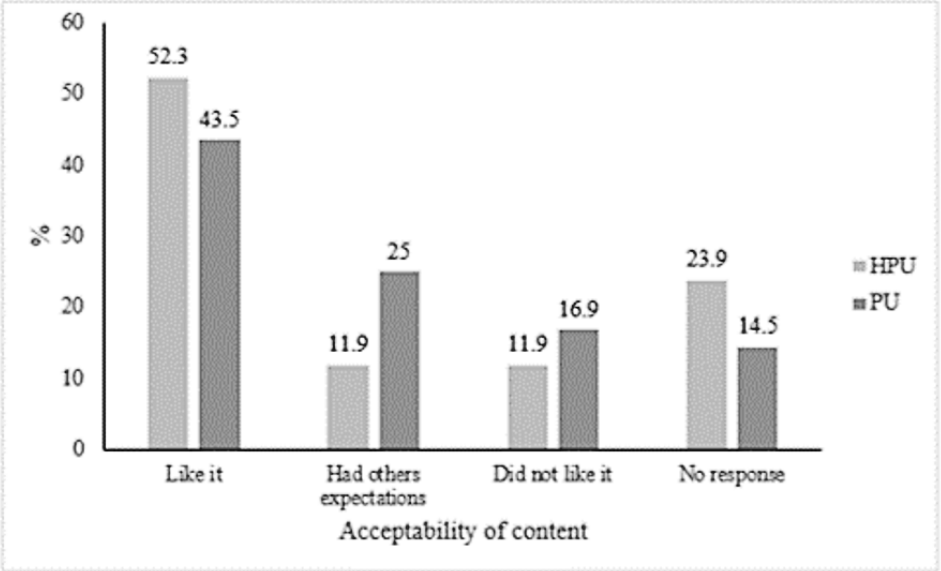
HDep Content

Responses to open-ended questions fell into one of three categories: (1) Liked it, (2) Had other expectations, or (3) Did not like it. The fourth category included those who did not respond (Figure 3). Examples of these explanations are presented in Table 8.

The three categories were as follows:

1. Liked the content—approximately half of the users liked the content: 52% (35/67) of the HPUs and 43.5% (54/124) of the PUs, with no significant difference observed between the 2 groups (Figure 3). HPUs considered the content good, that the help was excellent, and that the use of cases from everyday life encouraged reflection; however, they sometimes considered the web interface cold (Table 8). PUs who liked the content found it systematic, that it gradually made it easier to face life, that the content was meaningful and friendly, and that it allowed them to measure their personal progress. Some respondents who mentioned positive features also pointed out others that required improvement, including a need for additional resources to strengthen individual commitment and motivation.
2. Had other expectations—a significantly greater number of PUs had other expectations (31/124, 25%) than HPUs (8/67, 12%; Figure 3). HPUs reported signing up in search of new information and help and someone to tell them everything was okay, which they did not find. PUs also sought not only interaction with a machine but also contact with a human being, an expert, in forums and chat, with email and mobile phone reminders (Table 8).
3. Did not like the content—respondents who did not like HDep content included 12% (8/67) of HPUs and 16.9% (21/124) of PUs (Figure 3). HPUs thought HDep was neither helpful nor harmful, that they did not need *a pat on the back*, and that *a little rough treatment might not hurt*. PUs said that the content did not motivate them to continue; in the opinion of one, "there was too much content to read which you can't when you are depressed" (Table 8).

Figure 3. Acceptability of help for depression content and design. (A) Liked it (χ^2_1=1.32; *P*=.15); Had other expectations (χ^2_1=4.56; *P*=.02); Did not like it (χ^2_1=0.84; *P*=.24); No response (χ^2_1=2.60; *P*=.08). (B) Liked it (χ^2_1=0.77; *P*=.23); Had other expectations (χ^2_1=0.19; *P*=.47); Did not like it (χ^2_1=3.95; *P*=.03); No response (χ^2_1=9.13; *P*=.001). HPU: home page user; PU: program user.



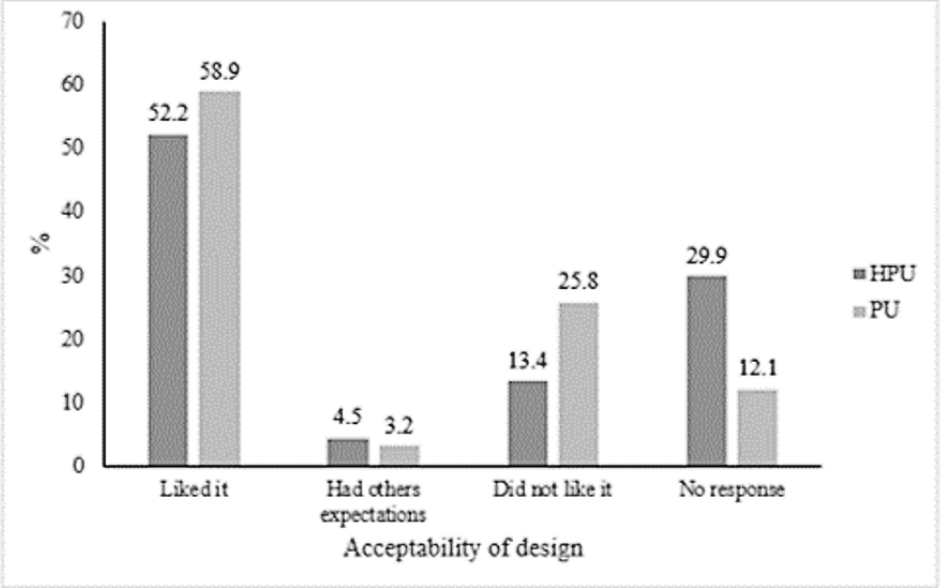


Table 8. Open-ended explanations of score given to acceptability of Help for Depression content.

Category	Home page users	Program users
Liked it	• "In general, its content is good." • "It seems like a very good page, with a lot of satisfactory content." • "The help has been excellent; however, I get the impression that the interface part of the webpage sometimes seems a bit cold." • "It seems to me that something important they get right is that they show phrases and cases from everyday life and that they encourage reflection on personal actions based on those examples."	• "Because it is very systematic, although some strategy is needed to strengthen individual commitment with the help." • "When I opened the page, I doubted it would help me. But as I did the exercises I realized that, although it was very gradual, my way of facing life was getting easier. The problems were getting smaller." • "The content seemed good to me, but not so motivating." • "The content is very meaningful and concrete, the way it is presented is very friendly and allows us to keep measuring our personal results." • "I understand that my level is very high, and there is support, but I think there should be other tools to address the problem, even if the level of depression is as high as mine. It is not a bad option, it is a good one, however, I would recommend increasing or improving the strategy a bit."
Had other expectations	• "I signed up for news and help, but it never got to me." • "They didn't give me any advice, they just gave me a number to search for psychologists in my city. I even said that all I wanted was for someone to tell me that everything was going to be okay."	• "For a topic like this, the human part is necessary, the information is good, but only being able to interact with a machine is cold, at critical times you need to be able to be heard by a person." • "Both in the forum and in the chat, there needs to be an expert moderator, since the participants share personal and often erroneous information." • "I think they need the interaction of email or cell phone reminders to keep the process going."
Did not like it	• "It didn't help me, but it didn't hurt me either." • "What's needed aren't pats on the back, a little severity might not hurt." • "To be honest, it didn't really help me, but thanks anyway."	• "Doesn't motivate to follow the steps." • "Because when someone is depressed you don't have the head to read a lot, in fact that's why I didn't continue with the modules." • "It's a lot of content to read, and due to insomnia, my eyes hurt and reading on the computer didn't help anything." • "Lack of content and motivation."

Design

Open responses regarding the HDep design were also organized into 3 categories, plus one for nonrespondents (Figure 3). Examples of open-ended explanations for the design ratings are presented in Table 9.

The three categories were as follows:

1. Liked the design—more than half of the users liked the design, with no significant difference between HPUs and PUs (HPUs: 35/67, 52%; PUs: 73/124, 58.9%; Figure 3). HPUs found it attractive, user friendly, and colorful; they considered the depression test to be active and they liked how it worked. PUs considered the site neat and well organized, the tools simple, the design motivating, intuitive, and entertaining but perhaps a little too long (Table 9).
2. Had other expectations—fewer participants in each group had other expectations (HPUs: 3/67, 5%; PUs: 4/124, 3.2%). HPUs said they did not receive the expected response or care for their symptoms and had no improvement; PUs believed that the web program, by its nature, reinforced the causes of their depression, not because of problems with its design, but simply because it was a website, meaning that it did not provide contact with a professional, which led to feelings of abandonment (Table 9).
3. Did not like the design—significantly more PUs disliked the design (32/124, 22.8%) than HPUs (9/67, 13%). HPUs noted that HDep was only readable on a computer screen, and it was not encouraging; from their perspective, it should have fewer bright colors and simpler graphics (Table 9).

Table 9. Open-ended responses to acceptability of Help for Depression design.

Category	Home page users	Program users
Liked it	• "It explains things and invites you to interact with the page." • "It's user-friendly." • "It's very colorful, you understand everything" • "The evaluation was active, which made it work nicely." • "The design lets you navigate to find the page, I would recommend it." • "It grabs you."	• "Very nicely organized." • "The tools are simple." • "Good design and motivating." • "It's practical and easy to navigate." • "It's intuitive and entertaining with graphics, maybe a little long." • "Gets your attention at a glance."
Had other expectations	• "I haven't gotten a reply." • "I didn't get attention." • "I haven't gotten better."	• "I believe that the program, by its nature, reinforced the causes of my depression rather than alleviated them. I mean, it's not that it's a bad platform, it's that it's a platform." • "Its lack of online specialists on the page was the constant issue I observed with the others in the chat." • "I felt abandoned."
Did not like it	• "Could be more attractive, I don't know." • "Because if you don't see it on the computer screen, it's a bit difficult to read, select and participate. I recommend that you move to a cell phone version in the future."	• "It's a bit confusing." • "It doesn't grab your eye, it's not encouraging." • "It should have softer colors and simpler graphics, something like headspace or calm." • "Not very motivating."

Discussion

Principal Findings

This study explored the satisfaction and acceptability of the updated version of the internet-based preventive intervention, HDep [14] and found them to be consistent with evaluations in a review of digital interventions in LMICs [29]. Two types of users were observed: HPUs, who visit only the home page, make use of the information available there, respond to the CES-D questions, and obtain feedback on their scores and PUs, who also register for a 6-module intervention. The results showed that HPUs and PUs with similar initial levels of depressive symptoms (CES-D>16; 97% and 100%, respectively) showed moderate levels of satisfaction (HPUs: mean 21.90, SD 6.7, range 8-32; PUs: mean 21.10, SD 5.8, range 8-32) and acceptability (HPUs: mean 13.84, SD 3.97, range 5-20; PUs: mean 13.97, SD 3.29, range 5-20). Among HPUs, women expressed higher satisfaction than men, and among PUs, those who were older, employed, not in therapy before, and reported no previous suicide attempts showed higher acceptability.

Of the survey respondents, 52% (35/67) of HPUs and 43.5% (54/124) of PUs reported liking the HDep content; 12% (8/67) and 25% (31/124), respectively, had other expectations, and 12% (8/67) and 16.9% (21/124), respectively, did not like it. With respect to the design, 52% (35/67) of HPUs and 58.9% (73/124) of PUs reported liking it; 5% (3/67) and 3.2% (4/124), respectively, had other expectations, and 13% (9/67) and 25.8% (32/124), respectively, did not like it. Thus, there was no evidence that PUs were more satisfied or indicated a higher degree of acceptability than HPUs, as was hypothesized, based on the fact that the latter received a smaller portion of the intervention. It may be that there is self-selection of users to the dose of the intervention they need. For some, the home page information and feedback about their symptoms seem to be sufficient, whereas others seem to need the entire intervention.

The satisfaction level was above the scale mean, suggesting that users were more satisfied than dissatisfied, to the degree that they "would recommend it to someone in need" or "would use it again if depressed." Less satisfied participants believed that HDep did not meet their needs. This finding may reflect the high levels of depressive symptoms reported by almost all participants, as well as possible psychopathologies in PUs. Such participants were not the target population of the intervention design, but they were the ones seeking help. Muñoz et al [5] found that this is a common phenomenon, as internet-based interventions intended to be preventive seem to attract individuals who are currently experiencing enough symptoms to screen positive for a major depressive episode; however, only 30% are appropriate for a depression prevention intervention. Other studies have also found a high percentage (up to 90%) of participants in web-based interventions who were highly depressed [30].

Consistent with this notion, higher satisfaction was observed in PUs with less disability owing to depression, no suicidal ideation, and no experience with psychotherapy. According to Rost et al [27], the severity of symptoms and possible comorbidities affect users' perceptions of acceptability and satisfaction. Self-guided interventions have been observed to be more efficacious for users with less psychotherapeutic experience [31].

Findings from the World Mental Health Survey show that in Mexico, 58.3% of people with a diagnosis of major depressive disorder who felt they needed treatment, only 6.4% received treatment that was minimally adequate [3]. This situation may explain why many people with probable mental health disorders seek help in web-based interventions. One-third of HDep users said they had, at some point in the past, sought either

psychological or psychiatric mental health treatment; a similar web-based intervention for depression reported by Christensen et al [32] also found that 64% of participants had previously sought professional help. Our findings show that users with previous experience in therapy were least satisfied and gave HDep lower acceptability ratings. Participants with this experience could be advised early on about what they could realistically expect from HDep.

The general acceptability ratings of HDep were above the mean, suggesting that users considered it acceptable but with room for improvement. Some of the features they valued were its user-friendliness and usefulness in managing their depression, but it did not fully meet their expectations. Regarding the content, more than half of the respondents described it as good, meaningful, and helpful in making them feel better, friendly, systematic, well-paced, and encouraging reflection. More than half of the respondents liked the design, describing it as easy to understand, well organized, attractive, user friendly, colorful, intuitive, and entertaining.

The test for depressive symptoms and feedback regarding results had the highest acceptability ratings, whereas forums and chats had the lowest ratings (Table 6). Some studies have found a high degree of satisfaction with mood-monitoring rating tools in web-based treatment for depression [33]. Questionnaires and psychometric tests sometimes give participants a feeling of personalized treatment [34]. The acceptability of HDep and similar interventions may therefore be improved by increasing the use of these tools.

It is noteworthy that forums received low ratings, although it has previously been observed that forums allow for meaningful social exchange of experiences [15]. One possible explanation may lie in the observation that although a large proportion of participants used forums (60.9%), far fewer posted comments (16.3%) [15]. The lack of participation of a professional in forums and chats is also a possible reason for the low ratings.

Three major areas were found to be lacking in the design and content of HDep. These were described as (1) not being sufficiently persuasive, dynamic, motivating, or appealing; (2) not meeting users' expectations; and (3) being cold, being *just a platform*, and lacking professionals to support, advise, and track people's progress. Other studies have also found that participants in automated programs are concerned about their being too impersonal [35]. Therapeutic persuasiveness, the incorporation of persuasive principles of design, and behavior change have been described as the most robust predictors of adherence [36]. Not meeting users' expectations may be particularly important for depressed users, because as Bernard et al [37] reported, these users become particularly upset when they find unexpected, irrelevant, or inappropriate content. Despite the importance of design in developing successful web-based interventions, Neilsen and Wilson [38] concluded in a literature review that design elements and human–computer interaction remain poorly understood and that "internet-based e-mental health interventions are routinely implemented without sufficiently describing the relevant human–computer interaction design features applied." In this respect, HDep would benefit from incorporating a user-centered design approach to improve the layout of its content [29].

The content deficiency perceived by HDep users was the need for professional help or specialized guidance. This issue has often been reported in the literature on unguided interventions [8,15], and it also turned out to be important for Mexican users in our survey. One of the most attractive aspects of web-based interventions for mental health problems is their reduced cost, including personalized professional help, which would be a significant burden. This is very much the case for HDep, which is supported by a public health institution as a translational research project. Features to compensate for the lack of professional support could include automated dialogue components, such as automated SMS text messages or email messages or gaming features [38].

Conclusions

Overall, HDep showed moderate levels of satisfaction and acceptability and high levels for more than half of its participants, despite a level of depressive symptoms high enough to suggest a major depressive episode. HPUs and PUs rated satisfaction and acceptability similarly, contrary to our hypothesis that the latter, having received a larger portion of the intervention, would be more satisfied. Respondents' ratings on satisfaction and acceptability may be related to their ability to choose how much of the program they want to do: whether they just want an overview from the home page or want to work on the intervention modules. They considered the content culturally sensitive, reflecting their everyday experiences; they found the design to be friendly, with tools that were well organized, simple, and motivating. The main limitations were the lack of contact with a professional, and in some cases, content that did not motivate and was not encouraging. Users who responded to the survey provided abundant suggestions on feasible ways to alleviate some of the deficiencies. Some of these deficiencies coincide with those observed in other web-based interventions for depression [8,27,35,38].

This study has the strength of being based in a real-world setting, not in a confined research environment, so that it reflects more closely what real participants do. However, this feature also makes it more difficult to implement strict methodological control. HDep is the first web-based self-help intervention for depression in Latin America and has been in operation for 11 years. It is a promising and cost-effective tool that can contribute to reducing the treatment gap for depression in Mexico [3]. It has the potential to provide mental health literacy to a large group of users and can be integrated into a preventive stepped-care approach [39]. Being a qualitative–quantitative study from a non–English-speaking LMIC, this study adds to existing research on acceptance and satisfaction with cognitive behavioral therapy–based programs for depression in high-income countries. There appear to be no studies directly comparing users' performance in web-based interventions to assess differences among countries with different income levels. These could include cultural differences: English-speaking users of web-based interventions tend to emphasize the benefits of introspection and self-awareness, which is congruent with *the dominant individualized focus of Euro-American cultural*

orientation compared to a more collectivist and relational Latin American cultural orientation [40].

Although there are many effective internet-based interventions for depression, there are far fewer with open access for general use [41]. Web-based interventions have great potential in Mexico, where it is estimated that 80.6 million people use the internet [42], 58% of whom are interested in health content [43]. The findings of this study are important for the creation and adaptation of web-based interventions in an LMIC, such as Mexico, where access to treatment is a major concern [2] and web-based prevention and treatment programs can help to deliver evidence-based alternatives. HDep is promising, but it is necessary to further document the pitfalls, strengths, and challenges of this type of intervention in this particular context.

Limitations

A major limitation of this study was its response rate of 1.45% (191/13,207). This response implied a CI of 95% and a margin of error of 7%. Low response rates are an important concern that affects the validity of web surveys [44]. In a meta-analytic study, Daikeler et al [21] found that web surveys yielded a response rate that was 12% points lower than other survey modes and concluded that the difference is not the result of a particular study design. They also found evidence that low response rates do not necessarily indicate a large nonresponse error.

Participants who did not respond may have been less satisfied and less positive than those who did [35]. The levels of depressive symptoms and other mental health problems of the people surveyed may explain the low response rate; people with emotional stability are more likely to complete a survey [44]. It is also likely that many of the people contacted were no longer using the intervention, as the survey was sent to those registered in the previous year. There was just 1 reminder email; additional reminders may have increased the response rates [21]. Some of those contacted may have visited HDep just once. It may also be that the incentive (receiving a list of positive thoughts to practice) was not found attractive [44]. There was also no confirmation that users received the survey; email questionnaires are often treated as spam or blocked [21,44].

To estimate other possible sources of bias, the characteristics of the study sample were compared with those of a previous study on HDep [15], which obtained data directly from registered users. No differences >10% were found between the 2 samples in terms of sex, depressive symptoms, disability, suicide attempts, previous psychological or psychiatric treatment, alcohol or drug use, or drug treatment. The proportion of users aged >30 years was >12.5% in the current sample. The proportion of HPUs and PUs in this study was similar to that in a previous study [15]: HPUs made up 35.1% (67/191) of respondents in this study and 38.32% (10,760/28,078) in the previous study; PUs made up 64.9% (124/191) and 61.69% (17,318/28,078), respectively. These figures suggest that the low response rate did not skew the sample with respect to these variables, but there could still be other biases, such as a self-selection bias of eagerness to respond.

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Authors' Contributions

MAL and MT conceptualized the study; MAL, MT, and PP worked on the methodology; PP and LN worked on the statistical and qualitative analyses; MAL wrote the original draft; MT reviewed and edited the manuscript. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CES-D: Center for Epidemiological Studies Scale-Depression
CSQ-8: Client Satisfaction Questionnaire-8
HDep: Help for Depression (in Spanish, ADep: Ayuda Para Depresión)
HPU: home page user
LMIC: low- and middle-income country
OR: odds ratio
PU: program user

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Original Paper

Efficacy of a Web-Based Intervention for Depressive Disorders: Three-Arm Randomized Controlled Trial Comparing Guided and Unguided Self-Help With Waitlist Control

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Abstract

Background: Digital health apps are efficacious treatment options for mild-to-moderate depressive disorders. However, the extent to which psychological guidance increases the efficacy of these apps is controversial.

Objective: We evaluated the efficacy of a web-based intervention, called Selfapy, for unipolar depression. We also investigated differences between psychotherapist-guided and unguided versions.

Methods: Selfapy is a cognitive behavioral therapy–based intervention for depressive disorders. Participants with mild-to-severe depressive disorders were assigned randomly to participate in either guided (weekly 25-minute duration telephone calls) intervention, unguided version, or waiting list (control group) for 12 weeks. We assessed depressive symptoms at the start of the study, midway through the intervention (6 weeks), at the end of the intervention (12 weeks), and at follow-up (6 months). The main outcome was difference in the Beck Depression Inventory score between the start of the study and the end of the intervention. Secondary outcomes were the Quick Inventory of Depressive Symptomatology—Self Report, the Hamilton Rating Depression Scale, and the Beck Anxiety Inventory.

Results: Of 401 participants, 301 participants (75.1%) completed the intervention. Changes in the Beck Depression Inventory from baseline differed significantly between groups at the postintervention ($F_{2,398}$=37.20, P<.001). The reductions in scores for both guided and unguided intervention groups were greater than that for the control group, with large between-group effect sizes (guided vs control: d=1.63, 95% CI 1.37 to 1.93; unguided vs control: d=1.47, 95% CI 1.22 to 1.73) at postintervention. No significant differences were found between guided and unguided intervention groups (P=.18). At follow-up (6 months), treatment effects on the primary outcome were maintained for both intervention groups (guided: $F_{1,194}$=0.62, P>.999; unguided: $F_{1,176}$=0.13, P>.999).

Conclusions: Both guided and unguided versions of the intervention were highly effective in reducing depressive symptoms. Follow-up data suggest that these effects could be maintained. The guided version was not superior to the unguided version.

Trial Registration: German Clinical Trials Register DRKS00017191; https://tinyurl.com/2p9h5hnx

International Registered Report Identifier (IRRID): RR2-10.1186/s13063-021-05218-4

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KEYWORDS

major depressive disorder; online intervention; blended treatment; public health; routine practice; randomized controlled trial; depression; disorder; intervention; treatment; efficacy; self-help; guidance

Introduction

Background

With more than 300 million people affected worldwide, unipolar depression is a common mental disorder [1]. Depressive disorders reduce quality of life for affected persons and are linked to an increased prevalence of suicide and a shortened lifespan [2,3]. However, access to treatment is limited, which represents an obstacle in the care of people with depressive disorders. Health care systems can only rarely give necessary acute help, such as immediate access to a psychotherapist [4]. In Germany, it takes approximately 20 weeks to obtain outpatient psychotherapeutic treatment [5].

In addition to evidenced-based treatments for depressive disorders, such as psychotherapy and pharmacotherapy, web-based interventions are becoming increasingly important in the treatment of depressive disorders. Web-based interventions based on cognitive behavioral therapy are suitable due to their structured and standardized approach, their focus on psychoeducation, and the homework tasks assigned in-between treatment sessions [6]. Various forms of web-based interventions exist, which differ in terms of the level of guidance that they provide to the participant. The guided forms of web-based interventions can involve support from a psychotherapist via email, chat, or telephone. Unguided forms of web-based interventions usually do not include personal contact.

The use of web-based interventions in the treatment of depressive disorders has been deemed efficacious in several controlled studies [7-9] and meta-analyses [10-12]. In one meta-analysis [10], self-guided web-based cognitive behavioral therapy was found to be more effective than the control treatment in reducing depressive symptoms severity (β=−0.21; Hedges g=0.27) and treatment response (β=0.53; odds ratio 1.95, 95% CI 1.52 to 2.50). In a recent systematic review and individual patient data network meta-analysis of 39 randomized control trials, Karyotaki et al [12] made the distinction between guided and unguided web-based cognitive behavioral therapy. Both guided (PHQ-9 score: mean difference −1.7, 95% CI −2.3 to −1.1) and unguided (PHQ-9 score: mean difference −0.9, 95% CI −1.5 to −0.3) were more efficacious in reducing depressive symptoms than treatment as usual, and both guided (PHQ-9 score: mean difference −3.3, 95% CI −3.9 to −2.6) and unguided (PHQ-9 score: mean difference −2.5, 95% CI −3.2 to −1.8) were more efficacious in reducing depressive symptoms than waitlist control [12]; guided web-based cognitive behavioral therapy was also more effective than unguided web-based cognitive behavioral therapy postintervention (PHQ-9 score: mean difference −0.8; 95% CI −1.4 to −0.2), however, not at follow-up at 6 or 12 months. Baseline severity of depressive symptoms was a modifying factor, with better effects for guided web-based cognitive behavioral therapy for patients with baseline PHQ-9 scores greater than 9 [12]. However, Karyotaki et al [12] used varying definition of guidance between the studies and only 6 trials included in the meta-analysis directly compared guided to unguided web-based cognitive behavioral therapy within a single trial.

Objectives

We aimed to evaluate the efficacy of guided and unguided versions of a web-based intervention, called Selfapy, to investigate the effect of psychological guidance in web-based interventions. In a randomized controlled trial, participants were allocated to 3 treatment groups: guided, unguided, and control.

Hypotheses

We hypothesized that participants in the 3-month Selfapy program would experience a greater reduction in depressive symptoms than the control group, and we hypothesized that participants in the guided version would experience a greater reduction in depressive symptoms than participants in the unguided version.

Secondary Hypotheses

We hypothesized that a greater reduction in depressive symptoms and anxiety symptoms would be present in both intervention groups after the 3-month Selfapy program than that in the control group.

Methods

Recruitment

Participants with depressive symptoms were recruited via the Selfapy website, advertisements in social media and numerous information brochures from health insurance companies. The recruitment took place throughout all of Germany. The central recruiting tool was a study website through which interested individuals could register their participation. This preregistered trial was conducted according to the study protocol [13].

Ethical Standards

The study was approved by the ethics committee of the medical faculty of the *Charité* University Medicine Berlin (EA/047/19). All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008 [14].

Inclusion and Exclusion Criteria

Potential participants were screened by telephone. Eligibility for participation in our study was assessed by conducting a diagnostic interview using the Mini International Neuropsychiatric Interview (MINI [15]), the Hamilton Rating Depression Scale (HRSD-24) [16] (score ≥8), and by collecting personal data. All MINI and HRSD-24 interviews were conducted by trained interviewers (psychologists and medical students, trained at the *Charité* Department of Psychiatry and Psychotherapy). The inclusion criteria were (1) age 18 to 65 years; (2) sufficient German-language skills to use and understand the web-based intervention (determined by interviewers); (3) reliable internet access; (4) a Beck Depression Inventory (BDI-II) [17] score ≥13; (5) willingness to provide electronic data; and (6) diagnosis of a major depressive disorder or dysthymia based on the MINI, in accordance with the International Statistical Classification of Diseases tenth revision (ICD-10: F32, F33, F34).

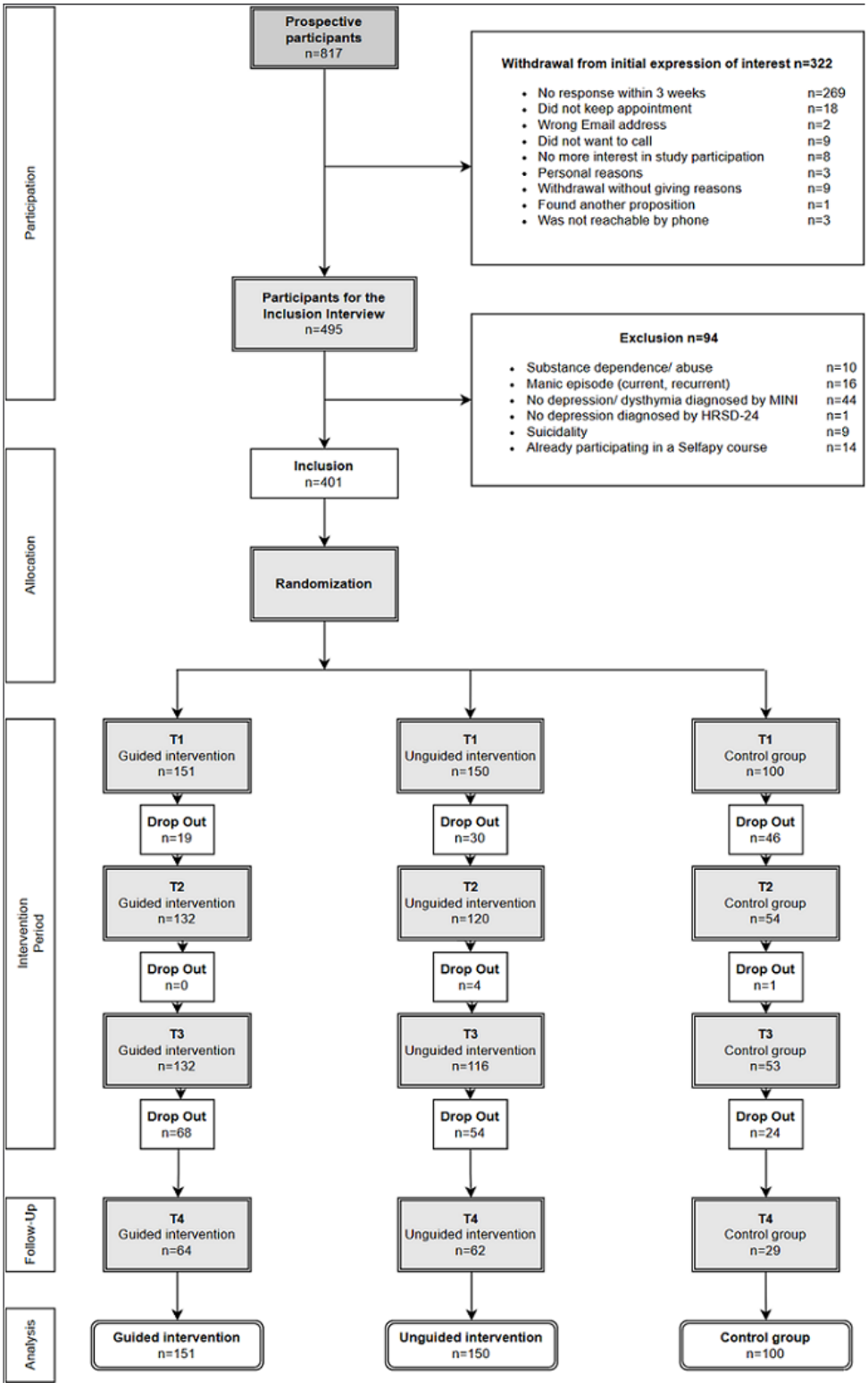
Exclusion criteria were (1) diagnoses of a bipolar disorder or schizophrenia; (2) acute psychotic symptoms; (3) current substance dependence (within the past 6 months) or withdrawal syndrome (ICD-10: F1x2, F1x3); (4) acute suicidality (assessed using HRSD-24; individuals were excluded if they had a score ≥3 on suicidality items). Individuals who were excluded from the study due to illness severity were advised to seek professional help. Additional details have been previously published [13].

Randomization and Blinding

Participants meeting eligibility criteria were randomly allocated to 3 groups (Figure 1). Participants were allocated in a 3:3:2 ratio (guided group: n=151, unguided group: n=150, control group: n=100). Block randomization was performed by an independent researcher using a random number assignment plan with a computer-controlled random number generator (Randlist, version 1.2).

Participants either received immediate access to the guided version of the program, immediate access to the unguided version of the program, or delayed access (24 weeks) to their choice of the guided or unguided program (ie, control group). Participants were informed via email about the result of the allocation process. Individuals in the intervention groups received an email with a link and their unique access code to register and start the intervention immediately. Individuals in the control group also received an email with a link to the assessment material. Therefore, participants enrolled themselves in the study. Diagnostic interviewers were blind to the assigned group of individuals.

Figure 1. Participant flowchart.



Intervention

The web-based intervention aimed to treat depressive symptoms in individuals with mild-to-moderate depressive disorders, with instructions on evidence-based methods and exercises in the areas of cognitive behavioral therapy, systemic therapy, and mindfulness training. The intervention consisted of 6 core modules and 6 additional optional in-depth modules representing different psychotherapeutic approaches (Multimedia Appendix 1), each of which could be completed in 10 to 60 minutes, depending on the user's reading speed, interest, motivation, and individual path through the program. The modules could be accessed repeatedly during the intervention period. The course was designed to engage the user in active exercises, provide helpful and interesting content, and encourage self-reflection. In addition, the intervention included short questionnaires to assess current mood, which allowed the mood trajectory to be visualized over the course of therapy. Furthermore, individual

goals could be set and reviewed. The program provided the user with printable summaries and worksheets for each exercise. Optionally, the user could receive reminder emails to use the course and reiterate program content.

Participants in both intervention groups used the same web-based course for 12 weeks, and access to course content was also available after the 12-week intervention period until follow-up. Telephone or chat support was only offered during the treatment period. Participants in the intervention and control groups were not influenced or advised to change their existing treatment patterns and were free to seek pharmacological or psychological treatments to meet the reality of care.

Guided Group

In the guided version of Selfapy, the participants received personal guidance by a psychotherapist-in-training (17 behavior therapists and depth psychologists in training, registered at German institutes) for the entire duration of the program. The topics discussed were in line with the course content (Multimedia Appendix 1). The therapists were able to set their own focal points within the weekly topic and the associated exercises. At the start of the program, the psychotherapist-in-training and the participant got to know each other, and psychotherapist-in-training and the participant had weekly telephone calls (25 to 30 minutes duration) throughout the intervention period. The telephone calls focused on discussing and reflecting on the exercises of each module. Each module addressed issues such as resources, behavioral activation, self-esteem, and automatic thoughts. All therapists who guided the participants received a 1-hour training session that included: general information on the study; risks and their mitigation; a discussion of the contingency plan; information on handling and documenting dropouts; and information on the standardization of telephone calls. The focus of the guided version was to support web-based intervention use.

Unguided Group

In the unguided version of Selfapy, the intervention was independently followed. There was no option to have contact with a psychotherapist-in-training via telephone. However, a chat functionality allowed the participants to ask questions regarding the correct use of the course. Active asynchronous communication occurred only in the event of patient safety concerns. For an increase in acute symptoms or suicidality, a specific protocol [13], for all study groups, was followed to secure the safety of each participant.

Control Group

During the 24-week waiting period, the control group received weekly standardized mindfulness exercises via email, with content comparable to that of a self-help mindfulness guide. A waitlist design with mood-stabilizing activities was chosen for the control group to control for changes related to treatment expectancy and to better mitigate loss of motivation compared with an untreated or passive waitlist control group [18]. These exercises were only available for the control group so that there was no content-related overlap between the intervention groups and the control group. The control group was also free to access other pharmacological and psychological treatments. After the 24-week period, participants from the control group were given access to the web-based intervention and allowed to choose which type of program (guided or unguided) they wished to participate in.

Measurements

Depressive symptoms were evaluated using the BDI-II (primary outcome), Quick Inventory of Depressive Symptomatology—Self Report (QIDS-SR-16) [19] and the observer-rated HRSD-24. The Beck Anxiety Inventory (BAI) [20] was used to measure changes in the self-assessment of anxiety symptoms (secondary outcome parameters). The primary and secondary outcome parameters were measured at the start of the intervention (T1), 6 weeks after the start of the intervention (T2), at the end of the intervention (12 weeks after the start of the intervention, T3), 24 weeks after the beginning of the intervention (follow-up, T4). All web-based questionnaires were completed independently by the participants.

Statistical Analyses

Consistent with CONSORT (Consolidated Standards of Reporting Trials recommendations) [21], we conducted (1) intention-to-treat (which comprised observed and imputed data from all randomized participants, regardless of whether they used the intervention or activated their access vouchers to enter the program), and (2) per protocol (which comprised data from participants who completed pretreatment and postintervention assessments) analyses (Multimedia Appendix 2).

The primary endpoint was the decrease in depressive symptoms in the BDI-II between study entrance (T1) and the end of the intervention (T3). One-way analysis of variance (within-factor group) was performed to analyze differences in the decrease of depressive symptoms between the intervention groups.

Repeated measures analysis of variance was used to evaluate secondary endpoints and effects of group (guided vs unguided vs control) and time interaction. If significant effects were found, pairwise comparisons were carried out by applying Bonferroni correction ($P<.016$) for multiple testing. Results of the posthoc comparisons are presented as the mean with 95% CI and SD.

The Kolmogorov–Smirnov test was used to test for a normal distribution. Values for the mean and SD of each variable were calculated in addition to the Kolmogorov–Smirnov Z-value, and the asymptomatic significance (for both intervention groups) was specified. $P<.05$ indicated that the data did not have a normal distribution.

Independent 2-tailed t tests and chi-square tests were used to estimate the differences between groups in terms of demographics and sample characteristics at baseline. Values for the mean, 95% CI, and SD were calculated. Interim analyses were not undertaken. Due to the high dropout rate from T3 to T4, repeated measures analysis of variance was performed for the follow-up-analysis, including only those who completed.

Moderator analysis was used to analyze the influence of various sociodemographic variables on the primary outcome. Regression analysis was directed at explaining the changes in the BDI-II (the difference between T3 and T1 was used as a criterion). The

predictors used were the BDI-II at baseline as well as potential moderators, assigned group, and sociodemographic variables (sex, age, relationship status, and number of children). All variables except age were dichotomous and coded as 0 or 1. The moderator variables were generated by multiplying the *z*-standardized BDI-II score at baseline with the dichotomous sociodemographic variables, the assigned group, and the *z*-standardized age. All dichotomous variables, assigned group, and *z*-standardized age were included as regressors. Subsequently, we used hierarchical linear regression, which had all predictors in the first block via the enter method and all moderators in the second block via the stepwise method.

Furthermore, response rates (decrease of BDI-II score from baseline of 50%), remission rates (postintervention BDI-II score ≤10 [22]), and the minimal clinical important difference (decrease of 17.5% of the BDI-II score from baseline [23]) for the primary outcome at postintervention were calculated and reported.

For the intention-to-treat analysis, missing values in the data were replaced using multiple imputation by chained equations (with m=5 imputations). The pooled data (the mean of all 5 imputations) were calculated using the data imputed by linear regression. Subsequently, scale values were determined from the imputed and existing values. After data imputation, imputed and observed results were compared. The pooled imputed values proved to be more conservative, therefore, the results of imputed data set were used to evaluate the outcome of the web-based intervention.

Results

General

Out of 401 participants, the number of dropouts at postintervention (T3, end of the intervention) was 100 (24.9%) for the BDI-II and the QIDS-SR-16, 128 (31.9%) for the HRSD-24, and 103 (25.7%) for the BAI, respectively.

Characteristics

Upon study entrance, 353 out of 401 randomized participants (88.0%) fulfilled the diagnostic criteria for a current major depressive episode (MINI interview), and 53 (13.2%) for dysthymia (Multimedia Appendix 3). Data at baseline indicated an average mild-to-severe level of depression in all participants (BDI-II: mean 30.5, SD 9.5, range 13-56). A one-way analysis of variance with the factor group revealed no differences at baseline ($F_{2,398}$=0.23, P=.80). The mean age of participants was 37.1 years (SD 11.0).

For factor relationships, fewer participants (33/151, 22.0%) reported themselves to be married or living with a partner in the unguided group than in the control group (52/100, 52.0%; χ^2_1=8.25, P=.01), whereas no difference was shown between the guided and control groups (χ^2_1=1.56, P=.21) or between the guided and unguided groups (χ^2_1=2.97, P=.08). More participants were employed in the guided group (82/151, 54.3%) and the unguided group (86/150, 57.3%) compared to those in the control group (57/100, 57.0%; guided vs control: χ^2_1=9.12, P=.01; unguided vs control: χ^2_1=18.98, P<.001), while there was no difference between the guided and unguided groups (χ^2_1=1.76, P=.18). More participants in the control group (25/100, 25.0%) were trainees than those in the guided group (12/151, 7.9%; χ^2_1=5.68, P=.01) or unguided group (6/150, 4.0%; χ^2_1=12.62, P<.001), while there was no difference between the guided and unguided groups (χ^2_1=1.27, P=.26). Lastly, more participants in the control group (14/100, 14.0%) than in the unguided group (3/150, 2.0%; χ^2_1=6.55, P=.05) reported other occupations.

Analyses of the other sociodemographic variables did not reveal a significant difference between groups (sex: P=.81, number of children: P=.93).

Being on waitlist (χ^2_2=6.76, P=.03), use of antidepressant medication both currently (χ^2_2=7.31, P=.03) and in the year before the intervention (χ^2_2=10.25, P=.006) differed at baseline, with more participants in the guided group having taken antidepressants than the unguided group in the year before the intervention (χ^2_1=9.36, P=.002) and currently (χ^2_1=6.56, P=.01). There were no differences compared to the control group in the year before the intervention (guided vs control: χ^2_1=0.66, P=.42; unguided vs control: χ^2_1=3.2, P=.07) and currently (guided vs control: χ^2_1=0.47, P=.49; unguided vs control: χ^2_1=2.11, P=.15). The groups did not differ with respect to current psychotherapy at baseline (χ^2_2=1.50, P=.47).

Table 1. Sociodemographic characteristics of the study cohort at baseline.

Characteristic	Guided (n=151)	Unguided (n=150)	Control (n=100)	Total sample (n=401)
Sex, n (%)				
Female	126 (83.4)	126 (84.0)	81 (81.0)	333 (83.0)
Male	25 (16.6)	24 (16.0)	19 (19.0)	68 (17.0)
Age (years), mean (SD)	38 (10.7)	37 (10.8)	36 (11.9)	37 (11.0)
Relationship status, n (%)				
Married or living with a partner	54 (35.8)	33 (22.0)	52 (52.0)	139 (34.7)
Not living with a partner	19 (12.6)	8 (5.3)	19 (19.0)	46 (11.5)
Single	68 (45.0)	75 (50.0)	26 (26.0)	169 (42.1)
Not reported	10 (6.6)	34 (22.7)	3 (3.0)	47 (11.7)
Children, n (%)				
Yes	31 (20.5)	33 (22.0)	11 (11.0)	75 (18.7)
No	89 (58.9)	99 (66.0)	37 (37.0)	225 (56.1)
Not reported	31 (20.5)	18 (12.0)	52 (52.0)	101 (25.2)
Professional qualification, n (%)				
Still in professional training	11 (7.3)	6 (4.0)	16 (16.0)	33 (8.2)
Apprenticeship	28 (18.5)	19 (12.7)	25 (25.0)	72 (18.0)
Master or vocational school	17 (11.3)	15 (10.0)	9 (9.0)	41 (10.2)
University or university of applied sciences	39 (26.0)	45 (30.0)	30 (30.0)	114 (28.4)
Without professional training	15 (9.9)	18 (78.7)	8 (8.0)	41 (10.2)
Other professional training	2 (1.3)	0 (0.0)	8 (8.0)	10 (2.5)
Not reported	39 (25.8)	47 (31.3)	4 (4.0)	90 (22.4)
Occupation, n (%)				
Employee	82 (54.3)	86 (57.3)	57 (57.0)	225 (56.1)
Self-employed	3 (2.0)	4 (2.7)	2 (2.0)	9 (2.2)
Trainee	12 (7.9)	6 (4.0)	25 (25.0)	43 (10.7)
Other	7 (4.6)	3 (2.0)	14 (14.0)	24 (6.0)
Not reported	47 (31.3)	51 (34.0)	2 (2.0)	100 (24.9)

Usage Data

A total of 301 participants received the intervention after baseline assessment. A mean of 9.4 (SD 2.3) modules were completed by each participant during the intervention period, and 254 participants (84.4%) completed the main course (Multimedia Appendix 3).

Primary Outcome

Descriptive statistics for the for each assessment point are shown in Table 2 for completer and intention-to-treat samples. Kolmogorov-Smirnov tests did not reveal any violation of the normal distribution for BDI-II scores. One-way analysis of variance revealed a significant interaction (factor group) in the intention-to-treat sample ($F_{2,398}$=37.20, P<.001). Posthoc pairwise comparisons with Bonferroni correction at postintervention (T3) revealed a significant higher reduction in depressive symptoms (BDI-II) in the guided group vs the control group (P<.001) and the unguided group vs the control group (P<.001). There was no significant difference (P=.18) between guided and unguided groups (Multimedia Appendix 4).

Within-group effect sizes for BDI-II (Table 3) were large both for the guided (d=1.44, 95% CI 1.21 to 1.68) and unguided (d=1.38, 95% CI 1.15 to 1.65) groups, whereas the control group showed no effect (d=0.07, 95% CI −0.21 to 0.37). Postintervention between-group effect sizes between the guided and control groups (d=1.63, 95% CI 1.37 to 1.93) and between the unguided and control groups (d=1.47, 95% CI 1.22 to 1.73) were large, whereas effect sizes between the guided and unguided groups were negligible (d=0.20, 95% CI −0.04 to 0.45).

Table 2. Assessment scores.

Outcome and group	Per protocol						Intention to treat			
	T1[a]		T2[b]		T3[c]		T2		T3	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Beck Depression Inventory-II										
Guided (n=151)	151	30.09 (9.18)	132	19.59 (6.60)	132	14.87 (8.77)	151	20.71 (6.98)	151	16.61 (9.55)
Unguided (n=150)	150	30.54 (8.53)	120	20.44 (7.22)	116	15.86 (8.03)	150	22.51 (7.83)	150	18.49 (8.88)
Control (n=100)	100	30.88 (10.74)	54	27.30 (7.05)	53	31.11 (8.30)	100	29.09 (6.39)	100	30.26 (6.97)
Quick Inventory of Depressive Symptomatology – Self Report										
Guided (n=151)	151	17.41 (6.17)	132	11.14 (4.63)	132	6.53 (3.55)	151	11.62 (4.54)	151	7.33 (4.01)
Unguided (n=150)	150	19.36 (5.44)	120	11.00 (3.71)	116	6.84 (4.09)	150	12.09 (4.03)	150	7.99 (4.31)
Control (n=100)	100	18.55 (6.04)	54	17.17 (4.50)	53	20.15 (3.78)	100	16.90 (3.60)	100	17.88 (4.06)
Hamilton Rating Depression Scale										
Guided (n=151)	151	23.23 (6.28)	N/A[d]	N/A	123	11.46 (6.81)	N/A	N/A	151	11.95 (6.50)
Unguided (n=150)	150	23.22 (6.75)	N/A	N/A	70	12.19 (6.57)	N/A	N/A	150	14.75 (5.88)
Control (n=100)	100	22.64 (6.76)	N/A	N/A	80	20.91 (8.78)	N/A	N/A	100	21.13 (8.20)
Beck Anxiety Inventory										
Guided (n=151)	150	32.46 (11.32)	132	23.36 (11.97)	128	14.45 (9.06)	151	24.65 (11.79)	151	17.25 (11.05)
Unguided (n=150)	150	34.09 (11.68)	120	20.43 (9.25)	118	16.22 (9.57)	150	23.27 (10.23)	150	19.98 (11.67)
Control (n=100)	100	31.83 (14.14)	52	37.92 (9.62)	52	31.02 (7.51)	100	37.56 (7.98)	100	34.91 (7.56)

[a]T1 represents the start of the study.

[b]T2 represents the midpoint of the intervention (6 weeks after the start of the study)

[c]T3 represents the end of the intervention (12 weeks after the start of the study).

[d]N/A: not applicable. No data were available because the Hamilton Rating Depression Scale was not used at the midpoint assessment.

Table 3. Within- and between-group effect sizes for all groups in the intention-to-treat sample.

Measure and group	Within group, Cohen *d* (95% CI)		Between group (vs unguided), Cohen *d* (95% CI)		Between group (vs control), Cohen *d* (95% CI)	
	T1[a]–T2[b]	T1–T3[c]	T2	T3	T2	T3
Beck Depression Inventory II						
Guided	1.15 (0.91, 1.40)	1.44 (1.21, 1.68)	0.24 (0.02, 0.48)	0.20 (−0.04, 0.45)	1.25 (0.99, 1.54)	1.63 (1.37, 1.93)
Unguided	0.98 (0.75, 1.25)	1.38 (1.15 1.65)	__[d]	—	0.92 (0.65, 1.20)	1.47 (1.22, 1.73)
Control	0.20 (−0.09, 0.47)	0.07 (−0.21, 0.37)	—	—	—	—
Quick Inventory of Depressive Symptomatology – Self Report						
Guided	1.07 (0.84, 1.33)	1.94 (1.68, 2.24)	0.11 (−0.10, 0.33)	0.16 (−0.06, 0.39)	1.29 (1.02, 1.53)	2.61 (2.28, 3.02)
Unguided	1.52 (1.28, 1.80)	2.32 (1.95, 2.72)	—	—	1.26 (1.04, 1.53)	2.36 (1.98, 2.82)
Control	0.33 (0.05, 0.63)	0.13 (−0.14, 0.45)	—	—	—	—
Hamilton Rating Depression Scale						
Guided	N/A[e]	1.76 (1.50, 2.05)	N/A	0.45 (0.21, 0.70)	N/A	1.24 (0.93, 1.59)
Unguided	N/A	1.34 (1.10, 1.61)	—	—	N/A	0.89 (0.62, 1.21)
Control	N/A	0.20 (−0.08, 0.48)	—	—	—	—
Beck Anxiety Inventory						
Guided	0.67 (0.44, 0.93)	1.35 (1.10, 1.64)	−0.13 (−0.37, 0.11)	0.241 (0.01, 0.46)	1.28 (1.04, 1.55)	1.87 (1.61, 2.20)
Unguided	0.99 (0.73, 1.25)	1.21 (0.94, 1.51)	—	—	1.56 (1.28, 1.86)	1.52 (1.25, 1.84)
Control	−0.50 (−0.79, −0.22)	−0.27 (−0.55, 0.01)	—	—	—	—

[a]T1 represents the start of the study.

[b]T2 represents the midpoint of the intervention (6 weeks after the start of the study)

[c]T3 represents the end of the intervention (12 weeks after the start of the study).

[d]No data.

[e]Not available because the Hamilton Rating Depression Scale was not used at the midpoint assessment.

Response and Remission Rate

Response, defined as the percentage of participants that had a reduction of depressive symptoms by 50% or more at postintervention (T3), was reached by 34.9% of all participants (n=140/401). In the guided group, the response rate was 48.3% (73/151), 43.3% (65/150) in the unguided group, and 2.0% (2/100) in the control group. Remission, defined as a postintervention BDI-II score of 12 or less, occurred in 25.4% of all participants (102/401) of the intention-to-treat sample. In the guided group, 39.7% of participants (60/151) reached remission, with 28.0% (42/150) in the unguided group. No participants in the control group reached remission.

Minimal Clinical Important Difference

Overall, 63.1% (253/401) of participants in the intention-to-treat sample had depressive symptom reductions greater than the minimal clinical important difference, with 74.2% (n=112/151) for the guided group, 70.7% (106/150) for the unguided group, and 35.0% (35/100) for the control group. In comparison, both the guided group (χ^2_1=36.44, *P*<.001) and the unguided group (χ^2_1=29.61, *P*<.001) had significantly more occurrences of symptom improvement than the control group, whereas no difference was found between the intervention groups (χ^2_1=0.30, *P*=.58).

Moderator Analysis

The regression analysis was conducted using the intention-to-treat sample. The number of data sets that could be used for the calculation was reduced to 279, due to missing values in the sociodemographic variables. The regression appeared to be unproblematic (Durbin-Watson-statistic 1.762 and collinearities <2.0). As the nonstandardized residuals had a mean of 0, homoscedasticity of the regression was indicated. The Kolmogorov-Smirnov-test was asymptotically significant (*P*=.03). The skewed distribution lay within the 5% confidence interval; the kurtosis lay slightly above. Based on the histogram, the normal distribution of residuals is accepted. In the first block of the hierarchical multiple linear regression analysis, a significant model was found (explained variance r^2=0.592; $F_{6,272}$=65.9, *P*<.001). Notably, age influenced the treatment outcome significantly—the older the participants, the greater the improvement in the BDI-II score (*b*=0.103; β=0.087, *t*=2.25, *P*=.02). In addition, a higher BDI-II score at T1 was associated with greater reduction in BDI-II score at T3 (*b*=−0.98, β=−0.632, *t*=−15.93, *P*<.001). In addition, being assigned to the control group was associated with a lower reduction in the BDI-II score at T3 (*b*=11.6, β=0.34, *t*=8.52, *P*<.001). The other variables (relationship status: *P*=.96; sex: *P*=.29; number of children: *P*=.90) did not significantly predict the outcome variables. In the second block of the hierarchical regression

analysis, the moderators that are the interaction terms of the variables from the first block at baseline were included using the stepwise method. None was found to be significant, therefore no moderation effect was indicated by the analysis.

Secondary Outcomes

Descriptive statistics of secondary outcomes are displayed in Table 2, and Table 3 shows within- and between-group effect sizes for all secondary outcome measures for the intention-to-treat sample. No violation of the normal distribution was identified for any of the secondary outcomes.

Repeated measures analysis of variance revealed a significant main effect for the factor time—QIDS-SR-16 ($F_{3,1194}$=200.08, P<.001, η^2=0.25), HRSD-24 ($F_{2,796}$=152.26, P<.001, η^2=0.19), and BAI ($F_{2,796}$=62.2 P<.001, η^2=0.09). Additionally, we found a significant interaction (factors group × time) for all secondary measurements in the intention-to-treat sample—QIDS-SR-16 ($F_{6,1194}$=33.2, P<.001, η^2=0.10), HRSD-24 ($F_{4,796}$=23.3, P<.001, η^2=.07), and BAI ($F_{4,796}$=30.4, P<.001, η^2=0.09) (Figure 2).

Bonferroni-adjusted posthoc analyses of the QIDS-SR-16 (Figure 3) revealed a greater reduction of depressive symptoms for both the guided group (P<.001) and the unguided group (P<.001) compared to the control group. However, no difference between the guided and unguided groups was found (P=.50).

Figure 2. Change in depressive symptoms. BDI-II: Beck Depression Inventory-II.

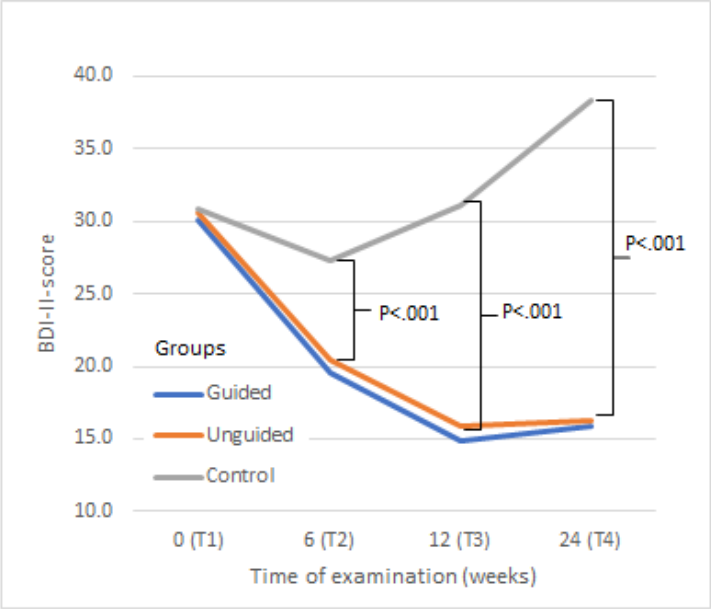
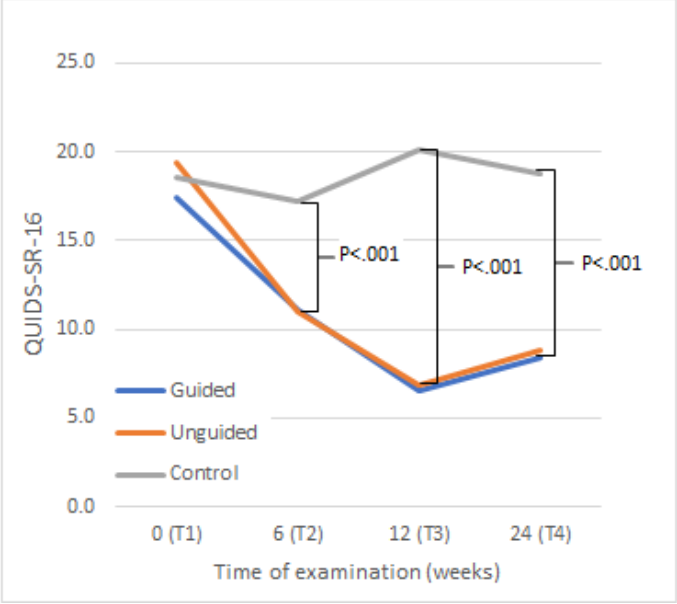


Figure 3. Change in depressive symptoms. QIDS-SR-16: Quick Inventory of Depressive Symptomatology—Self Report.



Similarly, posthoc analyses of the HRSD-24 (Figure 4) revealed a greater reduction of observer-rated depressive symptoms both for the guided group (P<.001) and the unguided group (P<.001) compared to the control group. A greater reduction in symptoms was found for the guided group compared to the unguided group (P=.001).

Finally, posthoc analyses of changes in BAI scores (Figure 5) revealed significantly greater reductions in anxiety symptoms in the guided (P<.001) and unguided groups (P<.001) compared to that of the control group. There was no significant difference between the guided group and unguided group (P=.08).

Figure 4. Change in depressive symptoms. HRSD-24: Hamilton Rating Depression Scale.

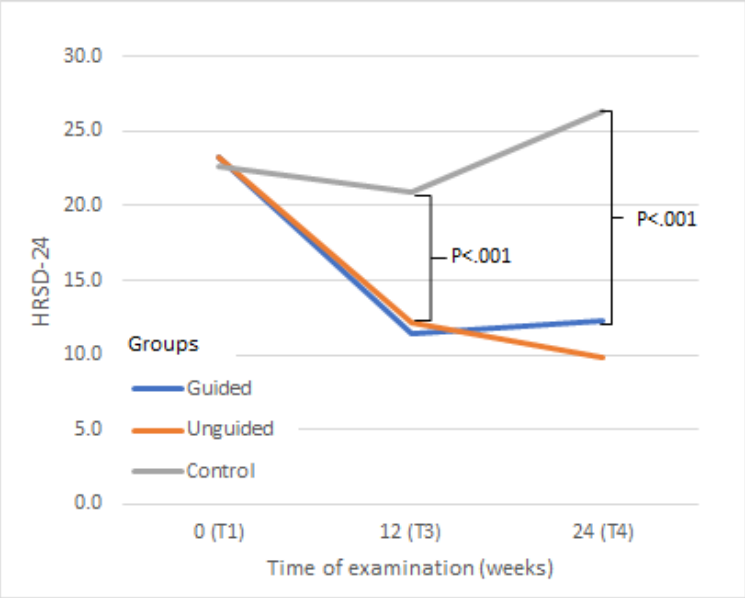
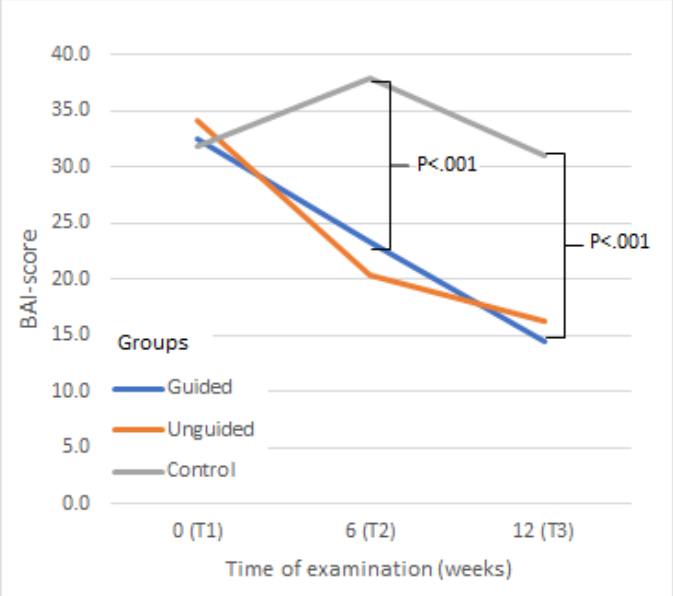


Figure 5. Change in anxiety symptoms. BAI: Beck Anxiety Inventory.



Three-Month Follow-up

For the follow-up assessment 24 weeks after the start of the intervention (T4), repeated measures analysis of variances were carried out using per protocol data for the BDI-II, the QIDS-SR-16, and the HRSD-24. Data were available at follow-up for 155 (38.7%) for the BDI-II, 156 (38.9%) for the QIDS-SR-16, and 30 (7.5%) for the HRSD-24 out of all 401 participants (Table 4).

Repeated measures analysis of variance revealed a significant interaction (factors group × time) for the BDI-II ($F_{2,152}$=3.7, P=.03, η^2=0.02). Pairwise posthoc comparisons with Bonferroni-correction at follow-up (T4) showed a significant difference between the guided group (P<.001) and the unguided group (P<.001) compared to the control group, but not between guided and unguided (P>.999) demonstrating a symptom deterioration in the control group and maintenance of the treatment effects in both intervention groups. Compared to baseline (T1), the BDI-II scores at follow-up (T4) remained significantly lower for both the guided group (d=1.58) and the unguided group (d=1.88). Moreover, the remission rate at T4 in the BDI-II was 29.2% for the guided group and 21.3% for the unguided group. Repeated-measures analysis of variance did not reveal a significant interaction effect (group × time) for the QIDS-SR-16 ($F_{2,153}$=3.32, P=.39, η^2=0.02) or the HRSD-24 ($F_{2,19}$=0.27, P=.77, η^2=0.15).

Table 4. Change from T3 to follow-up (T4) with completer data for depression outcomes.

Outcome and group	T3[a]		T4[b]		Test statistics (T3-T4)			Within group
	n	Mean (SD)	n	Mean (SD)	*F* test (*df1*,*df2*)	*P* value	η^2	T1−T4, Cohen *d* (95% CI)
Beck Depression Inventory-II								
Guided	132	14.87 (8.77)	64	15.92 (8.79)	0.62 (1,194)	>.999	.00	1.58 (1.29, 1.95)
Unguided	116	15.86 (8.03)	62	16.29 (6.47)	0.13 (1,176)	>.999	.00	1.88 (1.59, 2.24)
Control	53	31.11 (8.30)	29	38.28 (9.88)	12.2 (1,80)	.002	.13	−0.72 (−1.35, −0.28)
Quick Inventory of Depressive Symptomatology – Self Report								
Guided	132	6.53 (3.55)	65	8.42 (4.80)	9.67 (1,195)	.006	.05	1.63 (1.31, 2.00)
Unguided	116	6.84 (4.09)	62	8.85 (5.23)	8.05 (1,176)	.02	.04	1.97 (1.60, 2.45)
Control	53	20.15 (3.78)	29	18.76 (5.14)	1.96 (1,80)	.50	.02	−0.04 (−0.43, 0.37)
Hamilton Rating Depression Scale								
Guided	123	11.46 (6.81)	17	12.24 (7.02)	0.19 (1,138)	>.999	.00	1.65 (0.94, 2.63)
Unguided	70	12.19 (6.57)	6	9.83 (5.19)	0.73 (1,74)	>.999	.01	2.22 (1.81, 3.03)
Control	80	20.91 (8.78)	7	26.29 (4.15)	2.55 (1,85)	.342	.03	−0.65 (−1.35, −0.09)

[a]T3 represents the end of the intervention (12 weeks after the start of the study).

[b]T4 represents the follow-up point (24 weeks after the start of the study).

Discussion

Principal Results

We investigated the efficacy of a guided and unguided web-based intervention for the treatment of depressive disorders and found a significant improvement of depressive symptoms in the BDI-II (primary outcome) and the HRSD-24 for both intervention groups compared with those in the control group in the intention-to-treat sample, with large pre- and postintervention difference effect sizes observed for each intervention (BDI-II: guided group, *d*=1.44; unguided group, *d*=1.38; HRSD-24: guided group, *d*=1.76; unguided group, *d*=1.34). Similarly, self-reported measures for depression and anxiety symptoms revealed a significant pre- and postintervention difference intervention decrease in scores for both intervention groups (QIDS-SR-16: guided group, *d*=1.94 and unguided group, *d*=2.32; BAI: guided group, *d*=1.35 and unguided group, *d*=1.21) compared with those in the control group (QIDS-SR-16: *d*=0.13; BAI: *d*=−0.27).

In a similarly structured web-based intervention for depressive disorders, Meyer et al [24] investigated an unguided web-based cognitive behavioral therapy intervention for depressive disorders and found the web-based intervention to be highly efficacious (compared with waitlist control, pre- and postintervention differences using PHQ-9: *d*=1.32), which is comparable to our within-group effect sizes for the BDI-II.

In another trial with guided web-based intervention, Beiwinkel et al [25] investigated the efficacy of a 12-week web-based program for depression, with therapeutic support upon request (ie, psychologists gave feedback via telephone or email) compared with a waitlist control (which included unguided internet-based psychoeducation only) and reported pre-and postintervention BDI-II scores showed a significant reduction in depressive symptoms with large within-group effect size for the intervention group with guidance (*d*=1.42; control group: *d*=0.65).

In our randomized controlled trial, the treatment effects of both intervention groups were slightly higher than those in previous studies [24,25]. In [25], the intervention duration was also 12 weeks, but therapeutic support was offered only upon request. This approach might have stopped patients from seeking contact, and therefore, may have hampered the overall effect. Moreover, our interventions provided the option to contact a psychologist in both intervention groups (guided group: telephone calls; unguided group: standardized chat option) which, arguably, led to a better outcome. Other than differences in study design, the characteristics of the participants may also be a reason for the high effect sizes. Compared with other web-based cognitive behavioral therapy studies [24,26,27], the percentage of women in our randomized controlled trial (333/401, 83%) was higher (74.4% [24]). In general, women tend to seek web-based interventions more frequently than men [26,27]. Moreover, considerably more participants completed higher education, ie, university (28.4%) and vocational school (10.2%). A high education level is a predictor of high adherence to treatment [28] and a positive outcome of treatment [29] because participants are better able to transfer the content of a particular treatment to their life [30]. In individual patient data network meta-analysis, Furukawa et al [31] found a higher baseline severity of depressive symptoms associated with a better response to web-based interventions and being unemployed with a poorer outcome. Sex did not influence the response. We also found that baseline severity, treatment, and age (higher age with better outcome) were significant moderators of treatment outcome.

The efficacy of the web-based intervention over waitlist control is larger but consistent with previous literature on similar interventions for both guided (between-group effect size *d*=0.55

[24]) and unguided (between-group effect size d=0.57 [25]) web-based cognitive behavioral therapy. The response rate in our control group was relatively low compared to that in other web-based intervention trials (within-group effect size in BDI-II: d=0.07)—Meyer et al [24] found an average within-group effect size (d=0.71) in the primary outcome (PHQ-9) for the control group. Klein et al [32] reported for their control condition (care as usual alone) small effects in the pre- and postintervention comparison (PHQ-9: d=0.39). In contrast, Berger et al [33], also did not find significant changes between pre- and postintervention symptoms in their waiting list control group (BDI-II: d=0.14). Our results were similar. The low effects in our control group could be explained by many different reasons. Active waiting list condition, as in our control group, might have nocebo effects compared to no treatment condition [34]. Additionally, specific interventions in the waiting list condition may also have negative effects in internet interventions. For example, Furukawa et al [31] reported that relaxation training was even harmful compared to other components in web-based cognitive behavioral therapy.

The effects of could be maintained at 3-month follow-up. BDI-II scores remained significantly lower for the guided group (d=1.59) and unguided group (d=1.91) compared with baseline scores. Our findings are similar to those from previous research, which found web-based interventions have positive long-term effects [10].

We also investigated on the effects of guidance in web-based interventions. We found in both groups with different guidance as equally and highly effective to reduce depressive symptoms. Completely unsupported web-based interventions have been suggested to be less efficacious [8,12], associated with higher attrition rates [35], and to carry greater risks than supported interventions [34]. However, findings are to some extent heterogeneous: Berger et al [33] compared an unguided internet-based self-help program with the same intervention supported by a therapist and waitlist control group. Our comparison of guided and unguided did show differences, which, however, were not significant between the unguided group and guided group (mean groups difference at postintervention: d=0.24 in favor of guided self-help). In a recent investigation, Zagorscak et al [36] compared web-based cognitive behavioral therapy alone with therapy and semistandardized email feedback from psychologists. Again, between-group effects were nonsignificant across outcomes.

Regarding our study, the dose of psychological contact might not vary sufficiently to elicit substantial differences between the groups. Instead, both groups had contact with a therapist, although the unguided group could only reach out for non–content-related questions. Both groups also had a high main course completion rate, especially compared to nonguided web-based interventions in other studies [31]. Karyotaki et al [10] revealed that treatment adherence to web-based cognitive behavioral therapy (session completion rate) influenced the outcome. In contrast to the meta-analysis findings [12], we also did not find severity of depression to be a predictor for better outcome in the guided group.

Strength and Limitations

Our study has several strengths. We included self- and observer ratings and included a follow-up assessment. Furthermore, we compared different forms of guidance. We also considered multiple aspects in our evaluation, such as completion rate and sociodemographic factors. However, there are also some limitations. First, using wide inclusion criteria, we acquired a heterogeneous study sample [37]. Second, the option to receive additional treatment impeded the attribution of treatment effects solely on the web-based intervention. Additional treatment (12 people were in therapy and 70 were receiving psychiatric treatment in both intervention groups) could have contributed to the effects and possibly caused a reduction in internal validity. Third, although conversations between psychotherapists and participants were standardized in the guided group, we had no insights into the actual conversations and whether the structure of the predetermined content was followed. Last, our sample size might have been too small to detect differences between the guided and unguided groups.

Conclusions

The web-based intervention offers a highly efficacious and clinically relevant intervention for people with depressive disorders. Contrary to our hypothesis, the efficacy of the guided g and unguided intervention did differ. Our findings demonstrate the value and applicability of the Selfapy web-based intervention as a clinically significant treatment option for depressive disorders.

Authors' Contributions

RK, LKV, AS, and SK contributed to the design of the study and coordinated recruitment and data collection. All authors drafted, read, and approved the manuscript.

Conflicts of Interest

The study was funded by a commercial organization: Selfapy GmbH. RK worked for Selfapy as a student (November 2016 to September 2017). SK, LKV, and AS have no relationship with Selfapy GmbH.

Multimedia Appendix 1
Course content.
[DOCX File , 21 KB - formative_v6i4e34330_app1.docx]

Multimedia Appendix 2
Diagnoses according to Mini International Neuropsychiatric Interview (MINI).
[PDF File (Adobe PDF File), 518 KB - formative_v6i4e34330_app2.pdf]

Multimedia Appendix 3
Intervention usage data for the guided and unguided group.
[PDF File (Adobe PDF File), 507 KB - formative_v6i4e34330_app3.pdf]

Multimedia Appendix 4
Completer analysis.
[PDF File (Adobe PDF File), 514 KB - formative_v6i4e34330_app4.pdf]

Multimedia Appendix 5
CONSORT-EHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 114 KB - formative_v6i4e34330_app5.pdf]

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Abbreviations

BAI: Beck Anxiety Inventory
BDI-II: Beck Depression Inventory-II
CONSORT: Consolidated Standards of Reporting Trials
HRSD-24: Hamilton Rating Depression Scale
ICD-10: International Statistical Classification of Diseases, tenth revision
MINI: Mini International Neuropsychiatric Interview
PHQ-9: Patient Health Questionnaire
QIDS-SR-16: Quick Inventory of Depressive Symptomatology—Self Report

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Original Paper

In-Person Versus Telehealth Setting for the Delivery of Substance Use Disorder Treatment: Ecologically Valid Comparison Study

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Abstract

Background: The COVID-19 pandemic has profoundly transformed substance use disorder (SUD) treatment in the United States, with many web-based treatment services being used for this purpose. However, little is known about the long-term treatment effectiveness of SUD interventions delivered through digital technologies compared with in-person treatment, and even less is known about how patients, clinicians, and clinical characteristics may predict treatment outcomes.

Objective: This study aims to analyze baseline differences in patient demographics and clinical characteristics across traditional and telehealth settings in a sample of participants (N=3642) who received intensive outpatient program (IOP) substance use treatment from January 2020 to March 2021.

Methods: The *virtual IOP (VIOP) study* is a prospective longitudinal cohort design that follows adult (aged ≥18 years) patients who were discharged from IOP care for alcohol and substance use–related treatment at a large national SUD treatment provider between January 2020 and March 2021. Data were collected at baseline and up to 1 year after discharge from both in-person and VIOP services through phone- and web-based surveys to assess recent substance use and general functioning across several domains.

Results: Initial baseline descriptive data were collected on patient demographics and clinical inventories. No differences in IOP setting were detected by race (χ^2_2=0.1; *P*=.96), ethnicity (χ^2_2=0.8; *P*=.66), employment status (χ^2_2=2.5; *P*=.29), education level (χ^2_4=7.9; *P*=.10), or whether participants presented with multiple SUDs (χ^2_8=11.4; *P*=.18). Significant differences emerged for biological sex (χ^2_2=8.5; *P*=.05), age (χ^2_6=26.8; *P*<.001), marital status (χ^2_4=20.5; *P*<.001), length of stay ($F_{2,3639}$=148.67; *P*<.001), and discharge against staff advice (χ^2_2=10.6; *P*<.01). More differences emerged by developmental stage, with emerging adults more likely to be women (χ^2_3=40.5; *P*<.001), non-White (χ^2_3=15.8; *P*<.001), have multiple SUDs (χ^2_3=453.6; *P*<.001), have longer lengths of stay ($F_{3,3638}$=13.51; *P*<.001), and more likely to be discharged against staff advice (χ^2_3=13.3; *P*<.01).

Conclusions: The findings aim to deepen our understanding of SUD treatment efficacy across traditional and telehealth settings and its associated correlates and predictors of patient-centered outcomes. The results of this study will inform the effective development of data-driven benchmarks and protocols for routine outcome data practices in treatment settings.

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KEYWORDS

telehealth; substance use treatment; patient outcomes

Introduction

Background

In 2019, an estimated 20.4 million individuals aged ≥12 years met the criteria for a substance use disorder (SUD) in the United States. Substance misuse and use remain the leading causes of disability, years of life lost, and death [1,2]. Drug-related overdoses in the United States were responsible for >100,000 deaths in a 12-month period from April 2020 to April 2021 [3-5]. Research supports the idea that the COVID-19 pandemic has further exacerbated the substance use and drug overdose crisis in the United States. Provisional public health data illustrate that drug-related overdose deaths increased by 28.3% from 2019 to 2020 and subsequently by 28.5% from 2020 to 2021 [5]. A study found that 13.3% of US adults reported starting or increasing substance use to cope with pandemic-related stressors and emotions [6]. However, in any given year, <15% of individuals who need specialized substance use–related treatment receive it, illuminating the significant unmet need for substance use–related treatment services in the United States [3].

Novel applications of treatment are necessary to enhance access to care and reduce health care disparities. Before the pandemic, telehealth platforms were already growing in popularity among mental health providers and demonstrated similar treatment outcomes as in-person care [7]. The use of telehealth for the treatment of SUD has historically been lower than its use for general mental health conditions, often focused on individual digital recovery tools and applications [8-10]. A number of barriers exist that largely prevent widespread use including regulations, reimbursement issues, and usability of platforms [11]. The COVID-19 pandemic has created a catalyst for the rapid expansion of SUD services through telehealth platforms. Emergency federal and state policies removed geographic and site-of-service restrictions while increasing the number of telehealth services covered by insurers. Many states also expanded take-home services for methadone, allowed buprenorphine prescriptions without face-to-face requirements, and dropped prior authorization requirements for opioid use disorder medications.

Despite a nationwide increase in telehealth services within licensed substance use treatment facilities, little is known about the long-term effectiveness of substance use interventions delivered through digital technologies [12,13]. Preliminary evidence supports high user engagement across a variety of digital platforms but does not provide a strong evidence base for recovery-related outcomes [10]. Since the onset of the COVID-19 pandemic, the literature has highlighted the need for specific research considerations related to the delivery of telehealth for SUDs, including whether treatment outcomes are comparable between in-person and telehealth delivery methods [14]. Although scholars have contributed to this gap in knowledge, these studies of SUD telehealth have been primarily limited to samples and settings, including a large reliance on single clinics or populations with limited geographic scope that precludes comparisons across national variations. Furthermore, much has been focused on individual treatment formats, whereas even less data exist for telehealth group-based intensive SUD treatment services [15].

Objectives and Hypotheses

The primary aim of this study is to examine treatment-related outcomes and patient predictors of treatment effectiveness across traditional in-person and telehealth settings in an outpatient addiction treatment setting. This study also aims to better understand the correlates of treatment efficacy in telehealth group formats as well as how outcomes of data collection practices may differentially impact response rates in web-based programming. Finally, this study aims to identify clinician-level characteristics that contribute to the successful engagement of patients and whether these characteristics are also associated with enhanced patient outcomes. The findings of the study provide actionable evidence to sustain internet-based SUD services and offer data to guide an effective response to the SUD public health crisis. The authors hypothesized that patient outcomes and treatment effectiveness across in-person and web-based settings would be comparable while providing equitable patient access across rural and urban geographic locations.

Methods

Ethics Approval

This study was evaluated by Emory University's Institutional Review Board (Emory IRB ID: STUDY00001822) and was determined to have met human research exemption under 45 Code of Federal Regulations 46.104(d; 4), as all study data were collected in the context of Hazelden Betty Ford Foundation's (HBFF) standard routine outcome monitoring (ROM) practices. Similar to other health care organizations, HBFF's putative ROM practices include regular, methodical collection of diagnostics, patient progress, and overall treatment effectiveness data beginning at intake and ending 12 months after treatment discharge. The intent of ROM data is to provide direct care providers with consistent, reliable assessments of individual patient progress and treatment experience to reduce instances of treatment deterioration and failure and thereby bolster patient outcomes [16-18]. Similarly, these data inform patient-centered clinical operations and organizational quality improvement procedures to ensure that ethical quality health care is delivered [19,20].

Study Design and Procedures

The virtual intensive outpatient program (VIOP) study is a naturalistic, prospective longitudinal cohort design that followed patients discharged from IOP care for alcohol and substance use–related treatment at the largest nonprofit treatment provider for SUDs in the United States between January 2020 and March 2021. The HBFF provides SUD treatment for thousands of patients each year through its 17 locations nationwide. In 2019,

HBFF began piloting a single VIOP group to better understand the core functionality and acceptability of using a new web-based platform, with an incremental expansion of VIOP planned to begin in 2020. However, the onset of the COVID-19 pandemic greatly accelerated the internet-based rollout, necessitating immediate changes to in-person programming in March 2020. As a result, the HBFF quickly pivoted most IOP services to a web-based format while continuing to collect routine patient outcome data. Within a 2-week period beginning at the end of March, 74 IOP groups transitioned from in-person to web-based programming, representing 541 unique patients.

VIOP was developed to be as close a corollary to in-person IOP as possible while simultaneously expanding access to care to those who may not otherwise have lived close enough to a physical HBFF location to regularly attend the sessions. This included video-based, real-time group interactions and individual sessions, leveraging the use of technology that could accommodate low-bandwidth internet connections, thus ensuring the quality and stability of video feeds during sessions. In-person systems for patient accountability have also been adapted for internet-based care, including crisis or emergency response protocols, privacy monitoring, and random drug and alcohol testing using in-home testing kits or blood alcohol content devices with video support. Remote testing through laboratories in patient communities was also used when needed through a partnership with a remote testing company.

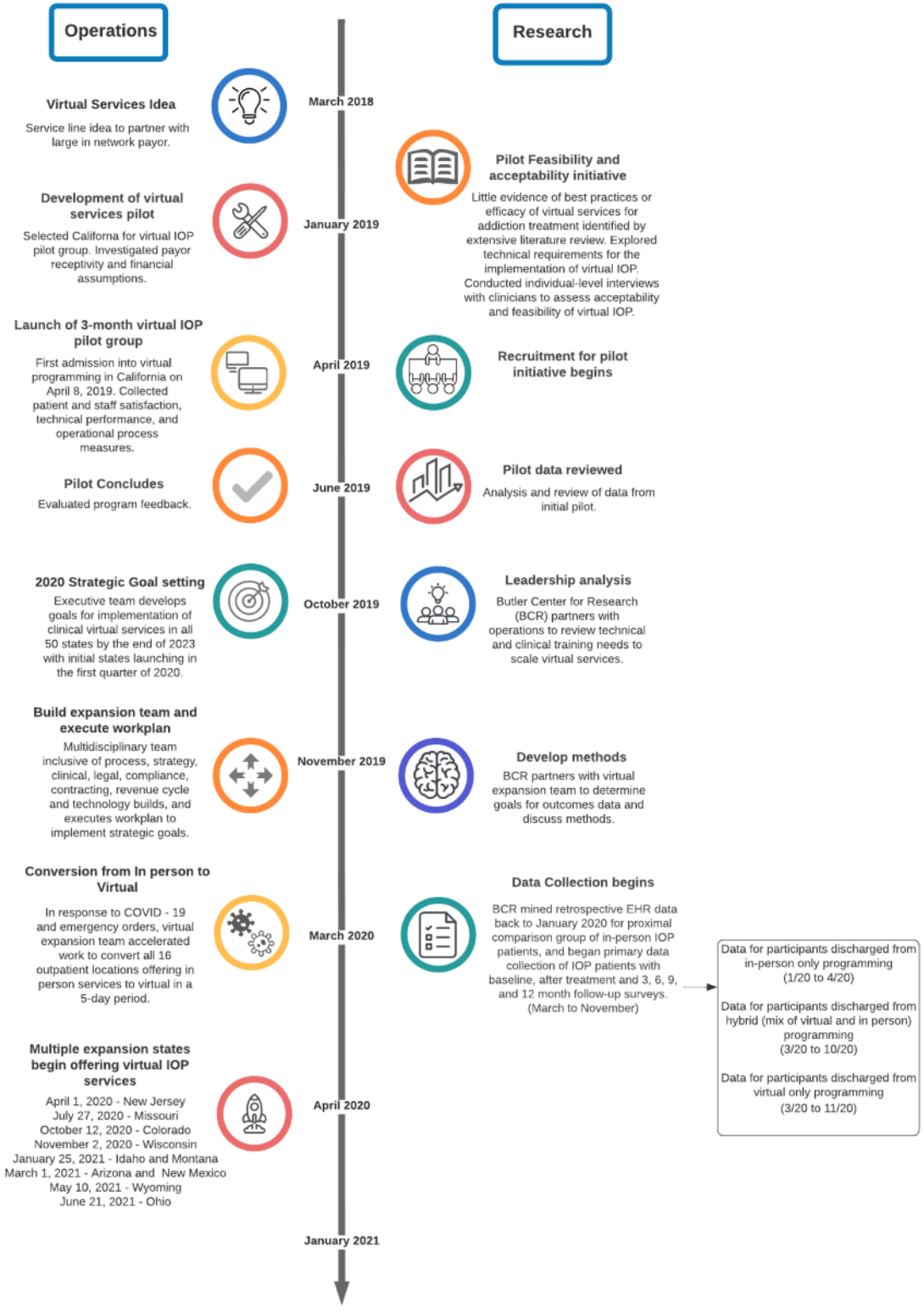
Individuals participating in VIOP who were identified as potentially benefiting from medication for SUD were either partnered with an HBFF provider for evaluation and follow-up or were recommended to obtain a local community provider educated in addiction treatment. Web-based clinical staff were trained to collaborate on treatment recommendations and to provide monitoring to ensure safe use and medication compliance. This monitoring was multifactorial and included increased toxicology, prescription drug monitoring reviews, and multidisciplinary case reviews.

An overview of the operations and study procedures is presented in Figure 1. All patients who were discharged from the IOP between January 1, 2020, and March 17, 2021, were considered eligible and contacted to participate. Although the transition to VIOP occurred at the end of March 2020, study data collection did not begin until May 2020. To capture a comparison group of those who attended IOP in person, all patients who were discharged from any in-person IOP on or after January 1, 2020, were opted to receive the IOP-specific outcome surveys. Owing to the timing of the mass opt-in and the shorter windows of the initial surveys (ie, 30 days from treatment admission for the baseline survey and 30-60 days following discharge for the 1-month survey), most of the in-person and hybrid cohorts were not eligible to complete the baseline or 1-month postdischarge survey.

Data were collected at six periods: baseline (within 30 days of admission) and 1, 3, 6, 9, and 12 months after discharge from IOP, through phone- and web-based surveys. Demographic data and IOP episode-level information, including length of stay, discharge status, and the number of sessions attended, were acquired from *Compass*, HBFF's electronic health record database management system. The baseline and postdischarge follow-up surveys asked patients to assess their recent substance use and general functioning across several domains, including previous treatment, craving level, peer-support group attendance, use of anticraving medications, substance use, quality of life, economic stressors, exposure to violence, psychological well-being, self-efficacy, gratitude, parental substance use, and parenting stressors.

Baseline and postdischarge follow-up surveys were administered by the HBFF's team of data collection specialists (DCSs). Each DCS team member was systematically and rigorously trained to follow the same set of procedures to ensure data integrity and security in adherence to patient confidentiality standards as per Health Insurance Portability and Accountability Act and 42 CFR Part 2 governance. As part of the ROM procedures, coordination of survey administration and completion includes a brief check-in between DCS and patients' primary clinical staff to alert patients of survey availability.

Figure 1. Timeline of development and implementation of web-based services. The left side of the figure depicts the conceptualization and delivery of internet-based services. The right side represents the underlying research and data collection across the protocol timeline. EHR: electronic health record; IOP: intensive outpatient program.



Study Population

Patients were considered eligible to participate if they were discharged from the IOP at HBFF between January 2020 and March 2021 and were aged ≥18 years at the time of treatment admission. No additional exclusion criteria were applied.

The final sample included 3642 patients who fell into three comparison groups: (1) those who received in-person only programming (957/3642, 26.28%), (2) those who received hybrid in-person and internet-based programming (541/3642, 14.85%), and (3) those who received internet-only programming (2144/3642, 58.87%).

Measures

Overview

Demographics were captured at the time of admission within HBFF's electronic health records.

The following measures were used to collect data across the 6 periods (Table 1).

Table 1. Study measures and time points.

Study measures	Time points					
	Before discharge	After discharge				
	Baseline	1 month	3 months	6 months	9 months	12 months
The System Usability Scale		✓				
Flourishing Scale	✓	✓	✓	✓	✓	✓
Consumer Financial Protection Bureau Financial Well-being Scale—abbreviated	✓	✓	✓	✓	✓	✓
The Gratitude Questionnaire—6-item Form	✓	✓	✓	✓	✓	✓
Patient Health Questionnaire-9	✓					
General Anxiety Disorder-7	✓					
Commitment to Sobriety Scale-5	✓					
Desires for Alcohol Questionnaire-6	✓					
World Health Organization Quality of Life-Brief	✓	✓	✓	✓	✓	✓
Self-efficacy of Sustained Sobriety Scale	✓	✓	✓	✓	✓	✓
12-step peer group engagement	✓	✓	✓	✓	✓	✓
Parenting Daily Hassles Scale	✓	✓	✓	✓	✓	✓
Modified Children of Alcoholics Screening Test-6	✓	✓		✓		✓
Revised Conflict Tactics Scale	✓	✓	✓	✓	✓	✓
Drug and alcohol use	✓	✓	✓	✓	✓	✓

Depression Symptoms

Patients were administered the 10-item Patient Health Questionnaire-9 (PHQ-9) to self-report any occurrence of the 9 depression-related symptoms representative of Diagnostic and Statistical Manual of Mental Disorders Volume 5 (DSM-5) Major Depressive Disorder [21]. Each patient was asked to evaluate and rate the frequency of each symptom statement using one of four ordinal categories: 0 (*not at all*) to 3 (*nearly every day*). Possible scores ranged from 0 to 27, with higher scores indicating a greater frequency and severity of the DSM-5 Major Depressive Disorder symptoms. The PHQ-9 had high internal reliability (Cronbach α=.89) [21].

Anxiety Symptoms

To measure symptoms indicative of co-occurring generalized anxiety disorder (GAD), patients were administered the 8-item General Anxiety Disorder-7 (GAD-7) screener [22]. Patients were asked to reflect on and estimate the occurrence of symptoms indicative of GAD in the past 2 weeks on a 4-point scale, ranging from 1 to 4. Sample questions included, "Over the last two weeks, how often have you been bothered by the following problems? Feeling nervous, anxious, or on the edge." The response categories included 4 Likert-type ranges of occurrence: 1 (*not at all*), 2 (*several days*), 3 (*more than half the days*), and 4 (*nearly every day).* Patient self-reports were scored and totaled; item scoring replaced the 1-4 scale with designated scores of 0, 1, 2, and 3. Scores range from 0 to 21, with higher scores indicating an increased occurrence and severity of general anxiety symptoms that impede daily functioning. Internal consistency calculations indicated high internal reliability (Cronbach α=.82) [22].

Confidence and Commitment to Staying Sober

The ratings of patient-perceived level of motivation and dedication to achieving initial and maintaining ongoing sobriety for substance use were measured using the 5-item Commitment to Sobriety Scale (CSS-5) [23]. Each statement was rated on a 6-point Likert scale, ranging from 1 (*strongly disagree*) to 6 (*strongly agree*). Example items included, "Staying sober is the most important thing in my life" and "I will do whatever it takes to recover from my addiction." The CSS-5 displayed high internal reliability at posttreatment follow-up (Cronbach α=.89) [23].

After the completion of the CSS-5, patients were asked to reflect and rate their level of confidence in their commitment to abstinence for the next 30 days using a 10-point scale, ranging from 1 (*not at all confident*) to 10 (*very confident*).

Desire and Intent to Use

The 6-item short form Desire for Alcohol Questionnaire was used to assess patient-reported desire (ie, cravings), intent to use, and the role of negative reinforcement on their primary substance of choice [24]. The word *alcohol* in the questionnaire was replaced with *drugs* to expand the measurements'

applicability to a wide range of substances. Patients rated their level of agreement with each statement on a 7-point Likert scale, ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). Statements are comprised two subscales: (1) desire and intention to use (ie, "I want to use drugs so much I can taste it" and "My desire to use drugs now seems overwhelming") and (2) negative reinforcement (ie, "I would feel as if all the bad things in my life had disappeared if I used drugs now" and "I would feel less worried about my daily problems if I used drugs now"). For each subscale, responses were summed and divided by 3, resulting in a score between 1 and 7, with 7 indicating higher levels of desire and intent to use [24]. Subscale internal reliability calculations illustrated high consistency for both subscales: desire and intention to use (Cronbach α=.94) and negative reinforcement (Cronbach α=.89) [24].

Web-Based Therapy Platform Evaluations

The 10-item System Usability Scale was used to measure patient-perceived evaluations of the usability of the software platform for the VIOP platform [25]. To better fit the applied context, the word *system* was changed to *VIOP platform*, and the word *cumbersome* was replaced with *awkward*. These minor adaptations had no adverse impact on the internal consistency of the scale (Cronbach α=.89). Patients were asked to assess and rate their level of agreement with a list of statements describing the usability of the VIOP platform using a 5-point Likert scale, ranging from 1 (*strongly disagree*) to 5 (*strongly agree)*. Example questions included, "I thought the virtual IOP platform was easy to *use*" and "I felt very confident using the virtual IOP platform."

Psychological Well-being

The self-reported Flourishing Scale is a measure of *psychological well-being* comprising 8 statement items indicative of predictors of social–psychological prosperity (ie, flourishing), such as social support, self-acceptance and capability, and leading a purposeful life [26]. As an example, item 5 reads, "I am competent and capable in the activities that are important to me." Patients were instructed to rate their level of concurrence with each item using a 7-point Likert rating scale. Responses were scored from 1 (*strongly disagree*) to 7 (*strongly agree*) and added together to provide a composite score, with higher scores indicating high social–psychological prosperity. Calculations of the scale's Cronbach α showed a high internal consistency (Cronbach α=.92).

Financial Well-being

Patient-perceived financial well-being, the belief that one is financially secure (ie, can meet current financial commitments) and has financial freedom (ie, the ability to make financial choices that go over and beyond purely basic needs), was assessed using the Consumer Financial Protection Bureau (CFPB) Financial Well-being Scale [27]. Applying a 5-point Likert scale, patients rated their level of agreement with 5 statements describing diverse financial situations. We adapted and recoded the response categories for items 1 through 3 from 5 (*completely)* to 1 (*not at all*) to 4 (*strongly disagree*) to 0 (*strongly agree*) for internal scale validity and reliability. Example item statements included, "Because of my money situation, I feel like I will never have the things I want in life" and "I have money left over at the end of the month." The alpha calculations indicated high internal consistency (Cronbach α=0.88). Higher scores indicated greater perceived financial well-being.

Attitudes of Gratitude

Patients' self-reported propensity toward attitudes of gratitude in day-to-day experiences was assessed using the Gratitude Questionnaire—6-item form [28]. Questionnaire Likert-type responses allowed patients to choose their level of agreement from 1 (*strongly disagree*) to 6 (*strongly agree*) for statements such as, "I have so much in life to be thankful for" and "As I get older I find myself more able to appreciate the people, events, and situations that have been part of my life history." Higher scores indicated a higher propensity to perceive gratitude in daily experiences. The Cronbach α for this measurement was high (Cronbach α=.84), indicating high internal consistency [28].

Quality of Life

Quality of life was measured using the 4-item self-reported Centers for Disease Control Healthy Days Survey [29,30]. An additional question assessing overall quality of life was also added: "How would you rate your overall quality of life?" Patients were asked to rate their overall quality of life and quality of general health using a 5-point Likert scale, ranging from 1 (*poor*) to 5 (*excellent*), and indicate the number of days out of the previous 30 days that they experienced either one or both: poor mental or physical health. A higher number of unhealthy days indicated a lower quality of life.

Self-efficacy of Sustained Sobriety

Self-reported measurements of patients' confidence in their ability to stay sober comprised an adapted form of the *Brief Situational Confidence Questionnaire* to create a sobriety self-efficacy scale [31]. Sample questions included, "I would be able to resist using alcohol or drugs right now if I were physically uncomfortable [eg, feeling sick, headache, and in pain]" and "I would be able to resist using alcohol or drugs right now if someone I cared about offered it to me [eg, a good friend at a gathering or a spouse at home]" [31].

The 7-point Likert response categories were reworded from 1 (*not confident at all*) to 7 (*totally confident*) to 1 (*strongly disagree*) to 7 *(strongly agree*) to maintain consistency across the different scales. Initial interitem correlations and α values indicated that in comparison with the other questions, the original Brief Situational Confidence Questionnaire question 5, "I could probably go back to social drinking or other moderate drug use if I wanted to," did not adequately add to the measure of sobriety self-efficacy. After discussing the inventory with the DCSs, it was determined that multiple patients were unable or unwilling to answer item 5 when prompted. This question was likely uniquely difficult for this population, given the abstinence-based focus of HBFF's programming and the consistent message during treatment that no amount of substance use is safe. This item was removed shortly after data collection began in 2020. After the removal of item 5, the adapted scale

of sobriety self-efficacy showed high internal consistency (Cronbach α=.89).

Peer Group Support Engagement

Self-reports of engaging in peer group support were measured by 1 item adapted from the Alcoholic Anonymous Involvement Scale, which asked respondents, "About how often have you been attending 12-step/peer support/mutual aid group meetings since you were discharged?" [32]. Adaptations were made to include peer support groups other than alcoholics anonymous. Participants answered using a 6-point ordinal scale: *daily, ≥4 times per week, 1-3 times per week, 2-4 times per month, once a month or less,* or *never.*

Parenting Stressors

The 20-item Parenting Daily Hassles Scale was used to measure the frequency and intensity (or impact) of common daily parenting or caregiver stressors [33,34]. Respondents were also asked to rate the frequency of occurrence of experienced hassles on a 4-point Likert scale, ranging from 1 (*rarely*) to 4 (*constantly*). In addition, *parents* was changed to *caretakers* for inclusion of nontraditional caregivers. Sample questions included, "For the past 6 months, how often have you found yourself continually cleaning up messes of toys or food" and "The kids are constantly underfoot, interfering with other chores." The internal consistency was excellent (Cronbach α=.91).

Finally, 2 questions were added to capture participants who had to manage homeschooling because of the pandemic: (1) "Since January 2020, have you had to manage homeschooling for children under 18 due to the pandemic?" which participants answered *yes* or *no* and "During any of the following months, did you have to manage homeschooling for children?" where participants selected all months in which they homeschooled.

History of Parental (Family of Origin) Alcohol or Drug Use

We used the 6-item modified Children of Alcoholics Screening Test to assess exposure to parental alcoholism [35]. Participants were able to opt out of this question if it did not apply. Questions were modified to include exposure to parental drug use, such as *drinking or drug problem* or *drunk or high*. In addition, the gendered language in item 3 was changed from *he or she* to *they* for gender inclusion. Respondents were asked *yes* or *no* questions related to past experiences with their parents and alcohol or drugs. Questions included, "Have you ever thought that one of your parents had a drinking or drug problem?" and "Have you ever heard your parents fight when one of them was drunk or high?" The internal consistency of this scale was a Cronbach α of .90.

Lifetime Exposure to Family and Intimate Partner Violence

The 3-item survey adapted from the study by Easton et al [36] based on the Revised Conflict Tactics Scale was used to measure the lifetime prevalence of family and intimate partner violence [37]. Participants answered *yes* or *no* to questions related to their lifetime exposure to childhood physical and sexual violence in addition to a history of perpetrating or experiencing intimate partner violence. For the purposes of this study, we modified 2 questions to parse out those with exposure to physical and sexual violence. For example, item 3 ("As a child, were you ever physically or sexually hurt by a parent, family member, friend of the family, or some other adult? [eg, slapped, pushed, punched, beat up, or sexually abused]" was changed to, "As a child, were you every sexually hurt by a parent, family member, friend of the family, or some other adult? [eg, sexually abused]" and "As a child, were you ever physically hurt by a parent, family member, friend of the family, or some other adult? [eg, slapped, pushed, punched, or beat up]." Other questions included, "In your lifetime, have you been in a fight with a spouse or partner in which you were physically hurt? [eg, slapped, pushed, punched, beat up, or sexually assaulted]." The internal consistency of the scale was a Cronbach α of .53. In addition, we added 1 question to measure the respondent-perceived impact of violence exposure on a 10-point Likert scale (ie, 1=*not at all* to 10=*enormous daily impact*).

Drug and Alcohol Use

To measure self-reported substance use duration and severity during the study period, we used the modified Form-90 Quick Drinking Assessment (Form-90-AQ) [38]. The Form-90-AQ was developed as a brief assessment tool to determine an individual's alcohol use during a discrete period leading up to the present day [38]. Questions were modified to improve clarity when given over the phone (eg, including each participant's specific period as well as the number of days in the period in every question, rather than only in the initial prompt). Sample questions included, "Have you used any alcohol since discharge or your last survey on [last survey or discharge date], a period of [number of days between today and last survey or discharge]?" and "On those days when you did drink, how much did you have to drink on average?" Next, the question included in the Form-90-AQ about binge drinking was updated to reflect the National Institute on Alcohol Abuse and Alcoholism's (NIAAA's) most recent recommendation for the definition of the concept, from 6 to 5 drinks (eg, "Of those days on which you drank, on how many days did you have five or more drinks?"). In addition, a question about blacking out from alcohol use was added (eg, "On those days on which you drank, on how many days did you drink so much that you *blacked out* or couldn't remember?") [39]. Finally, some questions were adapted to ask about other substance use (eg, "Have you used any drugs or alcohol since your last survey on [last survey date]" and "Have you used any drugs, not including tobacco/nicotine, since your last survey on [last survey date], a period of [number of days between today and last survey]?"

Statistical Analyses

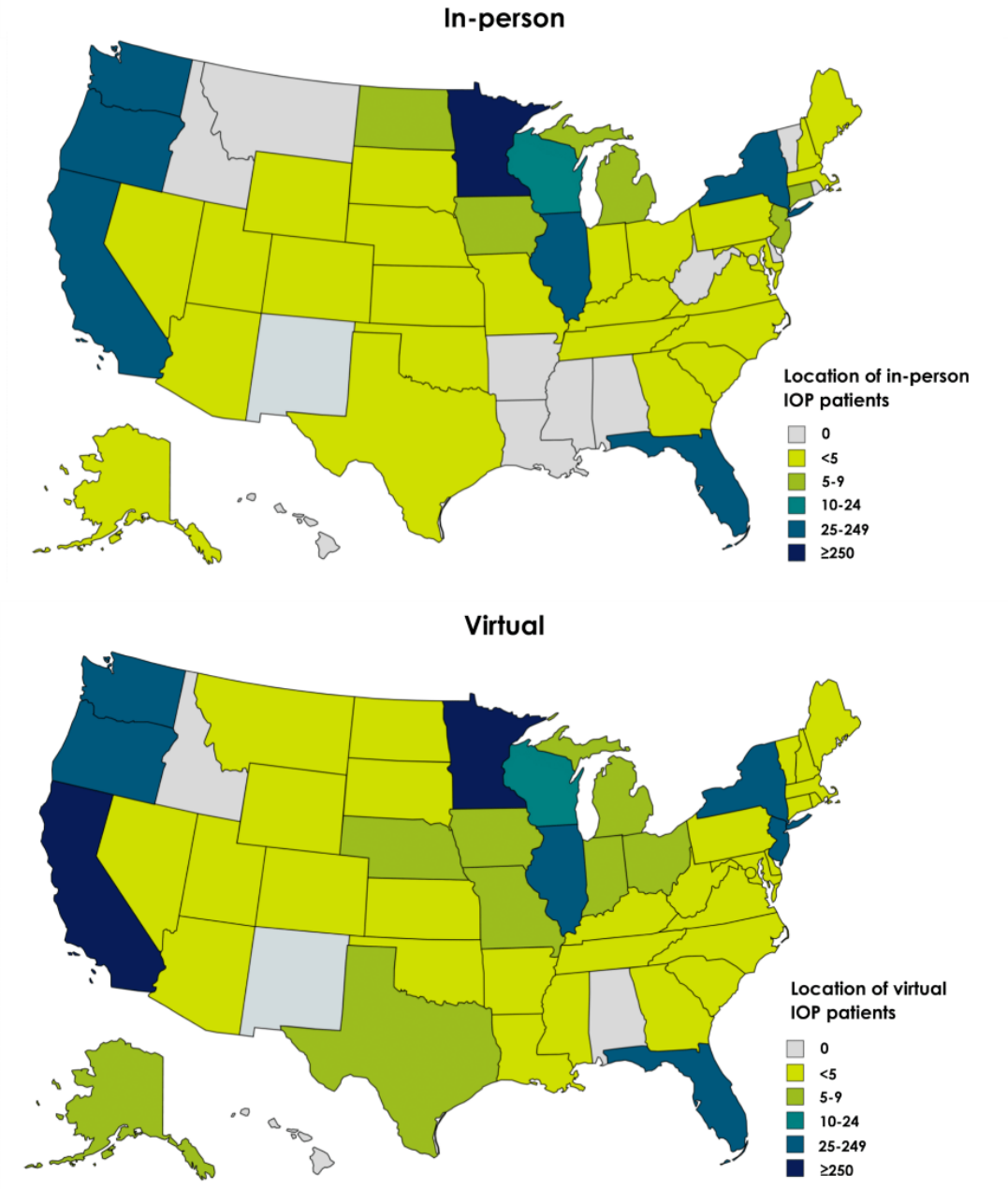
Analyses were conducted using SPSS statistics (*version* 28; IBM Corp) [40]. Chi-square tests of independence and 1-way ANOVA were performed to examine the relationships between the group format and baseline participant characteristics.

Results

Sample Characteristics

The sample characteristics are reported by IOP setting in Multimedia Appendix 1. Most patients were White (3296/3642, 90.49%) and men (2258/3642, 62%), with a mean age of 39.1 (SD 13.5) years. Approximately 37.97% (1383/3642) of the patients were diagnosed with 2 or more active substance use diagnoses, and the vast majority (3519/3642, 96.62%) accessed treatment through insurance. The national spread of patients by home state is shown displayed in Figure 2. Patients from a greater number of states attended VIOP (37 states: in-person and 46 states+Washington DC: internet-based), suggesting increased accessibility to care. Data were also considered according to the developmental stages presented in Multimedia Appendix 2, ranging from emerging adulthood to late adulthood to better understand how an individual's age may impact participation and engagement in different modalities of IOP.

Figure 2. Geographic distribution of participants by home state. IOP: intensive outpatient program.



Bivariate Group Comparisons: IOP Setting

At the beginning of the transition to web-based services in early 2020, a small proportion of patients were discharged before treatment completion when they elected not to switch to VIOP or when they stopped attending the sessions shortly after the change in treatment modality occurred. Patients who were discharged within 14 days of a group switching to internet-based were significantly more likely than those in the hybrid or web-based-only groups to be men (χ^2_2=8.7; P<.05), to be younger (χ^2_4=24.7; P<.001), and to have obtained a lower level of education (χ^2_4=12.7; P<.05). There were no significant differences between these groups in the proportions of White,

Hispanic, or Latinx individuals; employed full time or part time; or diagnosed with one or more SUDs.

Key features included differences in biological sex distribution, where participants in the hybrid group were significantly more likely to be men, whereas those in the internet-based group were more likely to be women. Significant differences were observed in age distributions. A greater number of individuals aged 18-25 years participated in the hybrid, and a greater number of individuals aged 45-64 years participated in the internet-based-only IOP. Regarding marital status, those in the hybrid group were significantly more likely to be single, whereas those in the web-based-only programming were more likely to be divorced, separated, or widowed. Individuals in hybrid programming had significantly longer lengths of stay and were significantly less likely to be discharged against staff or medical advice than individuals in both in-person and internet-only IOP. No significant differences were detected between formats by race, ethnicity, employment status, education level, or whether the participants presented with multiple SUDs. Similarly, no differences emerged in the type of SUD except for cocaine use disorder, where a significantly higher proportion of participants in the in-person group and a lower proportion in the internet-only group were diagnosed with a cocaine use disorder.

Developmental Stages

More differences emerged when examining the relationship between developmental stage and baseline participant characteristics, primarily driven by the emerging adults (those aged 18-25 years at treatment entry) in the sample (full results in Multimedia Appendix 2). Emerging adults were significantly more likely to participate in hybrid programming and less likely to participate in the web-based-only IOP. In terms of biological sex distribution, emerging and early adults were significantly more likely to be men, whereas middle-aged adults were more likely to be women. Owing to the preponderance of White participants in the sample, the race variable was collapsed to compare White with non-White participants (with full self-reported identification reported in Multimedia Appendix 1). Emerging adults were significantly more likely to be non-White, whereas middle-aged adults were significantly more likely to be White. Differences also emerged related to programming, with those aged 18-25 years engaging in treatment for a significantly longer period than older participants while also being more likely to be discharged against staff or medical advice. Emerging adults were less likely to be diagnosed with an alcohol use disorder and more likely to be diagnosed with all other SUDs, except for inhalant and other psychoactive disorders. Finally, emerging adults were significantly more likely to be diagnosed with multiple SUDs.

Regarding baseline clinical and functional measurements (Table 2), no differences emerged between the formats. Missing values reflect a delay in our ability to collect baseline and 1-month data from the in-person and hybrid groups.

Table 2. Baseline measurements of participants in intensive outpatient program.

Average baseline measurement scores	In-person only (n=957), mean (SD)	Hybrid (n=541), mean (SD)	Internet only (n=2144), mean (SD)	Overall (N=3642); missing, n (%)	Overall, *F* test (*df*)	*P* value
Psychological well-being	N/A[a]	N/A	42.81 (9.24)	2845 (78.12)	N/A	N/A
Financial Well-being Scale	N/A	N/A	49.37 (6.06)	2824 (77.54)	N/A	N/A
Gratitude Questionnaire—6-item form	N/A	N/A	34.36 (6.39)	2824 (77.54)	N/A	N/A
Quality of life	N/A	N/A	3.69 (0.88)	2810 (77.16)	N/A	N/A
Sobriety self-efficacy	N/A	N/A	5.57 (1.36)	2831 (77.73)	N/A	N/A
History of family violence	N/A	N/A	0.79 (0.94)	2859 (78.50)	N/A	N/A
History of parental substance use	N/A	N/A	2.06 (2.27)	2860 (78.53)	N/A	N/A
Frequency of parenting stressors	N/A	N/A	37.29 (10.33)	3464 (95.11)	N/A	N/A
Patient Health Questionnaire-9	6.18 (5.27)	5.73 (4.92)	6.48 (5.47)	2710 (74.41)	0.96 (2, 929)	.38
General Anxiety Disorder-7	6.20 (5.18)	5.95 (5.95)	6.85 (5.18)	2560 (70.30)	2.51 (2, 1079)	.08
Commitment to Sobriety Scale	27.01 (2.95)	27.04 (3.36)	27.14 (3.40)	2493 (68.45)	0.20 (2, 1146)	.82
DSQ[b]—desire and intention to use	1.72 (1.08)	1.70 (1.08)	1.74 (1.03)	1685 (46.27)	0.15 (2, 1954)	.86
DSQ—negative reinforcement	1.92 (1.37)	1.85 (1.11)	1.94 (1.23)	1685 (46.27)	0.52 (2, 1954)	.59

[a]N/A: not applicable.

[b]DSQ: Desire for Speed Questionnaire.

Discussion

Principal Findings

The VIOP study represents an important advancement in expanding our understanding of the role of telehealth in alcohol and substance use addiction treatment, providing richer insight into whether comparable care can be delivered through the internet.

At treatment entry, adults were similar across most demographic and substance use variables for all formats of IOP. Similarly, average scores on clinical inventories (eg, PHQ-9 and GAD-7) at baseline did not differ significantly by delivery setting, illustrating similar levels of psychiatric symptoms and physical cravings, regardless of the IOP delivery setting and timing of treatment in relation to the pandemic. This supports the literature on the use of web-based methods for the treatment of mental health symptoms and also shows that this treatment modality is viable for substance use populations as well. One notable difference emerged: individuals who participated in hybrid programming stayed in treatment significantly longer and were discharged against staff advice at a lower rate than those in traditional (in-person) or internet-based-only programming. Future publications will assess whether hybrid settings improved patient outcomes over and beyond those who received care in 1 setting only or whether it was a reflection of the extra support needed during a time of significant disruption in individuals' lives associated with the onset of the COVID-19 pandemic.

More differences emerged when comparing participants across developmental stages. Emerging adults (aged 18-25 years) in IOP showed consistent differences across a variety of demographic variables than those in early adulthood, mid-adulthood, and late adulthood and were more likely than patients at other developmental stages to present with multiple co-occurring SUDs, have longer episodes of care, and discharge early despite recommendations by program staff to continue treatment. These results suggest that patients in emerging adulthood have unique needs over and beyond those in older adult stages.

Strengths and Limitations

There are strengths and limitations to the use of ROM data. As these explorations are not bound by a clinical trial, there are inherent measurement errors that may affect the data, such as instances of inaccurate manual data entry, missed measurement scores, or diversity of standard measurements used in initial diagnostic assessments across clinical service departments and disciplines (ie, solely alcohol and substance use treatment vs co-occurring treatment). As a result, mental health diagnoses outside of substance and alcohol use disorders were not consistently documented and had to be excluded from the analyses. As data collection began in May 2020, much of our baseline data were pulled retrospectively through electronic health records, and in-person and hybrid patients missed some baseline measurements and what would have been their 1-month follow-up. Although not ideal, the remaining baseline measurements and 3-month follow-up can be compared, and any notable differences will inform future research. Furthermore, findings will be limited by the predominance of White, non-Hispanic men in our sample and therefore should not be generalized to patient populations' representative of minority and marginalized persons. Owing to the lack of randomization, our results do not allow for causal associations. However, these findings will provide an ecologically valid examination of web-based care in an existing health care system that is relevant and informative to other health care systems providing alcohol and substance use addiction treatment. Indeed, clinically efficacious explorations are inherently advantageous, and ecologic examinations may offer richer insight and practical implications in the real-world day-to-day lived experience of patients undergoing alcohol and substance use treatment.

Conclusions

Future findings hope to inform the effective development of data-driven benchmarks and protocols for routine outcome data practice. Investigations may also leverage these data to identify the patients for whom and circumstances under which telehealth is most efficacious, as these services are integrated into the standard of care for addiction treatment and recovery.

Acknowledgments

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Conflicts of Interest

JWW received consulting fees from the Applied Clinical Intelligence LLC. QMN, KG, JEB, and DNK are employees of the Hazelden Betty Ford Foundation.

Multimedia Appendix 1
Baseline demographic characteristics of patients enrolled in intensive outpatient program (IOP) in 2020.
[DOCX File , 25 KB - formative_v6i4e34408_app1.docx]

Multimedia Appendix 2
Baseline characteristics of intensive outpatient program (IOP) patients by developmental stage in 2020 (N=3642).
[DOCX File , 20 KB - formative_v6i4e34408_app2.docx]

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Abbreviations

CSS: Commitment to Sobriety Scale
DCS: data collection specialist
GAD-7: General Anxiety Disorder-7
HBFF: Hazelden Betty Ford Foundation
IOP: intensive outpatient program
PHQ-9: Patient Health Questionnaire-9
ROM: routine outcome monitoring
SUD: substance use disorder
VIOP: virtual intensive outpatient program

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Original Paper

Medication Optimization Among People With Type 2 Diabetes Participating in a Continuous Glucose Monitoring–Driven Virtual Care Program: Prospective Study

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Abstract

Background: The Onduo virtual care program for people with type 2 diabetes (T2D) includes a mobile app, remote lifestyle coaching, connected devices, and telemedicine consultations with endocrinologists for medication management and prescription of real-time continuous glucose monitoring (RT-CGM) devices. In a previously described 4-month prospective study of this program, adults with T2D and baseline glycated hemoglobin (HbA_{1c}) ≥8.0% to ≤12.0% experienced a mean HbA_{1c} decrease of 1.6% with no significant increase in hypoglycemia.

Objective: The objective of this analysis was to evaluate medication optimization and management in the 4-month prospective T2D study.

Methods: Study participants received at least 1 telemedicine consultation with an Onduo endocrinologist for diabetes medication management and used RT-CGM intermittently to guide therapy and dosing. Medication changes were analyzed.

Results: Of 55 participants, 48 (87%) had a medication change consisting of a dose change, addition, or discontinuation. Of these, 15 (31%) participants had a net increase in number of diabetes medication classes from baseline. Mean time to first medication change for these participants was 36 days. The percentage of participants taking a glucagon-like peptide-1 receptor agonist increased from 25% (12/48) to 56% (n=27), while the percentages of participants taking a sulfonylurea or dipeptidyl peptidase 4 inhibitor decreased from 56% (n=27) to 33% (n=16) and 17% (n=8) to 6% (n=3), respectively. Prescriptions of other antidiabetic medication classes including insulin did not change significantly.

Conclusions: The Onduo virtual care program can play an important role in providing timely access to guideline-based diabetes management medications and technologies for people with T2D.

Trial Registration: ClinicalTrials.gov NCT03865381; https://clinicaltrials.gov/ct2/show/NCT03865381

(JMIR Form Res 2022;6(4):e31629) doi:10.2196/31629

KEYWORDS

continuous glucose monitoring; digital health; GLP-1 receptor agonist; HbA1c; telemedicine; type 2 diabetes; monitoring; diabetes; optimization; medication; virtual care; prospective; app; lifestyle; coaching; self-management

Introduction

Background

The Centers for Disease Control and Prevention (CDC) estimates that approximately 35 million people have type 2 diabetes (T2D), which is approximately 11% of the US population [1]. The incidence and prevalence of T2D continue to climb and outcomes are not improving despite increases in the number of effective drugs and advances in management technology. A growing body of evidence suggests that telehealth programs for T2D including smartphone apps, connected devices, and remote lifestyle coaching may help to address this public health crisis [2]. Participation in these programs has been associated with improvement in glycated hemoglobin (HbA_{1c}) and other related comorbidities [3-14]. Recently, telehealth programs have begun to incorporate medical management and the use of advanced remote monitoring technology; however, data on methodologies and outcomes are limited [13,15].

The Onduo virtual care program for adults with T2D provides access to video consultations with endocrinologists for medication management and prescription of real-time continuous glucose monitoring (RT-CGM) devices, which are used to facilitate optimization of medication regimens and lifestyle coaching and participant self-management. A recent prospective trial of the Onduo program reported a reduction in laboratory-measured HbA_{1c} of 1.6% (SD 1.0; P<.001) from 8.9% (SD 1.0) to 7.3% (SD 0.9), and a significant improvement in continuous glucose monitoring (CGM)–derived glycemic metrics at 4 months in 55 adults with suboptimally controlled T2D [13]. Here we report the detailed medication management that occurred during the study.

Study Objective

The objective of this analysis was to evaluate remote medication management by Onduo endocrinologists during telemedicine visits in conjunction with RT-CGM use among participants who completed the recent 4-month prospective trial [13].

Methods

Participants

Detailed study methods have been previously reported [13]. In brief, participants were ≥18 years of age, had a confirmed diagnosis of T2D, had HbA_{1c} level ≥8.0% and ≤12.0%, were willing to use a blood glucose monitor and CGM device, and owned a smartphone. Major exclusion criteria included malignant cancer, dialysis or end-stage renal disease or dialysis, liver or pancreatic failure, cystic fibrosis, chronic heart failure, or use of an insulin pump.

Protocol

Baseline and final assessments were conducted in person at the 2 study sites and included physical measures, blood draws, and questionnaires. The intervention was conducted remotely through the Onduo virtual care program.

Virtual Care Program Participation

The Onduo virtual care program for adults with T2D combines connected devices, remote lifestyle coaching, and clinical support with a mobile app has been previously described [11,12,14]. In this study, participants were asked to engage at least once per week with their health coach or care team and to participate in a telemedicine consultation with an Onduo endocrinologist. All participants were mailed a RT-CGM device (Dexcom G6, Dexcom) for intermittent use as indicated in the American Diabetes Association (ADA) Standards of Medical Care in Diabetes for adults with T2D [16]. Participants were asked to wear six 10-day sensors, with an initial period of 20 days (2 sensors); the remaining 4 sensors were worn on a 10-day "on" and 11-day "off" cycle. CGM glucose data were used by the care team for education and lifestyle coaching on the impact of diet and exercise and by the Onduo endocrinologists for medication management and to evaluate the efficacy of medication changes on glycemic control. Optimization of medication regimens was done remotely by endocrinologists and incorporated medical history, laboratory test results, and patient preferences, and was done in accordance with the ADA Standards, which is analogous to an in-person clinical practice [16]. The ADA Standards indicate that glucagon-like peptide-1 (GLP-1) receptor agonists are recommended as the first injectable medication, preferable to insulin. GLP-1 receptor agonists are also preferred over dipeptidyl peptidase 4 (DPP-4) inhibitors and sulfonylureas due to greater potency and positive cardiovascular outcomes. In addition, GLP-1 receptor agonists have superior side effect profiles compared to sulfonylureas, which carry risks of severe hypoglycemia and weight gain [17].

Statistical Analysis

Change from baseline at 4 months for clinical characteristics and the number of diabetes medication classes prescribed to participants were evaluated by Wilcoxon signed-rank tests. The change in number of participants prescribed specific diabetes medication classes was evaluated by McNemar exact tests. Statistical significance was defined as P<.05. All analyses were performed in Python 3.6.7 (Python Software Foundation).

Ethics

The study protocol and informed consent forms were approved by the Western Institutional Review Board (20182873) and registered with ClinicalTrials.gov (NCT03865381).

Results

Participants

Of 55 participants, 48 (87%) had a medication change. Baseline and follow-up demographic and clinical characteristics of the cohort with a medication change are presented in Table 1. At baseline, 8% (4/48), 44% (n=21), and 48% (n=23) of participants

were prescribed 1, 2, and ≥3 classes of diabetes medications, respectively.

Table 1. Participant baseline and follow-up characteristics (N=48).

Parameter	Baseline	Follow-up	*P* value
Gender			N/A[a]
Male, n (%)	26 (54)	26 (54)	
Female, n (%)	22 (46)	22 (46)	
Age (years), mean (SD)	56.9 (11.1)	56.9 (11.1)	N/A
Weight (pounds), mean (SD)[b]	217.74 (60.5)	208.7 (54.4)	<.001
BMI, mean (SD)[b]	33.5 (7.0)	32.2 (6.3)	<.001
Baseline HbA_{1c}[c] (%), mean (SD)	8.9 (1.0)	7.3 (1.0)	<.001
Number of diabetes medication classes, n (%)			.03
0	0 (0)	0 (0)	
1	4 (8.3)	3 (6.2)	
2	21 (43.8)	14 (29.2)	
≥3	23 (47.9)	31 (64.6)	
Systolic blood pressure (mm Hg), mean (SD)[b]	133.6 (16.2)	128.4 (17.1)	.02
Diastolic blood pressure (mm Hg), mean (SD)[b]	81.5 (10.7)	80.5 (10.9)	.46
Total cholesterol (mg/dL), mean (SD)	169.9 (42.6)	151.8 (42.1)	<.001
HDL[d] cholesterol (mg/dL), mean (SD)	40.2 (9.6)	39.0 (11.0)	.35
LDL[e] cholesterol (mg/dL), mean (SD)	101.8 (36.1)	94.4 (32.3)	.01
Non-HDL cholesterol (mg/dL), mean (SD)	129.8 (42.6)	112.7 (38.7)	<.001
Total cholesterol/HDL ratio, mean (SD)	4.5 (1.4)	4.0 (1.3)	.006
Triglycerides (mg/dL), mean (SD)	242.7 (205.1)	197.0 (172.0)	.007

[a]N/A: not applicable.

[b]As one subject did not complete the 4-month assessment at the study site, but submitted results from an external laboratory, n=47.

[c]HbA_{1c}: glycated hemoglobin.

[d]HDL: high-density lipoprotein.

[e]LDL: low-density lipoprotein.

Medication Management

The baseline and final medications at 4 months are presented in Table 1 and Table 2. Time to first medication change was 36.4 (SD 17.6) days. The most notable changes were a decrease in use of DPP-4 inhibitors, a decrease in sulfonylurea use, and an increase in GLP-1 receptor agonist use from baseline to 4 months. Medication changes including additions, discontinuations, and dose changes are presented in Table 2. Overall, 31.3% (15/48) of participants had an increase in the number of classes of diabetes medications prescribed from baseline and 10.4% (n=5) of participants had a decrease in number of classes of diabetes medications from baseline. In addition, 31.3% (n=15) of participants had a dose titration of an existing medication or a new medication.

Table 2. Participant baseline and follow-up medications by drug class (N=48).

Diabetes medication classes	Participants, n (%)			
	Baseline	Baseline medication stopped	Medication addition during study	Follow-up
Alpha glucosidase inhibitor	1 (2.1)	0 (0)	0 (0)	1 (2.1)
Biguanide	40 (83.3)	0 (0)	3 (6.3)	43 (89.6)
DPP-4[a] inhibitor	8 (16.7)	7 (14.6)	2 (4.2)	3 (6.2)
GLP-1[b] receptor agonist	12 (25)	1 (2.1)	16 (33.3)	27 (56.2)
Insulin	18 (37.5)	0 (0)	2 (4.2)	20 (41.7)
SGLT2[c] inhibitor	18 (37.5)	2 (4.2)	3 (6.3)	19 (39.6)
Sulfonylurea	27 (56.2)	13 (27.1)	2 (4.2)	16 (33.3)
Thiazolidinedione	1 (2.1)	0 (0)	0 (0)	1 (2.1)
Other diabetes medications	0 (0)	0 (0)	4 (8.3)	4 (8.3)

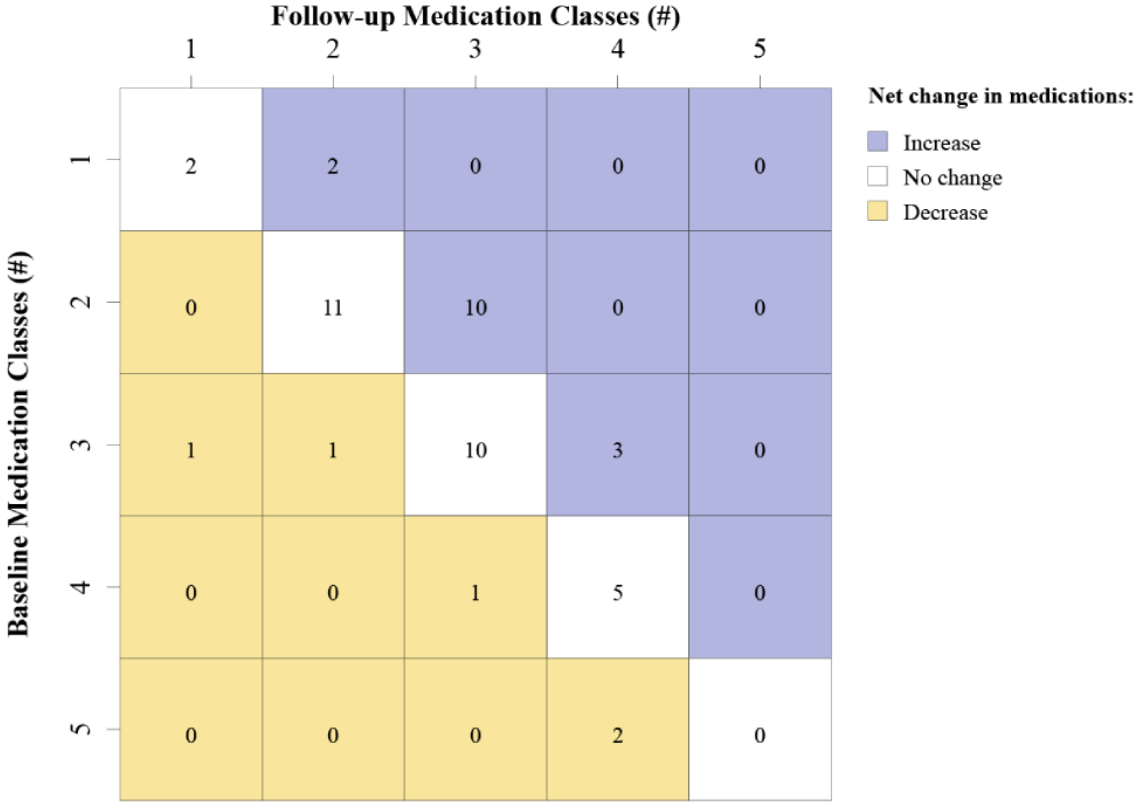
[a]DPP-4: dipeptidyl peptidase-4.

[b]GLP-1: glucagon-like peptidase-1.

[c]SGLT2: sodium/glucose cotransporter 2.

At a more granular level, the pattern of medication changes consisting of additions and discontinuations varied according to the baseline number of medication classes prescribed (Figure 1). The value in each cell represents the number of participants with a net increase, net decrease, or no change in number of medication classes prescribed from baseline to follow-up. Addition of a class was most frequently observed (n=10) for individuals on 2 classes at baseline. No additional classes were prescribed for individuals on 4 or 5 medications at baseline. Discontinuations were observed for individuals on 3, 4, or 5 medications at baseline and in one instance an individual on 3 classes at baseline had a final regimen of only 1 class at the end of the study.

Figure 1. Number of participants and net change in number of medication classes prescribed from baseline to follow-up. The value in each cell represents the number of participants with a net increase, net decrease, or no change in number of medication classes prescribed from baseline to follow-up.



Change in HbA_{1c}

HbA_{1c} for the present cohort (n=48) decreased by 1.6% (SD 1.0; P<.001) at 4 months, which was similar to change in HbA_{1c} reported for the full study cohort (n=55).

Use of RT-CGM for Medication Management Case Study

Figure 2 demonstrates the use of intermittent RT-CGM to accomplish medication management in a female study participant aged 66 years, baseline HbA_{1c} 12.0% and weight 174 pounds, taking 3 antidiabetes medications (glipizide, insulin glargine, and sitagliptin) upon entering the study. A total of 4 medications changes were made over the course of the 4-month study. Baseline sensor wear (two 10-day sensors) revealed mean glucose values ranging from 200-250 mg/dL and time in range (TIR) 70-180 mg/dL of <50%, with a few readings <70 mg/dL. Based on this glucose profile and the use of insulin, the Onduo endocrinologist made the following changes on day 27: the sulfonylurea (glipizide) was discontinued due to concurrent insulin use and the DPP-4 inhibitor (sitagliptin) was discontinued and exchanged for a GLP-1 receptor agonist (liraglutide) to address hyperglycemia. The dose of the GLP-1 receptor agonist was increased on day 47 due to glycemic excursions >200 mg/dL. Basal insulin was decreased on day 67. Further decreases in insulin were observed at day 108 in response to a small increase in CGM readings <70 mg/dL to minimize the risk of hypoglycemia. A comparison of the first CGM wear period to the last demonstrates less glycemic variability and reductions in postprandial glycemic excursions (Figure 3). The participant had a follow-up HbA_{1c} of 6.3% and lost 25 pounds during the 4-month study period.

Figure 2. Medication changes over 4 months for one sample participant (use of real-time continuous glucose monitoring for medication management). A total of 4 medications changes were made: day 27, sulfonylurea was discontinued due to concurrent insulin use, and the DPP-4 inhibitor was discontinued and exchanged for a GLP-1 receptor agonist to address hyperglycemia; day 47, GLP-1 receptor agonist dose was increased due to glycemic excursions >200 mg/dL; day 67, basal insulin was decreased; day 108, insulin was further decreased due to small increases in percent time <70 mg/dL. DPP-4: dipeptidyl peptidase 4; GLP-1: glucagon-like peptide-1.

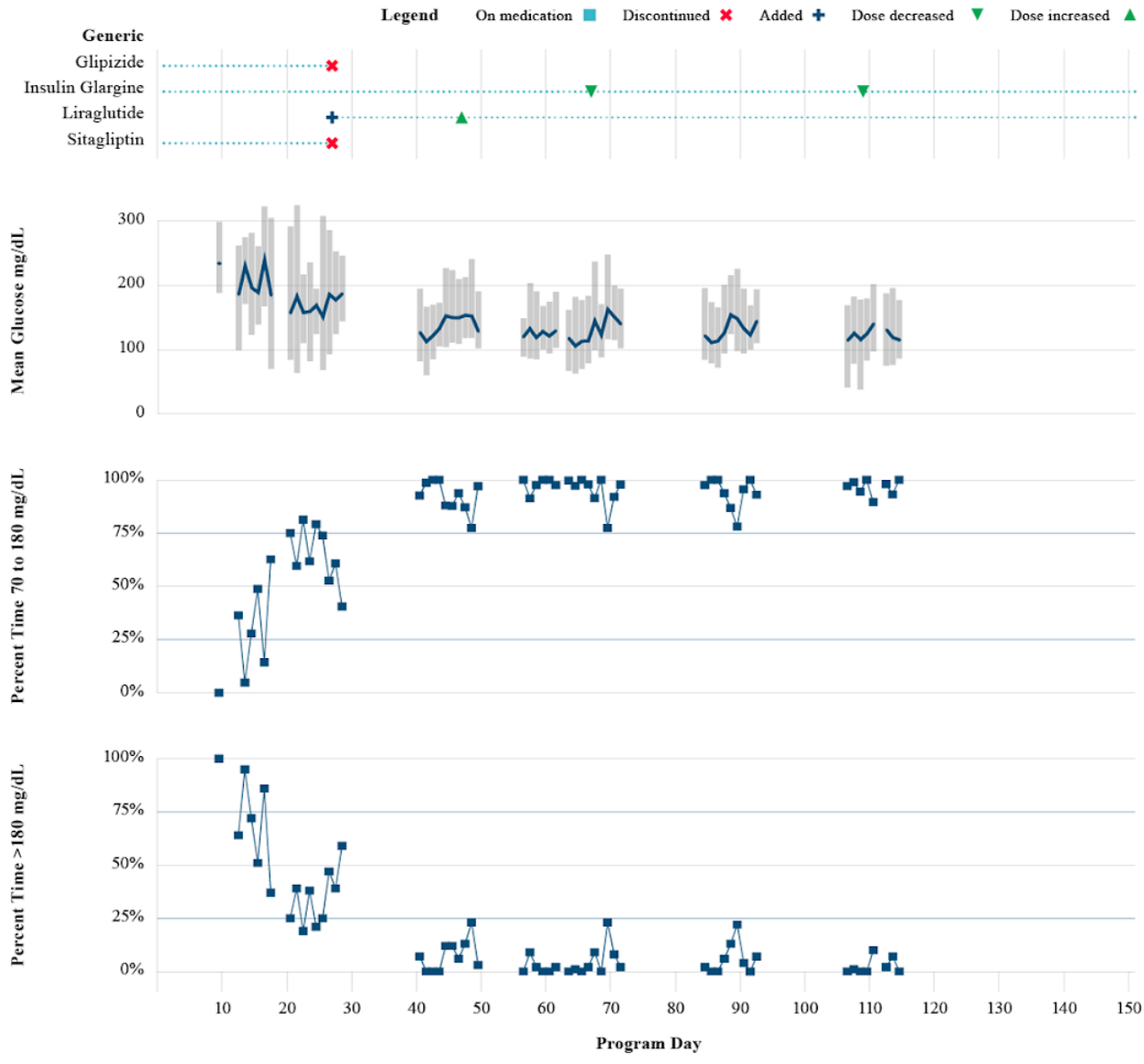
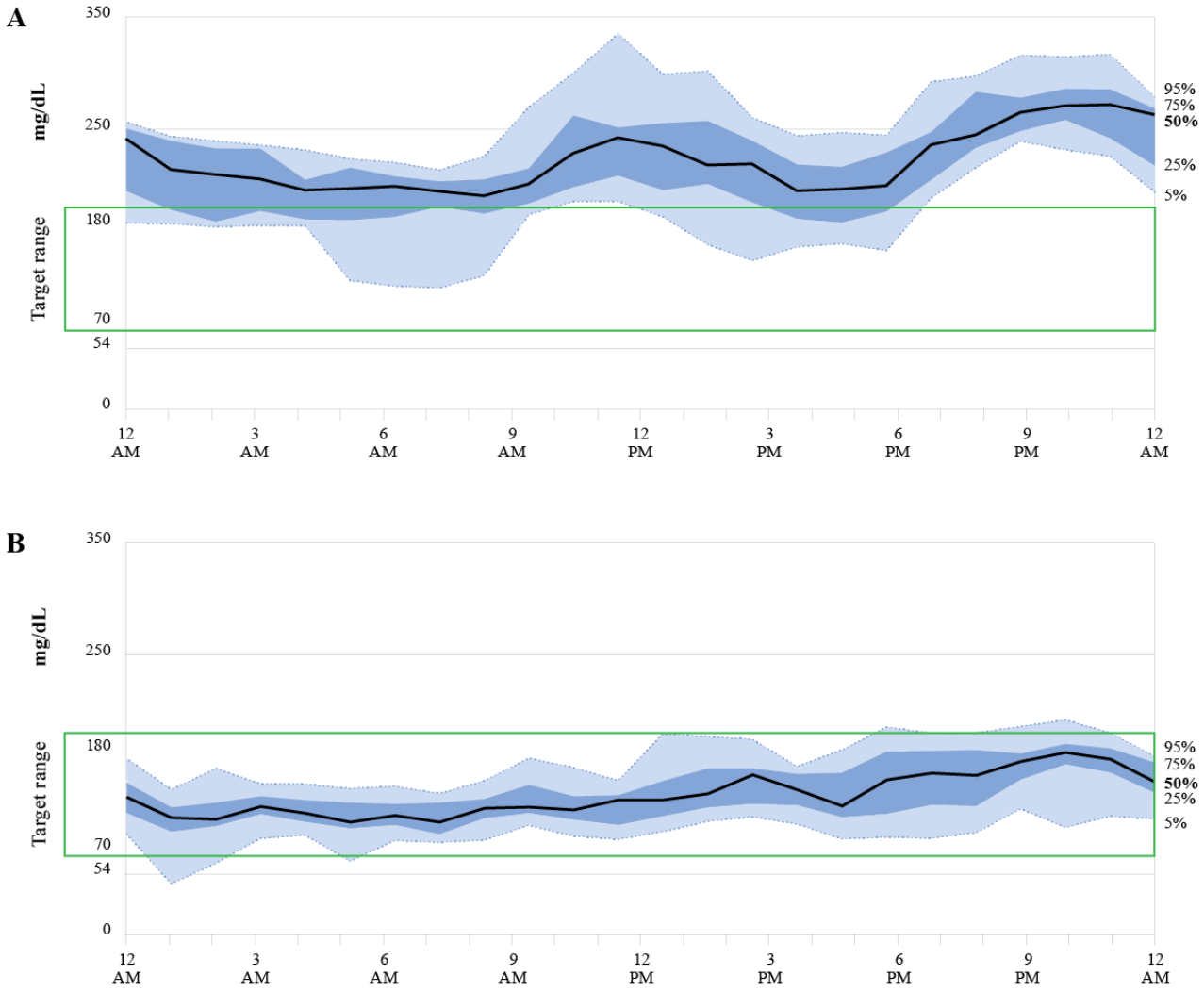


Figure 3. Median glycemic response over 24 hours for one sample participant. Comparison of the glycemic response for the (A) first 10-day real-time continuous glucose monitoring sensor wear period to the (B) last 10-day sensor wear period demonstrates less glycemic variability and reductions in postprandial glycemic excursions. Baseline HbA_{1c} improved from 12.0% to 6.3% at 4 months; baseline weight decreased 25 pounds at 4 months.



Discussion

Principal Findings

This prospective study of adults with suboptimally controlled T2D participating in the Onduo virtual care program resulted in improved glycemic control, which was achieved through a unique model of telemedicine consultations with specialists for medication management combined with remote health coaching and access to mid-level providers, all facilitated by intermittent use of RT-CGM. The major patterns of medication changes were discontinuation of sulfonylureas in approximately half of participants and a 2-fold increase in the number of participants prescribed GLP-1 receptor agonists over the course of the 4-month study.

Clinical inertia is a key barrier to optimal diabetes management, prolonging poor glycemic control and, as a result, increasing the likelihood of diabetes complications [18]. The rapid therapeutic feedback loop enabled by the Onduo care model through timely sharing of glycemic data and patient-provider communication is likely a key factor in reducing time to therapeutic intensification/change. In clinical practice, the delay in therapeutic intensification is prolonged, and tends to occur at a higher rate among patients already taking ≥2 oral antidiabetic drugs [19], which was the case for 92% (44/48) of participants at baseline. A recent study reported that approximately 50% of patients with an HbA_{1c} level between 8.0% and 8.9% on 2 oral antidiabetic drugs had no therapy intensification for 6 months following the identification of poor glycemic control [20].

Optimizing medication regimens in line with evidence-based guidelines, as was done in this study, is essential to improving glycemic control. Although GLP-1 receptor agonists are recommended based on efficacy, better side effect profiles, and demonstrated cardiovascular benefit, some reports indicate that these are prescribed in <6% of people with T2D, even those with established cardiovascular disease [20,21]. In contrast, by the end of this study, 56% (26/48) of participants were prescribed a GLP-1 receptor agonist and only 2 participants had therapeutic intensification with insulin. Thus, the data from the present analysis, when taken in context of the clinically significant improvements in HbA_{1c} and TIR we previously reported [13], support early medication intensification and optimization in people taking multiple oral antidiabetic drugs

who are particularly susceptible to clinical inertia [4]. The resulting improvement in glycemic control we observed, if sustained, may lower incidence of diabetes complications.

In addition to the Onduo program, there are several telehealth programs for T2D that have reported improvement in HbA_{1c} levels [3-10]. Although some of these programs are beginning to incorporate CGM use and telemedicine visits, to our knowledge there is only one recent study of a digital health program for people with T2D reporting medication management with CGM use [15]. However, the results of that study are not directly comparable to the present study due to substantial differences in study objectives and designs. This report by Shamanna et al [15] focused on deprescribing medications in participants provided a 90-day intensive nutrition intervention program in a retrospective design that analyzed only the 72% (64/89) of participants who were at least 60% adherent to the program.

The present study by contrast included the full range of medication management including class substitutions, dose titration, and additions, as well as deprescribing, in a prospective trial with an intent to treat analysis. Baseline glycemic control as measured by CGM was also better and met the clinical target [22] in participants in the Shamanna study (87% TIR versus 65% in this study). Both programs studied support the utility of CGM to improve short-term glycemic control, although longer duration studies are needed to evaluate acceptability, durability, and long-term clinical benefit for people with T2D.

Limitations of our study include the small sample size, the short duration, and lack of a randomized control arm, which limit the generalizability of our results. The intervention was intensive, which may not be reproducible or feasible for real-world telemedicine program participation. Although we were able to track and report recommended medication changes precisely in relation to real-time glycemia, we were not able to verify that prescriptions were filled from claims data due to the duration of the study. Thus, it is possible that participants did not make all the reported medication changes. In addition, we are not able to distinguish the clinical effects of individual components of the program (ie, lifestyle coaching, CGM use, and medication changes) from the program's overall clinical efficacy.

Conclusion

Although all aspects of the Onduo virtual care program may have contributed to improvement in glycemic control, telemedicine visits with endocrinologists and use of RT-CGM may have helped to overcome clinical inertia. Although further study is needed, optimization of medication regimens in line with current guidelines may be associated with long-term health benefits.

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Prior Presentation

Some of these data were presented at the 14th International Conference on Advanced Technologies & Treatments for Diabetes on June 2-5, 2021 [23].

Authors' Contributions

All authors contributed to the review of the report and approved the final version for submission. FRC, DME, and RJR contributed to the acquisition of data and all authors contributed to the interpretation of data. JEL and SMB developed the first draft of the manuscript. All authors contributed with a critical revision of the first and subsequent manuscript versions. RFD, CMK, AAL, ARM, HZ, and SR contributed to the study design. ARM is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

The authors declare the following potential conflicts of interest: ARM has received consulting fees from Onduo LLC; DME is an employee of Onduo Professionals PC; JEL and SMB are employees of Onduo LLC; RFD was an employee of Onduo LLC at the time the study was completed; CMK is an employee of Verily Life Sciences; and AAL, SR, and HZ were employees of Verily Life Sciences at the time the study was completed. RJR and FRC report no conflicts of interest.

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Abbreviations

ADA: American Diabetes Association
CDC: Centers for Disease Control and Prevention
CGM: continuous glucose monitoring
DPP-4: dipeptidyl peptidase 4
GLP-1: glucagon-like peptide-1
HbA_{1c}: glycated hemoglobin
RT-CGM: real-time continuous glucose monitoring
SGLT2: sodium/glucose cotransporter 2
T2D: type 2 diabetes
TIR: time in range

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Original Paper

Association Between Step Count Measured With a Smartphone App (Pain-Note) and Pain Level in Patients With Chronic Pain: Observational Study

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Abstract

Background: Chronic pain is the leading cause of disability, affecting between 20% and 50% of the global population. The key recommended treatment is physical activity, which can be measured in daily life using a pedometer. However, poor adherence to pedometer use can result in incorrect measurements. Furthermore, only a few studies have investigated a possible curvilinear association between physical activity and chronic pain.

Objective: In this study, we developed the Pain-Note smartphone app to collect real-world data on step count, using the smartphone's built-in pedometer. The aims of our research are (1) to evaluate the association between daily step count and pain level among patients with chronic pain and (2) determine if the association between daily step count and pain level was curvilinear.

Methods: We conducted a cross-sectional study based on step count data collected with the app and on the results of questionnaires, which measured the duration and intensity of pain, the widespread pain index, the symptom severity score, and the insomnia severity scale, including 7 questions for symptoms of depression. We analyzed the association between step count and pain level as a nonlinear relationship using a restricted cubic spline model. A prespecified subgroup analysis was also conducted based on fibromyalgia criteria.

Results: Between June 1, 2018, and June 11, 2020, a total of 6138 records were identified, of which 1273 were analyzed. The mean age of the participants was 38.7 years, 81.9% (1043/1273) were female, and chronic pain was present for more than 5 years in 43.2% (550/1273) of participants. Participants in the third and fourth quartiles for step count (more than 3045 and 5668 steps a day, respectively) showed a significant positive association between higher step count and lower numerical pain rating scale (mean difference –0.43, 95% CI –0.78 to –0.08, *P*=.02; –0.45; 95% CI –0.8 to –0.1, *P*=.01, respectively) than those in the first quartile (less than or equal to 1199 steps a day). The restricted cubic spline model for the association between step count and pain scale displayed a steep decline followed by a moderate decrease as the step count increased; the inflection point was 5000 steps. However, this association was not observed among participants who met the fibromyalgia criteria (491/1273), who showed a steep positive increase below 2000 steps. Data were collected between June 1, 2018, and June 11, 2020, and were analyzed on November 18, 2021.

Conclusions: Step count measured with the Pain-Note app showed a nonlinear association with pain level. Although participants with and without fibromyalgia showed a negative correlation between step count and pain level, participants who meet the criteria for fibromyalgia may present a different relationship between walking and pain perception compared to those in the general chronic pain population.

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KEYWORDS

smartphone; iPhone; cross-sectional study; chronic pain; fibromyalgia; step count

Introduction

Chronic pain is a global health problem that affects from 20% to 50% of the general population, depending on the level of severity and how it is reported. It is also a leading cause of disability [1-5]. Low back and neck pain, osteoarthritis, and fibromyalgia are the major chronic musculoskeletal disorders associated with chronic pain. Chronic pain limits physical function and reduces the long-term quality of life. Health care costs associated with chronic pain range from US $261 to $300 billion per year in the United States, with total costs, direct and indirect, over $600 billion [6]. A previous randomized controlled trial suggested the use of nonpharmacological interventions, such as walking, to reduce pain and improve physical function [7]. In particular, increasing the level of daily activity in fibromyalgia has led to lower perceptions of functional deficits and pain level [8]. Since the mechanisms of pain perception are different in fibromyalgia and other types of chronic pain, the effectiveness of physical activity also differs with the type of chronic pain [9,10].

The US Centers for Disease Control and Prevention/American College of Sports Medicine guidelines recommend a minimum of 30 minutes per day of brisk walking for most adults [11], while the Ministry of Health, Labour and Welfare of Japan guidelines for health promotion advise Japanese adults to perform 60 minutes of moderate to vigorous physical activity per day [12] to achieve beneficial effects. In addition to exercise, previous research suggests that daily step count can be used to measure daily activity [13,14]. Pedometers are commonly used to measure total walking activity. However, use of pedometers is limited due to poor patient adherence; therefore, unless their use is effectively encouraged, the results can be an underestimate [15]. To study real-life daily activity with higher adherence, we used the pedometer function that is built into the iPhone smartphone platform (Apple Inc). To utilize the built-in pedometer function, we designed an app we named Pain-Note, which was based on the Research Kit function built into the iPhone.

One previous study analyzed data based on the assumption that the relationship between physical activity and pain is linear [16]. Some studies have found that the relationship between health care outcomes and physical activity is nonlinear when a restricted cubic spline model is used. [17-19] Therefore, we hypothesized that the association between step count and numerical pain rating scale would not be linear, as in previous studies that utilized a pedometer to measure physical activity. By using a built-in smartphone pedometer that allowed high adherence, we obtained data that reflected real-world circumstances. Further, an analysis based on a nonlinear model allowed us to assess the relationship between daily step count and pain.

This study aims to (1) evaluate the association between daily step count and pain level in patients with chronic pain, with consideration to the subtypes of chronic pain, using a pedometer developed on a smartphone platform; and to (2) determine if the association between daily step count and pain level was curvilinear.

Methods

Data Source and Participants

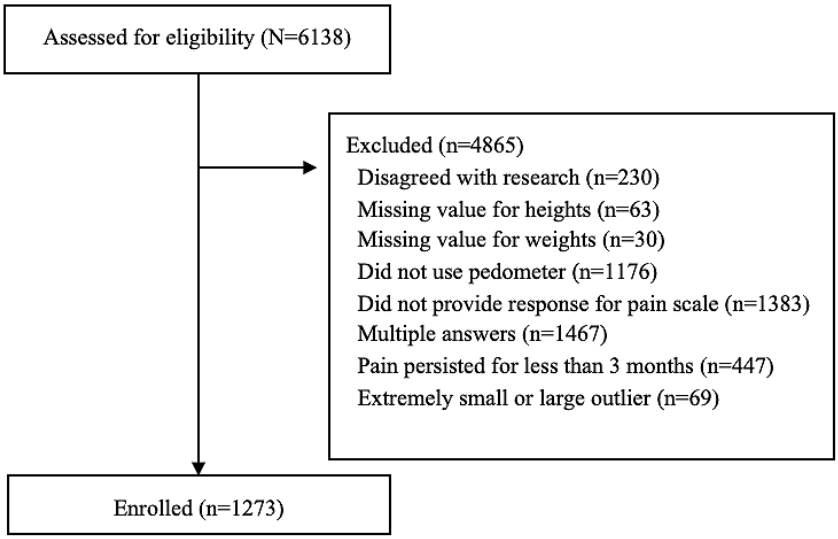
We conducted a cross-sectional study based on data collected with the Pain-Note app developed by Medical Logue Inc. (Tokyo, Japan). The company was under a consignment contract with the Faculty of Medicine of the Department of Psychiatry of our university.

The Pain-Note app was developed for subjects with chronic pain to help monitor their daily pain levels. It has been available in the Apple Store in Japan for free since June 1, 2018. This study included subjects who downloaded and used Pain-Note in Japan between June 1, 2018, and June 11, 2020, and completed the entire questionnaire. There was no financial compensation for participating in the study. Incomplete or duplicate answers were excluded.

Data Collection

Pain-Note collected baseline characteristics, including demographic information, medical history, and lifestyle information. Disease-specific questionnaires were used to obtain data on the duration of pain, the widespread pain index (WPI) and symptom severity (SS) score for fibromyalgia, and the insomnia severity scale (ISS) for sleeping disorders. The questionnaire also included 7 questions on symptoms of depression. Participants also reported daily subjective symptoms, including baseline pain, which was recorded using a 10-point visual analog scale. After providing written consent, the study participants provided the following information in the following order in the Pain-Note app: baseline demographic characteristics, medical history (including cancer status and cardiac, respiratory, brain, liver, renal, hematological, and collagen disease), subjective pain symptoms, WPI, SS score, ISS, and symptoms of depression (Figure 1).

Figure 1. Flow chart of the study sample selection.



Daily Step Count and Distance

We used the Research Kit function built into the iPhone to collect data on daily step count. The daily step count was automatically recorded in the participants' smartphones for 24 hours a day, 365 days of the year, regardless of whether the Pain-Note app was running or not. We categorized participants into quartiles based on step count distribution on the day the participants answered the questionnaires. Previous research has categorized step count into quartiles to estimate its association with other baseline variables [20]. Participants in the 2.5th and 97.5th percentiles for step count were excluded as outliers.

Chronic Pain Symptoms

Chronic pain data were collected using the WPI and SS score. WPI is a measure of pain or tenderness occurring within the 7 days before the test in 19 different body areas, from the jaws to the legs. The participants were also asked to rate their degree of physical pain on a scale of 0 to 19. The SS score measures the severity of symptoms on a scale of 0 to 12 by scoring fatigue, cognitive impairment, and unrefreshing sleep. Since the mechanisms of pain perception are different in fibromyalgia and other types of chronic pain, the effectiveness of physical activity also differs across types of chronic pain [9,10]. We determined the presence of fibromyalgia using the answers to the following questions in the questionnaire, based on the current fibromyalgia diagnosis guidelines: the duration of pain, WPI, and SS score [21]. The questions used to detect fibromyalgia symptoms included questions based on the validated Japanese version of the American College of Rheumatology 2010 criteria [22]. Based on answers from this section of the questionnaire, we classified patients into two groups: (1) those who fulfilled the criteria for fibromyalgia and (2) those who did not.

Symptoms of Depression

Symptoms of depression were evaluated using 9 questions (Multimedia Appendix 1) that were based on depression research conducted in Japan and were consistent with other depression scales [23]. The association between depression and chronic pain is well established [24], as is the relationship between depression and low levels of physical activity [25].

Symptoms of Sleep Disorder

Symptoms of sleep disorder were measured using the ISS, which assesses the severity of insomnia using 7 questions. The total score can range from 0 to 28 and indicates the severity of symptoms as follows: insomnia (0-7), subthreshold insomnia (8-14), and moderate and severe insomnia (15-28) [26]. The association between regular physical exercise and a lower incidence of sleep disturbance has been previously demonstrated [27]. In addition, sleep disturbance is common in chronic pain syndromes [28,29], especially fibromyalgia [29].

Statistical Analyses

We compared patients' baseline characteristics in all step count quartiles. Continuous variables are presented as the mean (SD) or median (IQR) based on their distribution. Categorical variables are presented as percentages. We conducted a 1-way ANOVA test for continuous variables and the chi-square test for categorical variables. We conducted multivariable regression analyses to identify and quantify the association between step count in each quartile and the pain scale; based on previous research, we adjusted for potential confounders, including age, sex, BMI, medical history (including cancer status and cardiac, respiratory, brain, liver, renal, hematological, and collagen disease), WPI, SS score, ISS, and depression questionnaire answers [23].

A previous study [16] suggested that there cannot be a linear relationship between physical activity, including step count, and clinical outcomes, such as pain level, in fibromyalgia. In response, we performed a restricted cubic spline analysis, which is able to investigate nonlinear relationships between 2 continuous variables. We followed the rationale reported by Marrie et al [30] and placed the knots, which are breakpoints representing inflections in the distribution of the data, at the 5th, 35th, 65th, and 95th percentiles, to make the model flexible enough for our assumed nonlinear association. We evaluated

nonlinearity using the likelihood-ratio test by comparing the model fit when cubic spline terms were used and when only linear terms were used [31]. To test the association between fibromyalgia and the number of steps, we also constructed linear regression models that included fibromyalgia symptoms as the independent variable and step count as the dependent variable. We then adjusted for potential confounders, including age, sex, pain level, ISS, and symptoms of depression.

Sensitivity Analysis

We conducted a sensitivity analysis to confirm the robustness of the main results. We used the daily distance moved, which was measured using the built-in smartphone GPS (rather than the step count) to confirm the relationship between distance moved and pain scale score. All comparison tests were 2-sided and set statistical significance as $P<.05$. We did not adjust the significance level for multiple comparisons due to the exploratory nature of our study. All statistical analyses were performed using Stata (version 16.1; Stata Corp).

Ethics Approval

This study was conducted after obtaining approval from the independent ethics committee of our university hospital. Written informed consent was obtained electronically from all participants before they answered the questionnaires. Ethical approval was obtained from the Research Ethical Committee of Juntendo University Nerima Hospital on March 3, 2020 (2019032). Data were collected between June 1, 2018, and June 11, 2020, and analyzed on November 18, 2021.

Results

A total of 6138 records were identified in our database. A total of 4865 records were excluded for the following reasons: consent was not provided for the research (n=230), height data were missing (n=63), weight data were missing (n=30), the pedometer function was disabled (n=1176), pain scale data were lacking (n=1383), data were duplicated (n=1467), pain history was less than 3 month (n=447), or the record was an extremely small or large outlier (n=69). A total of 1273 participants were included in the study (Figure 1). The mean age was 38.7 years (SD 13.4), and the number of women was 1043 of 1273 (81.9%). The participants mostly lived in large cities in Japan, such as Tokyo, Nagoya, Osaka, and Sapporo (Figure 2).

Figure 2. Geographic distribution of participants.

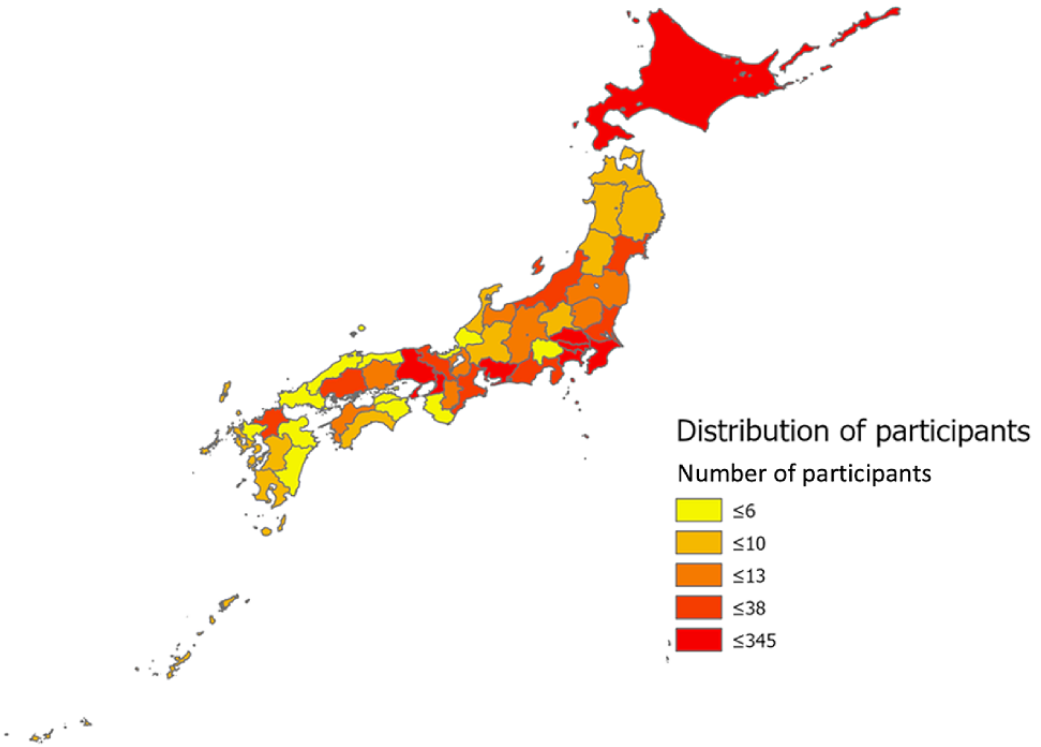


Table 1 shows the baseline characteristics of the participants. Participants in the first quartile had 24 to 1199 steps, the second quartile, 1205 to 3036 steps, the third quartile, 3045 to 5664 steps, and the fourth quartile, 5668 to 14,473 steps. Participants in the first quartile had the highest mean age at 40.22 years (SD 13.75) and the highest BMI at 23.8 (SD 5.6), while those in the third quartile had the lowest mean age at 36.97 years (SD 13.53) and those in the fourth quartile had the lowest BMI at 22.8 (SD 4.4). Among comorbidities, the largest proportion of participants had respiratory disease (210/1273, 16.5%). Among the 210 participants with respiratory disease, participants in the first quartile were the most numerous, followed by patients in the third, fourth, and second quartiles (66/210, 21%; 57/210, 18%; 44/210, 14%; and 43/210, 14%, respectively).

Table 1. Patient characteristics.

Characteristics	Total	First quartile (24-1199 steps)	Second quartile (1205-3036 steps)	Third quartile (3045-5664 steps)	Fourth quartile (5668-14,473 steps)	*P* value[a]
Age (years), mean (SD)	38.72 (13.47)	40.22 (13.75)	39.53 (12.77)	36.97 (13.53)	38.14 (13.65)	.01
Female sex, n (%)	1043 (81.9)	281 (88.1)	265 (83.3)	260 (81.8)	237 (74.5)	<.001
BMI, (kg/m^2), mean (SD)	23.2 (4.9)	23.8 (5.6)	23.3 (5)	22.9 (4.7)	22.8 (4.4)	.04
Smoking						.30
Nonsmoker, n (%)	844 (66.3)	210 (65.8)	205 (64.5)	217 (68.2)	212 (66.7)	
Current smoker, n (%)	178 (14)	45 (14.1)	50 (15.7)	49 (15.4)	34 (10.7)	
Past smoker, n (%)	251 (19.7)	64 (20.1)	63 (19.8)	52 (16.4)	72 (22.6)	
Heart disease, n (%)	78 (6.1)	16 (5)	19 (6)	23 (7.2)	20 (6.3)	.71
Respiratory disease, n (%)	210 (16.5)	66 (20.7)	43 (13.5)	57 (17.9)	44 (13.8)	.04
Stroke, n (%)	44 (3.5)	17 (5.3)	12 (3.8)	8 (2.5)	7 (2.2)	.12
Liver disease, n (%)	45 (3.5)	14 (4.4)	14 (4.4)	7 (2.2)	10 (3.1)	.36
Renal disease, n (%)	59 (4.6)	15 (4.7)	16 (5)	12 (3.8)	16 (5)	.86
Hematological disease, n (%)	37 (2.9)	12 (3.8)	6 (1.9)	13 (4.1)	6 (1.9)	.19
Cancer, n (%)	42 (3.3)	11 (3.4)	10 (3.1)	10 (3.1)	11 (3.5)	.99
Collagen disease, n (%)	91 (7.1)	21 (6.6)	25 (7.9)	23 (7.2)	22 (6.9)	.93

[a]*P* was calculated with ANOVA for age and BMI and the chi-square test for all other variables.

Data on pain level, depression, and sleeping disorders are shown in Table 2. More than 40% (550/1273) of the participants had chronic pain for at least 5 years. The second quartile had the fewest participants with chronic pain lasting more than 5 years (122/318, 38%). The second quartile had the largest number of participants with clinical insomnia (62/318, 20%). Participants in the first quartile had the most symptoms of depression, while those in the fourth quartile had the least.

Table 2. Step count and findings on pain, sleeping disorders, and responses to depression questionnaire.

	Total group	First quartile for step count	Second quartile for step count	Third quartile for step count	Fourth quartile for step count	*P* value[a]
Step count, median (IQR)	3036.0 (1199.0-5664.0)	324.0 (95.0-636.0)	1995.5 (1557.0-2454.0)	4281.5 (3623.0-4927.0)	7998.5 (6602.0-10,050.0)	
Chronic pain, n (%)						.009
Current	1180 (92.7)	307 (96.2)	298 (93.7)	289 (90.9)	286 (89.9)	
Past	93 (7.3)	12 (3.8)	20 (6.3)	29 (9.1)	32 (10.1)	
Duration of pain, n (%)						.52
3-6 months	140 (11)	38 (11.9)	30 (9.4)	35 (11)	37 (11.6)	
6-12 months	118 (9.3)	25 (7.8)	32 (10.1)	28 (8.8)	33 (10.4)	
1-2 years	254 (20)	58 (18.2)	69 (21.7)	66 (20.8)	61 (19.2)	
3-5 years	211 (16.6)	55 (17.2)	65 (20.4)	48 (15.1)	43 (13.5)	
>5 years	550 (43.2)	143 (44.8)	122 (38.4)	141 (44.3)	144 (45.3)	
Presence of fibromyalgia and severity of symptoms						
Fibromyalgia, n (%)	491 (38.6)	160 (50.2)	131 (41.2)	112 (35.2)	88 (27.7)	<.001
Widespread pain index, mean (SD)	8.6 (6.7)	9.9 (6.8)	9.2 (6.6)	7.9 (6.7)	7.2 (6.6)	<.001
Symptom severity score, mean (SD)	4.1 (2.3)	4.6 (2.3)	4.1 (2.4)	4.0 (2.2)	3.8 (2.3)	<.001
Insomnia severity scale, n (%)						<.001
Not clinically significant	536 (42.1)	96 (30.1)	139 (43.7)	142 (44.7)	159 (50)	
Subthreshold insomnia	521 (40.9)	172 (53.9)	117 (36.8)	123 (38.7)	109 (34.3)	
Clinical insomnia	216 (17.0)	51 (16)	62 (19.5)	53 (16.7)	50 (15.7)	
Questionnaire for depression, n (%)[b]						
Do you enjoy your life?	696 (58.2)	210 (68.2)	165 (56.7)	172 (58.5)	149 (49.3)	<.001
Do you enjoy things the same way that you used to?	683 (57.2)	209 (67.9)	172 (59.1)	155 (52.7)	147 (48.7)	<.001
Do you feel tired when doing things you could easily do before?	254 (21.3)	49 (15.9)	56 (19.2)	59 (20.1)	90 (29.8)	<.001
Do you feel as well as other people?	664 (55.6)	187 (60.7)	142 (48.8)	169 (57.5)	166 (55)	.03
Do you think about death?	555 (46.4)	133 (43.2)	136 (46.7)	135 (45.9)	151 (50.0)	.41
Do you feel so depressed that you think about suicide?	743 (62.2)	184 (59.7)	181 (62.2)	177 (60.2)	201 (66.6)	.29
Recently, do you find things very difficult or painful?	339 (28.4)	66 (21.4)	74 (25.4)	85 (28.9)	114 (37.7)	<.001
Do you have a good appetite?	689 (57.7)	159 (51.6)	171 (58.8)	176 (59.9)	183 (60.6)	.09
Do you feel depressed?	269 (22.5)	57 (18.5)	60 (20.6)	71 (24.1)	81 (26.8)	.07

[a]All *P* values were calculated with the chi-square test.

[b]Data for depression represent "yes" answers on the questionnaire.

A restricted cubic splines model was used to assess the association between step count and pain scale; it revealed an obvious nonlinear association in the overall sample (Figure 3). When compared to the results of the linear regression, the results of the likelihood test were nearly, but not quite, statistically significant, which suggests that a model including patients with and without fibromyalgia would accommodate a nonlinear relationship with a better fit than a linear model for the association between step count and pain scale (P=.06). The results of the multivariable linear regression model for pain scale (divided in quartiles) are shown in Table 3. Participants in the third and fourth quartiles, who had a higher step count, were significantly less likely to report pain (mean difference –0.43, 95% CI –0.78 to –0.08, P=.02; mean difference –0.45, 95% CI –0.8 to –0.1, P=.013, respectively). Stratifying the sample into 2 groups based on the fibromyalgia criteria revealed no significant association between step count and pain scale score in any of the 4 quartiles in the fibromyalgia group.

However, the restricted cubic spline curve in the fibromyalgia group showed a mild increase in pain level as step count increased, until an inflection point around 2000 daily steps, followed by a decrease between 2000 and 5000 steps, suggesting the importance of visualization with the restricted cubic spline curve. The nonfibromyalgia group showed a steep negative association between step count and pain until around 3000 daily steps, followed by a nearly unchanging, steady line above that (Figure 4, Figure 5). Among participants with chronic pain but without fibromyalgia, the second, third, and fourth step count quartiles demonstrated a significant linear association between step count and reduced pain (mean difference –0.61, –0.59, and –0.78, P=.01, .02, and .002, respectively) (Table 3).

Figure 3. Association between step count and pain scale using restricted cubic splines. Four knots restricted the cubic spline curve. The curve showed an inflection point around 5000 steps.

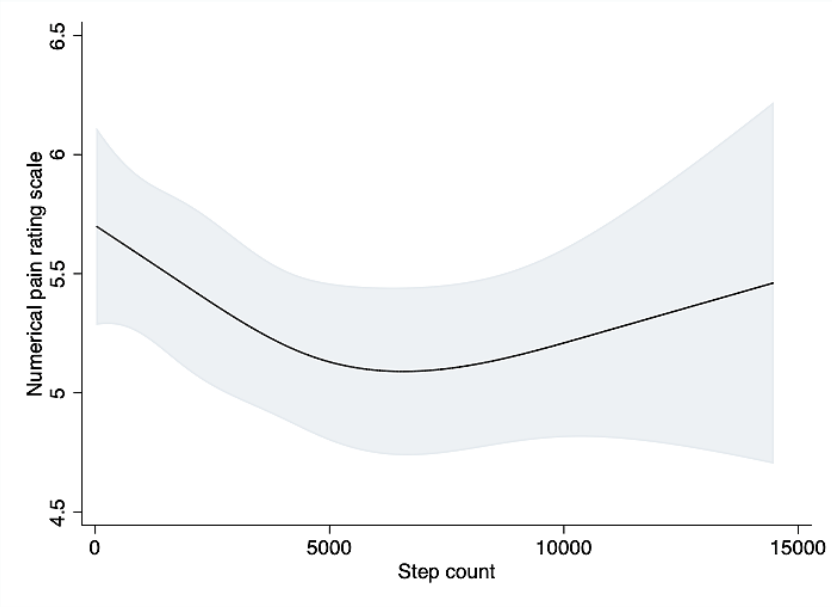


Table 3. Association between step count by quartile and pain scale in a multivariable regression model.[a]

Type of pain	Mean difference (95% CI)	*P* value
Overall chronic pain		
1st quartile (24-1199 steps)	Reference	
2nd quartile (1205-3036 steps)	–0.19 (–0.54 to 0.16)	.29
3rd quartile (3045-5664 steps)	–0.43 (–0.78 to –0.08)	.02
4th quartile (5668-14,473 steps)	–0.45 (–0.8 to –0.1)	.01
Participants fulfilling fibromyalgia criteria		
1st quartile (25-657 steps)	Reference	
2nd quartile (662-2187 steps)	0.26 (–0.23 to 0.74)	.30
3rd quartile (2188-4578 steps)	0.29 (–0.2 to 0.78)	.25
4th quartile (4600-14,264 steps)	0.17 (–0.33 to 0.66)	.51
Participants not fulfilling fibromyalgia criteria		
1st quartile (24-1396 steps)	Reference	
2nd quartile (1397-3537 steps)	–0.61 (–1.09 to –0.12)	.01
3rd quartile (3538-6198 steps)	–0.59 (–1.08 to –0.1)	.02
4th quartile (6199-14,473 steps)	–0.78 (–1.27 to –0.29)	.002

[a]All models were adjusted for age, sex, and comorbidities that included cardiological, respiratory, stroke, liver, renal, and hematological disease, cancer, symptom severity scale, insomnia scale, and the results of the depression questionnaire.

Figure 4. Association between distance and pain scale using restricted cubic splines in fibromyalgia patients. Four knots restricted the cubic spline curve. The curve showed an initial peak in numerical pain rating scale around 2000 steps and started to increase after 5000 steps.

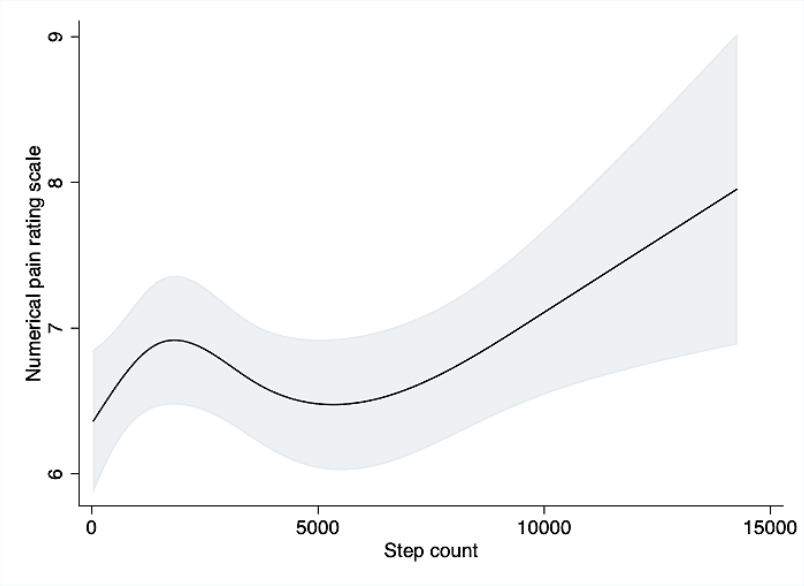
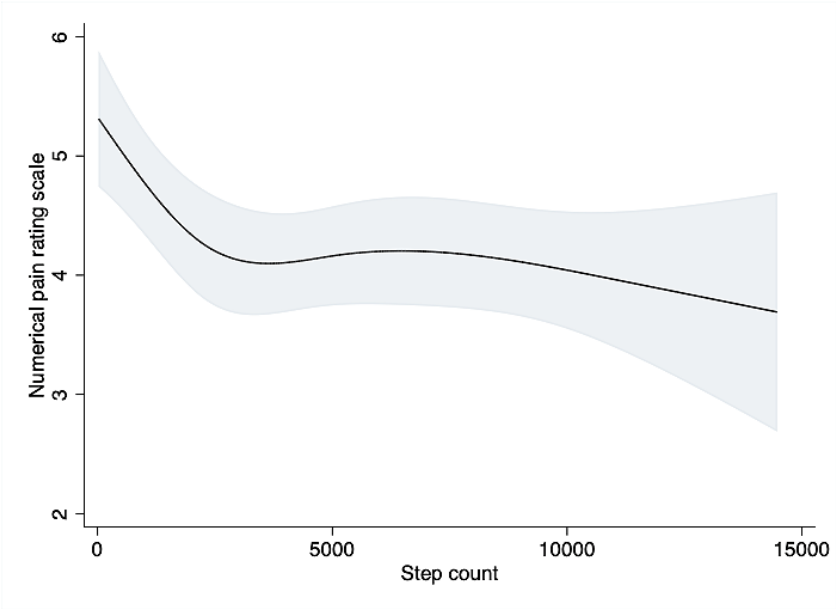


Figure 5. Association between distance and pain scale using restricted cubic splines in nonfibromyalgia patients. Four knots restricted the cubic spline curve. Step count and numerical pain rating scale were negatively correlated before 3000 steps, then showed no association past 3000 steps.



As the spline curves suggested a curvilinear association, the likelihood test for both restricted cubic spline curve models (ie, patients with fibromyalgia and those without) showed that the fit was statistically significantly superior to that of a linear regression model (P=.03 and P=.007, respectively) when the data were stratified for the presence of fibromyalgia, while in the overall model, the difference was not significant (P=.06). This suggests that the relationship between step count and pain scale should be considered separately in patients with and without fibromyalgia. In our sensitivity analysis, the association between distance and pain scale was similar to our main analysis.

The results of the univariate linear regression model revealed a statistically significant association between the presence of fibromyalgia and step count (mean difference –1.13, 95% CI –1.69 to –0.58, P<.001). In the multivariable models adjusting for age, sex, pain level, and the ISS score, the association remained significant (P=.01). However, when we added depression symptoms to the model, this association became nonsignificant (P=.1), suggesting that depression acts as a major confounder in the association between step count and the presence of fibromyalgia.

Discussion

In this study, we compared pain level with step count data collected with a smartphone app (Pain-Note). This is the first known study to examine the relationship between step count, measured objectively with a smartphone pedometer, and pain

scale in patients with chronic pain. We recruited diverse participants across Japan and obtained real-world data. Using smartphones to obtain step count data enables the data to be easily translated to the general population. Our study shows that a high daily step count is associated with a lower pain scale score except in participants who meet the criteria for fibromyalgia.

One concern of our study is the accuracy of step counts obtained with smartphones. This could be affected both by adherence to use of the smartphone app and by the accuracy of the built-in pedometer itself. A past validation study of adherence to smartphone pedometer use compared step counts derived from a smartphone pedometer and an accelerometer in a free-living test and found that there was an approximately 20% bias between the smartphone and the accelerometer [32]. Therefore, our step count results may be biased by a deviation of, at most, 20% from the true step count. The accuracy of smartphone pedometer step counts has also been investigated, such as in a previous study that showed that a pedometer app was more accurate when data from the built-in pedometer was compared to data from the built-in GPS function [33]. In our study, we used the distance moved (as measured with GPS) in the sensitivity analysis and decided to use only the built-in pedometer in the final analysis. The results obtained with GPS and the pedometer were similar, highlighting the robustness of our procedure. A previous study also reported that adherence to pedometer use was a limitation [15]. Although one-third of our participants disabled the pedometer function during this study, we believe that once they had enabled the pedometer, few of them repeatedly turned the pedometer function on or off during the day. We attribute our relatively low disagreement rate (230 out of 6138) to this. A plausible explanation for why some participants disabled the pedometer function was that they wanted to reduce battery consumption caused by the app working in the background of the smartphone. Therefore, we consider that our study results reflect real-life step counts and that data from the pedometer were complete.

The total daily step count of a typical elderly person in the United States ranges from 2000 to 9000 steps [34]. In a prospective study conducted in Yokohama, Japan, the average daily step counts throughout the year for participants between 40 and 69 years old was 9304 for male participants and 7246 for female participants [35]. In our study, the mean daily step count of the participants was approximately 3000 steps, which is less than half of the previously reported mean daily step count for women in Japan. This discrepancy could be due to the fact that most of the participants in our study had chronic pain; since the Pain-Note app was intended for this population, their step count was lower than that of the general population.

In our study, patients with symptoms of both insomnia and depression had lower walking counts. This result is consistent with previous studies, which have demonstrated that patients with a sleeping disorder or depression participated in fewer daily activities than individuals without these conditions. [36-38] Therefore, a lower daily step count might indicate insomnia or depression; identifying lower step counts might be useful for screening patients with these conditions.

We found, using restricted cubic splines, that there was a noticeable association between higher step count and a lower pain level. Furthermore, the slope of the association was steeper in participants with a smaller step count. Previous studies that have investigated the effect of walking or exercise therapy on pain reduction have assumed a linear association. In fact, the favorable association between increased step count and lower pain level is seen only among patients with chronic pain who do not have fibromyalgia. Participants with fibromyalgia show a different association between step count and pain level. Gracely et al showed that fibromyalgia alters the threshold of pain perception and makes patients more afraid to move [39]. This fear of moving could affect pain level, regardless of step count, but could also help explain the particular increase in pain level we observed in patients with fibromyalgia who had a daily step count below 2000. A meta-analysis of randomized studies with exercise as an intervention found that patients with fibromyalgia reported initial pain when they started to exercise at the beginning of the trials [40]. A previous study also revealed that daily exercise, including walking, reduced pain in fibromyalgia patients [40]. However, there was no association between step count and pain level in patients with fibromyalgia in our study. This may be because the participants who were classified as fulfilling the criteria for fibromyalgia in our study had not been diagnosed and did not have access to proper treatment by health care providers. Furthermore, these patients may not have been informed of the importance of exercise. Previous research suggests that a multidisciplinary approach combining physical exercise and education is important for pain reduction [41-43]. The results from our linear regression analyses, with step count as the outcome and the presence of fibromyalgia as the independent variable, also highlighted why the association between step count and pain level was different in our population. The fact that symptoms of depression are a major confounding variable in the association between fibromyalgia and step count suggests that, as expected, several variables can influence activity level in individuals with this complex syndrome.

This study has several limitations that should be noted. First, our results cannot determine causal associations because the study used a cross-sectional design. Second, there may have been selection biases for age, socioeconomic status, and user characteristics because of the requirement that participant be able to use iOS and the iPhone; in addition, our app is currently available only in the Japanese App Store and in the Japanese language. We also excluded more than 70% of participants who downloaded the app. This large proportion of excluded patients can be explained by the free distribution of our app. We believe that this free distribution means that the accessibility of our app was relatively high, but it also means that a large number of subjects were excluded from the analysis, mainly due to lack of complete data. On the other hand, to improve adherence, we could have distributed the app through a subscription or one-time purchase, but this might have led to additional selection bias, as only participants who could purchase the app would then have been included in the study. Third, our study suffers from self-reporting bias, because the data were collected using self-administered questionnaires. In addition, our analyses related to the presence of fibromyalgia were based on the

American College of Rheumatology 2010 criteria, which has been validated in the Japanese language, but has not been validated for use in the form of a smartphone app. Therefore, we must interpret our results as as being obtained from subjects who fulfilled the criteria for fibromyalgia, rather than subjects who had a clinical diagnosis. Finally, step count does not precisely reflect daily physical activity if participants turn off the pedometer function or if they perform activities that do not involve walking, such as swimming or mind-body practices. Considering that previous research has found a 20% bias in smartphone-based step trackers, the step count recorded by our app might have been an underestimate by as much as 20%.

Future research might include a longitudinal study to further explore the causal relationship between step count and pain. Analyzing predictors of the development or improvement of chronic pain would allow the planning of notification strategies or interventions in high-risk populations to reduce the burden of chronic pain.

In conclusion, our study revealed a significant association between high step count and low pain level among participants who did not meet criteria for fibromyalgia. In data that were stratified for patients with and without fibromyalgia, the likelihood test of a spline model did not show statistical significance; this could be the result of a lack of power, since the association was nonlinear in the overall sample. The characteristic shape of the association between patients with fibromyalgia and those without fibromyalgia might reflect different mechanisms of physical movement and pain perception. To find the causal association between step count and pain level, future studies should be designed to obtain longitudinal data and include participants from other countries who speak different languages; this would broaden the generalizability of our findings to a more diverse population. The extensive health care data that can be obtained with our Pain-Note app may ultimately help raise awareness regarding the importance of daily activity for preventing chronic pain.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Flow chart of data collection in Pain-Note app and results of sensitivity analysis.
[DOCX File , 309 KB - formative_v6i4e23657_app1.docx]

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Abbreviations

ISS: insomnia severity scale
SS: symptom severity
WPI: widespread pain index

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Original Paper

The Rapid Development of Virtual Care Tools in Response to COVID-19: Case Studies in Three Australian Health Services

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Abstract

Background: News of the impact of COVID-19 around the world delivered a brief opportunity for Australian health services to plan new ways of delivering care to large numbers of people while maintaining staff safety through greater physical separation. The rapid pivot to telemedicine and virtual care provided immediate and longer term benefits; however, such rapid-cycle development also created risks.

Objective: The aim of this study was to understand the sociotechnical aspects of the rapid-cycle development of seven different COVID-19 virtual care tools, and to identify enablers, barriers, and risks at three health services in Victoria, Australia.

Methods: A qualitative, embedded, multiple case study design was adopted. Researchers from three health services collaborated with university researchers who were independent from those health services to gather and analyze structured interview data from key people involved in either clinical or technical aspects of designing and deploying seven different virtual care tools.

Results: The overall objectives of each health service reflected the international requirements for managing large numbers of patients safely but remotely and for protecting staff. However, the governance, digital maturity, and specific use cases at each institution shaped the methodology and specific outcomes required. Dependence on key individuals and their domain knowledge within an existing governance framework generally enabled rapid deployment, but sometimes posed barriers. Existing relationships with technical service developers enabled strong solutions, which in some cases were highly scalable. Conventional project methodologies such as steering committees, scope, budget control, tight functional specification, consumer engagement and codesign, universal accessibility, and postimplementation evaluation were ignored almost universally in this environment.

Conclusions: These three health services took a variety of approaches to the rapid-cycle development of virtual care tools to meet their urgent needs for triaging and remote monitoring during the first year of the COVID-19 pandemic. Their experiences provided insights into many social and technical barriers and enablers to the development of virtual care tools. If these are addressed proactively, they will improve clinical governance and technical management of future virtual care. Some changes can be made within individual health services, while others entail health system policy reforms. Enhancing the environment for virtual care tool design and implementation now will yield returns not only during future health emergencies but also in many more routine care settings.

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KEYWORDS

COVID-19; health system innovation; rapid development and deployment methods; remote patient monitoring; software development

Introduction

The COVID-19 pandemic overwhelmed health resources in many countries. To handle unprecedented health risks and patient loads, health systems rapidly changed their models of care. In a matter of weeks, acute care health services around the world developed web and mobile applications to triage confirmed or likely COVID-19–infected patients (including their own health workers) to the most appropriate location, including outpatient testing clinics, hospital admission, in-home quarantine, or a dedicated isolation facility. Digital tools also enabled the hospitals to maintain clinical oversight of each remote patient through daily or more frequent contact (voice, text message, email, or other online service) and through the use of patient self-assessment tools to monitor symptoms (eg, temperature, heart rate, oxygen saturation, and respiratory rate). The term "virtual care tools"—including remote monitoring and tools (eg, [1])—describes this range of digital health interventions that track, monitor, assess, and manage decisions about care by health care workers and their patients when they are not colocated [2].

Health services had to make major decisions rapidly about their priorities for innovating with this range of virtual care tools. Some aimed at initial screening or triage of the general public or hospital staff, such as self-screening questionnaires (eg, [3-8]) and even chatbots [5]. Some aimed at follow-up of COVID-19–positive low-risk patients discharged from hospital, such as by providing them with pulse oximeters, thermometers, or similar digital devices; these innovations are described in an increasing number of articles (eg, [3,9-19]). Many virtual care solutions included web platforms with functionality for patients to report daily physiological data and symptoms of concern; if these data fell outside predetermined levels, suggesting deterioration, an automated message alerted the clinical team (eg, [10,11,15]). Other so-called "virtual ward" initiatives (reviewed by [18]) used technologies ranging from telephone calls to patient monitoring apps to capture the details of symptoms and personal data.

Some virtual care initiatives leveraged technologies already implemented in a health service, such as using or adapting existing electronic medical record (EMR) functionality to develop integrated tools for screening, triage, generating treatment order sets, remote monitoring of patients at home, and using health data effectively (eg, [5,6,10,12,14]). The implication is that patients were already enrolled in a health service EMR or could be enrolled readily in the EMR as necessary. Similarly, existing telehealth and video health applications were the foundation of some COVID-19 screening initiatives [20]. Other virtual care initiatives required novel technical solutions. Apps were developed for self-triage [4], for symptom grading [9], for reporting daily signs or to initiate a teleconsultation if a patient were concerned [11,14,17], or for use within the hospital emergency department [8]. Patient registries were established to identify, track, and monitor at-risk patients [12,20]. Purpose-built dashboards and analytics tools were used in some sites [6,9,10,20,21]. Survey software was also used for screening questionnaires [22] and for symptom tracking [17]. Continuous virtual monitoring infrastructure was adapted to monitor COVID-19 inpatients in negative pressure rooms and emergency department screening tents [20].

Design, development, and deployment of virtual care tools, which otherwise might take years to progress through research trial phases and clinical approval of software as a medical device (eg, [23]), were fast-tracked or short-circuited by the health care crisis. Few health services had time and even fewer had digital health expertise to attend to standards of technical development [24] or standards of clinical evidence [25]. Reviews published in late 2020 [18,26,27] summarized studies of the rapid deployment of digital technologies to cope with the COVID-19 pandemic in the early months of 2020, largely in the United States and Europe, most with fewer than 1000 participants. A case example in the University of Washington health care system [21] illustrates clinical informatics experts' involvement in supporting the clinical management of COVID-19 patients, and highlights the rapid governance and change control mechanisms that enabled this rapid shift. Commenting on the difficulty of data exchange within and between countries, O'Reilly-Shah and colleagues [28] proposed rapid development and implementation of data standards to overcome fundamental barriers to a data-driven response to the risks posed by pandemics. Likewise, Lenert and McSwain [29] argued for wider informatics innovations to enable electronic health record data from health systems to flow into collaborative public health data repositories.

Many sociotechnical aspects of developing and implementing virtual care tools in these circumstances—decisions about hardware and software, clinical content, human computer interaction, people, workflow and communication, policies and procedures, laws and regulations, and system-level monitoring [30]—have not yet been described in detail. Therefore, in this study, we examined, from a sociotechnical perspective, rapid virtual care tool innovations in three health services, and consolidated the lessons they learned in the first year. In particular, we addressed the following two questions: (1) which virtual care approaches were chosen and how were they designed? (ie, hardware and software, clinical content, human computer interaction, clinical workflow and communication), and (2) how was innovation influenced by factors internal and external to the organization? (ie, policies and procedures, laws and regulations).

The pandemic affected Victoria, Australia, from the time it was first declared by the World Health Organization (WHO) in early 2020. Health services began preparation for the transition to virtual care when the virus' impact on China, Europe, and the United States became evident through clinical communications, social media, and traditional media. Victoria's COVID-19 case numbers fluctuated over the course of the pandemic and regional

variation in numbers due to intermittent lockdowns was also apparent. This variation had minimal impact on the need to prepare proactively for worst-case scenarios, even though the utilization of the applications did vary greatly based on actual regional case numbers and infection waves.

The aim of this study was to provide insight into organizational readiness for future virtual models of care or service delivery through close examination of the evolution of virtual care tools during COVID-19 at three health services in Victoria, Australia. Understanding barriers and enablers that can be addressed in policy can inform the streamlining of current practices, and can ensure that digital health responses to future health crises and future routine care are managed and governed optimally.

Methods

Setting

This research was performed under the auspices of the Centre for Digital Transformation of Health at the University of Melbourne to address the need to facilitate cross-institutional learning during the pandemic [31]. The study took place at three health services in the State of Victoria, Australia. Austin Health (site A) and Melbourne Health (site C) are major metropolitan hospitals providing acute care and community services, and Bendigo Health (site B) is a major rural health alliance with 17 partner services.

Ethics Approval

The Royal Melbourne Hospital (part of site C) is the designated state-wide provider for quarantinable diseases. Melbourne Health Human Research Ethics Committee approved this study (HREC/67522/MH-2020; October 16, 2020); this ethics approval was recognized by the other organizations involved, and governance authorization was obtained for each participating site.

Design

This research used a qualitative, embedded, multiple case study design whose value has been demonstrated in previous health services research (eg, [32-34]). Researchers from the three health services collaborated with university researchers who were independent from those health services to initiate the project (project-managed by researcher URK), and gather and analyze data from people who had been involved in either clinical or technical aspects of designing and deploying the virtual care tools that were the focus of study: Austin Health community self-assessment platform [35], Austin Health COVID-19 symptom monitoring system, Austin Health COVID-19 symptoms management tool, Bendigo Health teamplay myCare Companion “Pandemic” [36,37], Royal Melbourne Hospital Home Monitoring [22,38], Royal Melbourne Hospital Screening Clinic tool, and Royal Melbourne Hospital COVIDCare. Table 1 describes the virtual care tools’ functions and features.

Table 1. Virtual care tools' functions and features.

Health service	Tool type	Short description	Hardware and software requirements	Location of potential or current patient
A	Screening app (members of the public)	App that issues the patient or visitor with a QR code after they identify themselves and respond to COVID screening questions	Internal: internet connectivity, accessed through smartphones or web portal	In hospital
A	Screening app (staff)	Web page form in which staff identify themselves and their workplace and answer COVID screening questions	Internal: internet connectivity, accessed through smartphones or web portal	In hospital
A	Home monitoring	Patient routing self-assessment and triage app	Internal: Microsoft Azure cloud data storage; external: audio recording of breathlessness, pulse oximeters. Internet connectivity: smartphone	Out of hospital
B	Home monitoring (digital)	Patient routing self-assessment and triage	Internal: Amazon Web Services using Australian cloud data storage; external: pulse oximeters, digital thermometers. Bluetooth capability and internet connectivity on smartphone or tablet computer	Out of hospital
B	Home monitoring (with manual option)	Patient monitoring at home using manual and electronic Excel forms for self-assessment	Internal: Amazon Web Services using Australian cloud data storage; Microsoft Excel; external: internet connectivity. Computer or tablet (to read and input into Excel) or print capability to manually enter form	In hospital and out of hospital
C	Screening app (members of the public)	App that issues the patient or visitor with a QR code after they identify themselves and respond to COVID screening questions	Internal: Local data servers; external: internet connectivity. Smartphone with basic functionality: web browser–enabled and/or text message receiving–enabled	In hospital and out of hospital
C	Home monitoring	Patient monitoring at home for self-assessment	Internal: Local data servers; external: pulse oximeters, tablet computers with internet connectivity, or smartphone with internet connectivity/text message receiving–enabled	Out of hospital

Interview Protocol

A semistructured interview protocol was developed based on the WHO digital health monitoring and evaluation guidelines phases 1 and 2 (prototyping and piloting), which focus on feasibility, usability, and efficacy [39] (see Multimedia Appendix 1). The questions sought individuals' descriptions and observations of the process of developing and deploying the virtual care tools at each health service, including what clinical and technical features were prioritized and how the tools functioned in early stages of actual use.

Three site-based researchers who had lead roles in tool development at their site (GH, MD, MB) were interviewed themselves, and also nominated additional people to be invited for an interview by a university researcher (TW). Subjects for the interview were identified on the basis of their key roles in information technology (IT) and informatics or their clinical pivot to virtual care in the case of emergency medicine, respiratory medicine, or infectious diseases staff members. Participation was voluntary; all who were nominated agreed to participate given the strategic nature of the work (N=13, Table 2). In health services that developed more than one tool, interviews with staff who had been involved in development of each tool were conducted separately and data about each tool were collected separately. The interviews were conducted between December 2020 and March 2021 via video conference and were audio-recorded. They occurred after the tools had been deployed and significant numbers of cases had been processed. The interviewees therefore spoke with that experience in mind.

Table 2. Interview participants

Health service	Position
A	Clinical lead for virtual care tools/infectious diseases physician
A	Contracted external programmer
A	Director of information technology services
A	Chief Medical Information Officer (site-based PI[a] in this study)
B	Director of Nursing
B	Executive Director of Information Services
B	Nurse Unit Manager (Admissions)
B	Registered Nurse (Psychiatry/Admissions)
B	Clinical lead, Integrated Care Services (site-based PI in this study)
C	Emergency physician/clinical lead (site-based PI in this study)
C	Assistant Manager, Nursing (Emergency)
C	Contracted external programmer
C	Emergency research director/senior physician

[a]PI: principal investigator.

Analysis

Analysis of the interviews followed the 7-step process of the framework method, which provided a structured and systematic approach to analyze data, while also providing the necessary rigor required in qualitative research [40]. First, the interviews were transcribed with the aid of an online voice-to-text transcription service, and interviewees reviewed the transcripts for accuracy. Second, the interviewing researcher (TW) worked with two experienced qualitative researchers from the university (AB, CG); the three familiarized themselves with the transcripts, and TW annotated them with contextual notes that he had made during interviewing. Subsequently, the three researchers began the process of coding, independently analyzing and coding the first three interview transcripts using NVIVO software. They used WHO digital health monitoring and evaluation guidelines to characterize the tools deductively; they also performed inductive coding to characterize the interviewees' comments thematically and to ensure that no themes were missed. The inductive approach used the open coding method, followed by constant comparison to refine the themes. The three researchers met regularly to discuss the codes, which underwent several iterations until they reached agreement on a working analytical framework. This framework was then used by AB and CG to code the rest of the transcripts. They aggregated comments at the level of each health service to reduce individual participants' public identifiability. Thereafter, they sought corrections and clarifications on matters of fact from the principal researcher at each health service. All codes with relevant illustrative quotes were exported to a spreadsheet in the form of a framework matrix to summarize the data. The commissioning and coordinating university researchers (WC, KG) then applied Sittig and Singh's [30] sociotechnical lens to review and organize the data into themes and subthemes for reporting. The three site-based researchers (GH, MB, MD) worked iteratively with the university researchers to reach consensus among all authors on the interpretation of the data and the implications for the Discussion section of the paper.

Results

Which Virtual Care Approaches Were Chosen and How Were They Designed?

Three priority aims for developing virtual care tools were described: reducing exposure (of staff and patients noninfected with COVID-19) by reducing admissions (including emergency department attendances), efficiency, and patient experience. See Textbox 1 for representative quotes for each aim.

The content of virtual care tools built by all three health services incorporated state government triage and management criteria [41]. Department changes and updates to their official case definitions were progressively incorporated into the screening and triage tools of the respective health services. Tools included risk stratification questionnaires relating to the general wellness of the patient ("How do you feel?") and screening information related to travel and general symptoms (eg, headache, fever, diarrhea, cough, sore throat, and shortness of breath). Specific physiological aspects of heart rate, blood pressure, oxygen, and temperature were included in home monitoring for self-assessment, but patient data were collected in more than one way, using both digital and manual means and depending on the home context.

Textbox 1. Representative quotes reflecting the three priority aims for developing virtual care tools.

- **Reducing exposure by reducing admissions**

"What we needed to do in the first instance was to make our staff as safe as possible to reduce the potential spread of the virus…The design [was] around two things: keeping patients away from the hospital - because we didn't want to be overwhelmed, and we needed to keep the staff safe so that we had a workforce that was able to do the work... [also] Being able to give people up-to-date information and to have a screening tool, that could triage patients, to stop them from coming to the hospital, to go to centers that were closer to their home. So that we could just bring the sicker ones and the ones that needed our care." [site A]

"The context was that we were asked to start a virtual home team which was looking after COVID-positive patients who were in the community...The key users that we targeted were COVID-positive patients who didn't require hospitalization. The whole idea of this home monitoring is to prevent frequent presentations. That precludes the need for a lot of people to actually come into hospital." [site B]

- **Efficiency**

"There's been a huge efficiency bonus—we could never have triaged that number of people, if they'd all physically come up and lined up in the car park, it would have been impossible. And the amount of data that's been assessed would also have required hundreds, tons and tons of staff if we'd had to do it on fax or paper or any other technology. So it's been very efficient for the hospital because the number of staff that have had to be deployed actually to managing this triage and a follow-up process has remained, I think, at three or four which we could never, ever have possibly done if it had been a more manual process." [site A]

"Our senior emergency clinicians stepped back, asking, 'What's going to happen when we get a planeload of potentially exposed travelers from overseas who are going to land in Melbourne and arrive at the emergency department all at once for screening? They're probably all well. They're all potentially infectious. How are we going to manage this?' It became obvious to us that we would need to do something different fairly quickly." [site C]

- **Patient experience**

"Patients are able to isolate within their own home yet feel like somebody's watching them and monitoring them. There is a physical benefit because they can be in an immediate intervention if something is noticed to be wrong." [site B]

"We want people to arrive in hospital just at the point in their illness when we can make a difference, and to leave when we can no longer make a difference." [site C]

Virtual care tools' functions are described in Table 1. All three health services provided home monitoring kits with digital devices such as pulse oximeters and thermometers and recording devices for breathlessness. Patients were provided with options for reporting their data; for example, they could manually record their oxygen levels measured using pulse oximeter devices and send the data via text message, or they could report to the triage team by phone call; tablets for connecting to web-based virtual care tools were provided to patients who had the capacity to use them. A variety of patient interfaces were described:

> *…can be configured to send the text to a carer, not just the patient. We do have knowledge of whether it's a carer-based or a patient-based response.* [site A]

> *…if someone had difficulty utilizing the system, then we'd find someone else to add the numbers into the system, or they would phone us with the numbers and we'd enter their data on the system.* [site B]

> *If you're coming to a screening clinic…you could have six QR codes, with six languages and if you speak Italian, you just click the Italian one and the form will be sent to you in Italian and the information will go back in whatever format we want it to go to…in the screening clinic [we] have a couple of tablets or iPads, that can be handed out to people while they're in the queue, to fill in the information* [site C]

Data management solutions varied from sophisticated cloud applications to Excel spreadsheets. Each health service developed local clinical workflows for reporting data, and in most cases for triaging respondents on clinical needs. Extraction of reportable information to the State Department of Health was enabled but had variable manual dependencies. No common clinical terminology (eg, SNOMED CT [Systematized Nomenclature of Medicine-Clinical Terms]) was adopted; however, Department of Health requirements mandated reasonably consistent word forms. How these were represented in underlying data structures was not consistent across sites. Data integration and systems interoperability were considered but were also foregone for the sake of expediency.

> *Generally speaking [the solutions] are quite separate and sole-purpose. Where relevant, data has been shared and there's interoperability. Integrates with the contact tracing solution so we can monitor potentially exposed or at-risk staff for symptom. No integration with the [state government] contact tracing system.* [site A]

> *We know that integration is a key thing for us from a user point of view.* [site B]

> *It doesn't integrate directly into the EMR.* [site C]

Data privacy and security measures were implemented through local processes at each site. A participant from health service A noted:

> *Health is a very legislated and regulated environment. There were standard operating procedures under which this was all done…For example, we didn't collect date of birth, just the age; not full addresses,*

> *just postcodes. So these principles were built into the apps*
>
> *…a role-based approach to ensure that only certain people are allowed to see certain data; encrypted link sent to the patient or their carer*

Platform choice was directed by ascertaining that data were stored in Australia on secure facilities, governed and secured by their own staff. Tools provided on browser interfaces relied on secure socket layer encryption. Health service C noted "Hopefully the robustness of the REDCap [Research Electronic Data Capture] platform is providing a layer of security." Strategies such as segmentation of data sets were used to keep screening records for health services staff separate from reports for patients and visitors at the sites; health service B commented on the potential for staff to become patients themselves: "Because of staff privacy issues and confidentiality, [information] was segmented." All used two- or three-factor authentication steps for patients to access portals or for staff accessing dashboards from their own devices. IT staff also reported using penetration tests and running vulnerability assessments on their systems.

How Was Innovation Influenced by Internal and External Factors?

All three health services had to create new project teams and use a rapid cycle design ("agile") philosophy [42], necessitated by the clinical requirements and human resource management prescribed by public health officials and local infection control experts. Projects were built on existing staff capability, assisted by contract programmers or developers, led by senior IT and clinical staff who were familiar with privacy and security requirements and who had the authority to proceed. The agile project team had responsibility for each of the rapid-cycle applications. This was a shared experience at each site. There were daily design, build, test, and adapt meetings to ensure the fastest possible deployment. Once a stable base system was established, additional functionality was added in a similar rapid-cycle format. Traditional considerations such as final functionality specification, design, tender, contract, and project governance largely were suspended. In applications where internal clinical staff were the end users, there was significant informal engagement in the design and build phases, including testing functionality and wording. This was not the case where the end users were consumers. User acceptance testing was incorporated into the rapid-cycle development framework. Postimplementation evaluation was mainly informal and based on functional user acceptance and utilization numbers. In addition, some of the virtual tools were adopted by other Victorian health services for use in the pandemic or were modified for use in other clinical settings.

The solutions deployed at each site were dependent, in part, on existing infrastructure, agile teams, applications, and relationships. Victoria differs from other states in Australia in having a decentralized system where each health service operates under its own board, following objectives and outcomes set by the State Department of Health. Each health service in this study uses a different EMR (site A, Cerner Millennium; site B, Intersystems; site C, Epic). These are at various stages of implementation, but fall within intermediate to high bands of digital health maturity, that is, levels 3-6 of the Healthcare Information and Management Systems Society's Electronic Medical Record Adoption Model. At each site, access to informatics and IT staff to rapidly build and deploy COVID-19 applications was not straightforward; they were generally fully engaged in other projects or intensive adaptations to prepare for COVID-19 in business-as-usual operations. However, internal development was essential due to the short timeframe for decision-making, without specific direction from state health authorities or market-ready software. Where local staff could not be redeployed, additional contract staff with relevant computing expertise were engaged through existing relationships with external consulting companies for this purpose, and all external service providers contributed substantial goodwill to these projects.

Site A had standing multiyear master services agreements in place that enabled application development within enterprise software solutions. Health service A is also moving toward procurement panels similar to larger-scale state procurement panels to reduce the effort and time to project commencements. In this case, there was a continuity of mutual understanding and trust that the intent of organizational policies and procedures would be observed during the rapid-cycle deployment. Health service A had been building knowledge and capability of artificial intelligence, machine learning, and natural language processing in their Microsoft Azure tenant together with external developers familiar with that platform. This platform allows flexibility in application selection and is highly scalable. As this relationship already existed, it was used to rapidly build and scale the applications. Together with the product developers, they agreed on a base application and rapidly designed electronic forms for a symptom reporting web-based application hosted on the health service's Microsoft Azure cloud.

Similarly, site B leveraged an existing relationship with the commercial product developers of their patient monitoring platform. Prior to the pandemic, health service B was in discussion with Siemens about a chronic disease management home monitoring tool and app. Senior management approval was granted to proceed to pilot on this basis. The clinical team responsible for chronic disease home monitoring became the group that took on the monitoring of COVID-19 patients.

Site C used an existing online research data system (REDCap) to rapidly build their capability. The clinical requirement at health service C was determined by local clinicians to manage expected high numbers of attendances at the emergency department. Development was driven by emergency clinicians and the tools were programmed in the service's established REDCap electronic data capture system [43]. REDCap was already approved for clinical research use; its three virtual care tools (patient screening, staff screening, and home monitoring) were granted a waiver of ethical clearance, as a quality improvement program. This system was highly dependent on two clinicians not normally involved with IT or EMR development to maintain service and alter software in a rapidly evolving data content environment.

Three enabling factors were noted to accelerate development of the tools in all three health services: having access to external IT developer expertise, close collaboration between internal clinical and technical staff and external developers, and strong support from senior management. Comments from site C summed up the organizational obstacles to be overcome, "the hospital bureaucracy committees, red tape permission, all of that," and the enabling characteristics, "it helps to have someone in the organization with the ability to question what is the outcome that's needed, and you need a small group able to work intensively on a solution that matches this."

Being enabled by working within an integrated health information environment was also expressed, but as an unmet need:

> *Victoria needs […] to have a single EPR [electronic patient record] or EMR so that these things would all link uniformly into the same platform…*
>
> *You need adequate architecture linked to systems and the workforce.*
>
> *Companies want to deal with you […] and they don't have a vision about an integrated, a fully integrated connected care model.* [site B]

Enabling funding was deemed secondary to rapid and effective deployment at the metropolitan health services, as those sites faced substantially increasing COVID-19 case numbers. The regional and rural health service (site B), with a lighter case load, voiced a greater sense of the financial resource limitations:

> *You can have whatever you want, provided you're prepared to pay for it.*
>
> *A major intervention like this requires a considerable amount of development. If you're buying something off the rack, so to speak, to tailor it to the needs of your particular area takes time and effort and work, which again, equates to money at some point, but it's resourcing and availability of resourcing.*

Social barriers to design and implementation of the virtual care tools emerged at all three sites. The prime concern was the digital divide affecting some groups of health service users:

> *There were concerns about accessibility for the non-English language speakers and the elderly, or the "digitally challenged," if you like.* [site A]
>
> *We initially looked at connected oximeters and trying to capture that data automatically. What we found was that that seemed to be a barrier of entry because the patient would then have to figure out how to connect at home and go through that process.* [site A]
>
> *We're contacting people and finding out they didn't have computers or didn't understand computers.* [site B]
>
> *The cohort that we had with these chronic complex issues were elderly patients. So there were very few patients who were computer literate and very few patients who even had phones and computers.* [site B]
>
> *You've got to look at the user interface to see whether it's practical and whether it provides a product that they can utilize fairly intuitively.* [site B]
>
> *A little bit more challenging for the uptake by the consumers because 12 months ago, a lot of us didn't know what a QR code was. But we built in some education around that…installed some big posters on the wall on how to access a QR code.* [site C]

To sum up, key results reported here can be mapped against the eight dimensions of a sociotechnical framework summarized in Textbox 2. Multimedia Appendix 2 presents additional interview quotes that illustrate these sociotechnical themes.

Textbox 2. Dimensions of the sociotechnological framework.

- **Hardware and software**

The sites worked around rather than through their electronic medical record systems; their solutions to store and process patient data varied from local servers to cloud services. Solutions assumed that the majority of people had ready access to internet-connected phones or tablets.

- **Clinical content**

Clinical content was structured in the most expedient way and prioritized to the essential elements for two decision support scenarios: triaging emergency attendance at a hospital and monitoring home-based care remotely.

- **Human-computer interaction**

An array of novel reporting and analysis interfaces was assembled for staff, with little concern for their overall user experience under the circumstances. Unfamiliar information interfaces such as QR codes, oximeters, and teleconsultations became normalized for health service consumers.

- **People**

Small teams of digital health champions undertook extraordinary development efforts. Given infection rates, both health service consumers and health care workers were likely to be patient "end users" of the solutions.

- **Clinical workflow and communication**

Initiatives at these three sites went beyond the scope of routine care and practice. They contributed efficiently and effectively to preserving health workforce capacity and preventing health service overload.

- **Internal policies and procedures**

Routine business processes for planning and implementing digital innovations did not run at the speed required by the health crisis. Innovation arose in organizational cultures where there was a foundation of trust in key staff and industry partners.

- **External policies and procedures**

In the absence of shared, centralized management of hospital information systems, the sites in this study mobilized informal communities of practice. This approach to sustain and extend the use of virtual care solutions beyond the health crisis will depend on shifts in digital health regulation and resourcing.

- **System monitoring**

The sites in this study have committed to formative evaluation of the development and piloting stages of their virtual care solutions in the form of research reported in the present paper. The World Health Organization staged evaluation model referenced here carries the expectation of further monitoring of solution performance and outcomes over a longer term of implementation.

Discussion

In summary, all three cases showed priorities, issues, and outcomes similar to those in the COVID-19 virtual care literature around the world: rapid development and iteration, staff and community safety through distancing and virtual care, scalability and efficiency, uncertainty, and constraints of business-as-usual models. The ability to rapidly leverage existing infrastructure and relationships proved critical in each case, even though the technical responses varied considerably. None of the sites used their EMRs as the primary digital tool, largely due to the administrative difficulty of enrolling so many new patients formally into the EMR. The tools that were developed enabled consumers to self-register and hence reduced the administrative burden, which is known to be significant in other jurisdictions where an EMR was used (A Ritchie, Chief Medical Information Officer, Sydney Local Health District, Royal Prince Alfred Virtual, personal communication, May 13, 2021).

Governance maturity was just as important as technical maturity; organizational dependence on trusted employees to drive these projects in a responsible and defensible manner was critical to timely, successful application deployment. Maturity implies that the organizations had developed sufficient internal processes and policies, so that responsible staff could rapidly deploy within those principles without necessarily following the operational and committee procedures, which would have taken too long. Informal sign-offs were more often the case, even though one health service found that there was a tension between formal and informal processes. Projects at all three sites had a high level of risk because of their critical dependencies on a few key actors. These were pressing factors in the pandemic setting, but these might not be as relevant in postcrisis or in less threatening situations.

Difficult choices needed to be made regarding time to deployment versus equity of access. All respondents noted that there were certain consumer groups who could not access these applications due to limitations in language, technical access, or skills. These issues were identified internationally, such as by Houlding et al [1], where barriers to the use of remote monitoring technologies included equity-related barriers (such as affordability of technology for users, poor internet connectivity, poor health and digital literacy), the need for good practice guidelines for use in clinical care, and the need for additional resources to develop and support new technologies.

In our study, some access issues were mitigated by use of patient proxies and one health service enabled some multilingual content. Consumer consultation and codesign were noticeably absent as were formal evaluation and benefits realization. To overcome these issues systematically as virtual care tools become part of business as usual, health services will need to establish consumer engagement structures proactively and embed them in usual practice so that these ways of working with consumers are trusted and effective. Another victim of development and deployment speed was the failure to use recognized coding systems and terminologies in the apps design. There was congruence of clinical concepts, clinical triage criteria, and state government reporting requirements, which drove content in these apps; however, the underlying data structures are inconsistent and would require mapping to consolidate the data. This is another area where embedding capability into usual practice, specifically stronger informatics skills within health services' IT teams, would provide benefits.

Health services have widely recognized the success of these rapid IT implementations and now have more confidence in enabling and sustaining virtual health care applications [3]. Although it is a limitation that consumer views have not yet been assessed in our study sites, we note that strong consumer satisfaction is reported in the literature (eg, [3,15]). Further developments would be streamlined by formalizing the enabling and success factors identified in this study and building in mitigations for the deficiencies (eg, consumer panels and multilanguage capabilities embedded in consumer-facing digital health applications). Formal partnerships and collaborations between health services and IT companies may offer a significant long-term benefit for in-house design and deployment and should have a legitimate place alongside the competitive project tendering mechanism. This is especially the case where enterprise platforms are used for related deployments.

The authors of this study brought our diverse experiences and perspectives as practitioners, technologists, administrators, and researchers to bear to reflect on the data that we highlighted in our Results section and on additional thematic data garnered in this study (as summarized in Multimedia Appendix 2). Our collective lessons learned about barriers, enablers, and suggestions for future work are captured in the recommendations we propose in Table 3 and Table 4.

Table 3. Recommendations for improvement in policy and practice, based on barriers experienced in rapid virtual care tools development (after Houlding et al [1]).

Barriers	Normal practice	Rapid cycle	Suggestions for future
Poor internet connectivity	Solution delivery platform designed for optimal functionality for the target population; multichannel delivery with "low tech" where possible	Solution delivery can take into consideration the availability, access, speed, and other requirements of applications depending on the project context. The latter can encompass pilot applications across any of 3G, 4G, 5G, and WiFi	Create a registry of available technology platforms for areas where optimal solutions are unavailable; these could be related to geography, topology, rurality, service outages, or cost of access
Low health literacy	Design with language optimized for target populations	Considerations often overlooked or unavailable in the project context due to emphasis on rapid prototyping without participation of a spectrum of service users	Create design templates for developers to utilize in specific low literacy populations
Low digital literacy	Design with "low tech" optimized for target populations	Considerations often overlooked or unavailable in the project context due to emphasis on rapid prototyping without participation of a spectrum of service users	Consider development of support models for users (eg, training, adoption support)
Need for quality, best-practice guidelines for use of remote monitoring technologies in clinical care	Project design and funding aimed to support optimal solutions	Utilize technology already available and approved; design interface around available devices	Development and maintenance of tool sets and guidelines for remote and home monitoring use
Lack of resources to develop and support new technologies	Project design and funding aimed to support optimal solutions, which may include new technologies where feasible	Rapid design of applications leveraging existing technologies, devices, and/or platforms. Innovation is often in the reuse of technologies to extend and/or enhance functionality	Structured simulation and validation frameworks for rapid-cycle development, testing, clinical trial, and deployment. Consider total cost of ownership (eg, unmeasured development costs, hosting costs). Manage human resources cost (eg, informal time of subject matter expert clinicians, technical developers' time)
Equity-related unaffordability of technology for users	Scoping outcomes and target clientele; mitigations for identified consumers; alternate funding models or subsidies; design for least-cost technology; stratified interventions	Equity considerations frequently not addressed; 80/20 rules due to rapid prototyping process for majority service users; mitigations for descoped users may be considered in a subsequent evaluation phase	Identify and resolve long-standing equity and access issues so that standing solutions are available to be incorporated at short notice; build in multilanguage capability; develop policies and mitigations for equity access as part of business as usual; apps delivered if possible over multiple channels, including low-cost SMS and phone

Table 4. Recommendations for improvements in policy and practice, based on enablers experienced in rapid virtual care tools developments (after Houlding et al [1]).

Enablers	Normal practice	Rapid cycle	Suggestions for future
Governance: policies reflect required outcomes and describe allowable emergency and rapid-cycle processes and permissions framework	Review internal policies and ensure they reflect both business-as-usual and emergency situations to enable appropriate rapid responses	Existing policies describe acceptable process and outcomes in the absence of conformance with standing committee and approvals framework in defined circumstances	Identify "special needs and emergency" situations; review business-as-usual practice to reduce unnecessary delays
Master services contracts: reducing procurement delays with trusted providers	Individual projects defined, budgeted, and tendered; project management framework defined	Existing relationships leveraged to create short-term team with focused but flexible and evolving outcomes as external environment evolves	Establish panels of approved partners and consultants to enable rapid design and deployment, especially using existing enterprise solutions
Standing consumer working groups for rapid cycle codesign	Consumer groups engaged on project basis, often ad hoc	Consumer groups might be largely ignored in the rapid prototyping process and in participatory practices over the course of the rapid cycle	Establish panels of educated consumers who can contribute knowledgeably across all projects and be available at short notice; actively engage a spectrum of users and consumer organizations; cocreate a participation framework with a cross-section of consumers/service users throughout the life of the service, including options for training (eg, digital and health literacy)
Upskilling and enabling clinicians and subject matter experts to lead projects targeted at their specific issues (eg, predicting issues and rapid problem enunciation)	Clinician-led projects battle for priority and resourcing against "top-down" projects	Clinician-led and developed applications target local requirements using defined, secure, integrated platform applications; informal international clinical networks and peer review rapid publications flag concerns prior to official body pronouncements: lead the local curve	Training and enabling clinicians in supported platform applications (eg, Dynamics, Forms, REDCap[a]), reduces lead time and impact on core IT[b]/EMR[c] applications teams. Clinical networks promote data conformance and spread of successful applications
Collaboration (clinical and technical) networks facilitate shared understanding and requirements for development, together with resource sharing	Organizational, cross-organizational, and professional and clinical networks advise on priority applications and consulted ad hoc regarding application selection and deployment issues	Existing networks should be convened as priority to coordinate and share resources to expedite planning development and implementation. Parochial variation should be reduced or eliminated	Convene, support, and sustain these networks as business as usual so they deliver benefits and are functional when required in emergency scenarios

[a]REDCap: Research Electronic Data Capture.

[b]IT: information technology.

[c]EMR: electronic medical record.

This study provides an in-depth qualitative assessment of the sociotechnical environment in three large Australian health services during the rapid deployment of staff- and consumer-facing COVID-19 applications. Its strength is in capturing the diversity of technology platforms and development models and sharing the reflections of key personnel across these three sites. Although the number of interviewees perhaps seems limited, in fact, all key decisions were made by those few people, in consultation with other key clinical groups. Where possible, clinical staff who both provided expert advice on form and content of the applications and who became key testers and users of the applications were interviewed. In terms of a full sociotechnical evaluation, the paper has limitations due to the focus on operational efficiency at a time-critical period in history. The availability of multiple cases located within the same state of Australia (Victoria) provided an opportunity to describe and analyze varied experiences of virtual care innovation within a national health care system.

During the initial period of the pandemic, state health policy makers were occupied in managing whole-of-system preparedness, state and national reporting systems and contact tracing systems, vaccination preparation, and quarantine. In Victoria's decentralized public health system, each health service is responsible for implementing state policy in its own way, and this will be partly determined by prior decision making around EMR/paperless administration system selection, implementation stage, and other elements related to digital maturity. In a similar manner, hospital executives, who are often overwhelmed by preparations and hospital ward reconfigurations, staff protection and visitor policies, logistics, and supply chain challenges, provided support but not direction for those clinicians and EMR/IT experts charged with response and virtual care preparation. The state government provided a significant funding stream for COVID-19–related activities, including virtual care preparation. Expenditure allocation was authorized by department heads in consultation with finance department officials.

This context makes our results less comparable with other states in Australia where digital health strategy and implementation are more centralized. A limitation of our study is that we were constrained from including cases from additional major health services in Victoria, in part due to onerous, site-by-site research

ethics and governance processes. Further work needs to be done on evaluation. In particular, we could not meaningfully interpret usage data to give a clear picture of immediate uptake of these applications, and we are not yet able to provide a full sociotechnical analysis of longer-term, scaled-up experiences or outcomes. Such evaluation research is the focus of another study.

Despite these factors, our findings are consistent with other reported projects of similar nature in the international literature. The presence of mature EMR and supporting IT infrastructure and governance models enables rapid development and deployment of digital health applications in support of new models of care. Preexisting contractor relationships at two study sites enhanced the capacity of those services to deploy rapidly. All of the relationships reported here underwent standard probity assessments when initially contracted (eg, fairness, avoidance of favoritism, hidden inducements); however, within these contracted relationships there was scope to modify and evolve service requirements within reason. The preexisting personal and technical engagement enabled the rapid-cycle design and development of the COVID-19 virtual care tools. Conventional governance models are essential for establishing normative behaviors, checks, and balances; however, emergency, rapid-cycle developments can be performed safely using the principles established by this governance without rigid adherence to committee structures and procedures. User acceptance of virtual digital applications described in the international literature is high, and the intent to support large cohorts of at-risk people and manage emergency service utilization has been demonstrated. Direct consumer involvement and codesign were not features of our study cohort, nor were these aspects comprehensively described in the literature about other COVID-19 applications. Applications supporting clinicians were more likely to have undergone some degree of codesign, with short-cycle deploy review and revision, simply because clinician users were in proximity to app developers.

In conclusion, we agree with Boyle and Henderson [44]: “As we move from a pandemic to an endemic state, delivery of care must also change to ensure this—and similar diseases—can be managed safely, alongside regular emergency care, within our departments and wider healthcare systems.” The findings of our study confirm that the pandemic has affected us in similar ways to the rest of the world and that our responses have been similar. Lessons learned elsewhere have relevance for Australia; it is clear that rapid deployment of triaging and remote monitoring technologies has occurred successfully in numerous countries and contexts. These findings support clinical recommendations, to governments and other funders, that structures and systems for developing virtual care tools should be strengthened in organizational and funding models. This will not only engender resilience in health emergencies but also has the potential to transform chronic disease management and routine clinical care to be more accessible and less costly and to reduce pressure on fixed health service infrastructure.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Indicative interview questions about virtual care tools.
[DOCX File , 14 KB - formative_v6i4e32619_app1.docx]

Multimedia Appendix 2
Additional interview quotes illustrating sociotechnical themes.
[DOCX File , 31 KB - formative_v6i4e32619_app2.docx]

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Abbreviations

EMR: electronic medical record
IT: information technology
REDCap: Research Electronic Data Capture.
SNOMED-CT: Systematized Nomenclature of Medicine-Clinical Terms
WHO: World Health Organization

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Original Paper

Online Searching as a Practice for Evidence-Based Medicine in the Neonatal Intensive Care Unit, University of Malaya Medical Center, Malaysia: Cross-sectional Study

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Abstract

Background: The use of the internet for research is essential in the practice of evidence-based medicine. The online search habits of medical practitioners in clinical settings, particularly from direct observation, have received little attention.

Objective: The goal of the research is to explore online searching for information as an evidence-based practice among medical practitioners.

Methods: A cross-sectional study was conducted to evaluate the clinical teams' use of evidence-based practice when making clinical decisions for their patients' care. Data were collected through online searches from 2015 to 2018. Participants were medical practitioners and medical students in a Malaysian public teaching hospital's neonatal intensive care unit who performed online searches to find answers to clinical questions that arose during ward rounds.

Results: In search sessions conducted by the participants, 311 queries were observed from 2015 to 2018. Most participants (34/47, 72%) were house officers and medical students. Most of the searches were conducted by house officers (51/99, 52%) and medical students (32/99, 32%). Most searches (70/99, 71%) were directed rather than self-initiated, and 90% (89/99) were completed individually rather than collaboratively. Participants entered an average of 4 terms in each query; three-quarters of the queries yielded relevant evidence, with two-thirds yielding more than one relevant source of evidence.

Conclusions: Our findings suggest that junior doctors and medical students need more training in evidence-based medicine skills such as clinical question formulation and online search techniques for performing independent online searches effectively. However, because the findings were based on intermittent opportunistic observations in a specific clinical setting, they may not be generalizable.

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KEYWORDS

evidence-based practice; online information searching; information retrieval; information seeking; clinical setting

Introduction

Online Searching Practice for Evidence-Based Medicine

Internet use for information searching has increased significantly since the early 21st century. There has been a significant increase in medical information searching because of the availability of health information online [1-3]. While searching for health information online allows laypeople to learn more about their health, medical experts search for information to make informed clinical decisions for their patients [4,5]. Evidence-based medicine (EBM) refers to the process of seeking medical information to make informed clinical decisions. The definition of EBM is "the conscientious, explicit, and judicious use of current best available clinical evidence, with the integration of clinical expertise, to make clinical decisions for the care of patients" [6]. Because the human brain has limited capacity, EBM allows medical practitioners to make decisions based on validated and reliable evidence. This will improve the overall health care quality by ensuring consistency of care provided to patients through informed clinical decisions [7,8].

Many medical practitioners have reported difficulties encountered while performing an EBM search. Among them are a lack of resources, a lack of search skills and experience, a lack of role models practicing EBM, and a lack of time to practice EBM [9-12]. These are the challenges that online EBM practitioners in resource-limited countries face [9,10,12-15]. One reason for this is the unavailability of adequate resources. As a result, it is critical to comprehend how information is sought during EBM practice in resource-limited country hospitals. Such research is limited and still in its early stages [9]. According to a review of literature from resource-limited countries in this context, interviews and questionnaires are used to investigate the challenges faced by online EBM practitioners [13,16-20]. These research studies may not provide data on real challenges encountered during a live information retrieval process. Examining real and live challenges can provide insight into actual searching behavior in situations where challenges with query expression and results review may arise during the information-seeking process. Thus, there is a need to investigate medical practitioners' true searching behavior during live clinical rounds so that recommendations can be made based on the findings from actual searching challenges that arise during EBM practice.

This study focuses on online EBM practice in a resource-limited country, specifically Malaysia, which meets the World Bank's definition [21]. Early research studies on EBM practices in Malaysia revealed that many medical practitioners are aware of EBM and have used the Cochrane database, and 6.7% of those polled have used MEDLINE to conduct a literature search [13]. According to these findings, the overall uptake of performing online EBM is lower. Malaysia, as a Southeast Asia—Optimizing Reproductive and Child Health in Developing Countries (SEA-ORCHID) project participant, took part in a large intervention project that took place throughout the region [22]. The SEA-ORCHID project sought to investigate how evidence-based teaching and practices are carried out in the departments of obstetrics and gynecology. Despite such an intervention, a recent study found that challenges remain around the knowledge and skills required for conducting searches for relevant information during EBM practice [12,23].

Related Works

According to research, the practice of EBM requires medical practitioners to integrate 3 important aspects during clinical decision making: (1) the medical practitioner's clinical expertise, (2) the best available evidence from multiple resources, and (3) patient values and preferences [8]. The second criterion is closely related to online information-seeking behavior and EBM. It is not the same as searching for information, in general, to be able to use the best available evidence from multiple sources. This is because the practice of EBM is governed by a specific set of procedures. As a result, only EBM-trained medical practitioners and allied health experts are known to be able to practice EBM [24]. Improper EBM practice, especially when searching for evidence, may result in the retrieval of incorrect or inappropriate information, posing threats and risks to patients' lives. Medical practitioners must search multiple resources for validated and reliable evidence to support their medical decisions [24]. When making clinical decisions, medical practitioners were initially encouraged to rely on facts derived from books and printed materials as their primary sources of offline health information [25]. In recent years, however, medical information has been deployed and searched through online resources via information and communication technology (ICT) [26-30]. This indicates a shift in the EBM practice from offline to online. By providing access to online medical information, ICT facilitated the practice of online EBM [31-34].

Furthermore, the emergence of the internet and the World Wide Web sparked the development of online medical search domains and medical databases. Medical search domains and databases are designed with built-in customized search features to assist the searcher in finding relevant medical information in the shortest amount of time. Examples of such online medical search domains are PubMed, UpToDate, and the British Medical Journal. Information seeking is also an important part of the learning process, which includes searching, obtaining, and using information for evidence [35]. According to the findings of research studies, medical practitioners who use specialized medical information retrieval systems find them useful. They specifically reduced the amount of time needed to search for information and made it easier to incorporate searching into their medical workflow processes [4,26,36-38]. Nonetheless, it is critical to ensure that evidence is searched appropriately using ICT to retrieve only validated and reliable medical information during EBM practice [4,38].

Information Searching Process Model

No evidence that explicitly defines the online searching process within the practice of EBM as the practice of EBM moved from offline searching to online searching. As a result, no search models exist to describe online EBM searching. However, EBM guidelines were developed to help medical practitioners practice EBM [24,39-41]. Sackett's 5-step guide, depicted in Figure 1, is the most used guideline, and consists of 5 parts: inquire, access, appraise, apply, and evaluate [6].

As EBM practice has shifted to online, the information searching process (ISP) model (Figure 2) is the closest model that adapts to the online EBM searching process and describes the holistic experience of a typical searcher when searching for information [42]. It is the most appropriate model to explain the ISP within the context of EBM practice because it is a groundbreaking theory that models the holistic approach of a typical searcher. The ISP model is divided into 6 stages: initiation, selection, exploration, formulation, collection, and presentation [42]. All stages in the ISP model are adaptable and can be mapped to the EBM searching process.

When looking at the stages of the ISP model, there are 3 that are related to the online searching process: exploration, formulation, and collection. These stages describe the process of searching for information on the internet, including the formulation and reformulation of queries as well as the collection of desired information. They are analogous to the second step of the EBM guidelines, namely the access phase when practicing online EBM. In the EBM guidelines, the access phase denotes the process of searching for medical information (ie, accessing online resources to obtain information for clinical queries). As a result, the ISP model and EBM guidelines can be better classified as (1) querying behavior and (2) result viewing behavior. A thorough investigation of these behaviors was conducted in this study to provide a better understanding of online information-searching behavior during EBM practice. Another technique for searching for information, described by Bates [43], is insufficient because it involves interaction between the documents to be searched and the systems or browsers used, like the berry-picking process. The search for information will alter the overall search process, requiring users to investigate new information. This will provide the user with new directions to follow, which will change the search terms and queries.

Figure 1. The 5-step guide to practice evidence-based medicine (adapted from Sackett [6]).

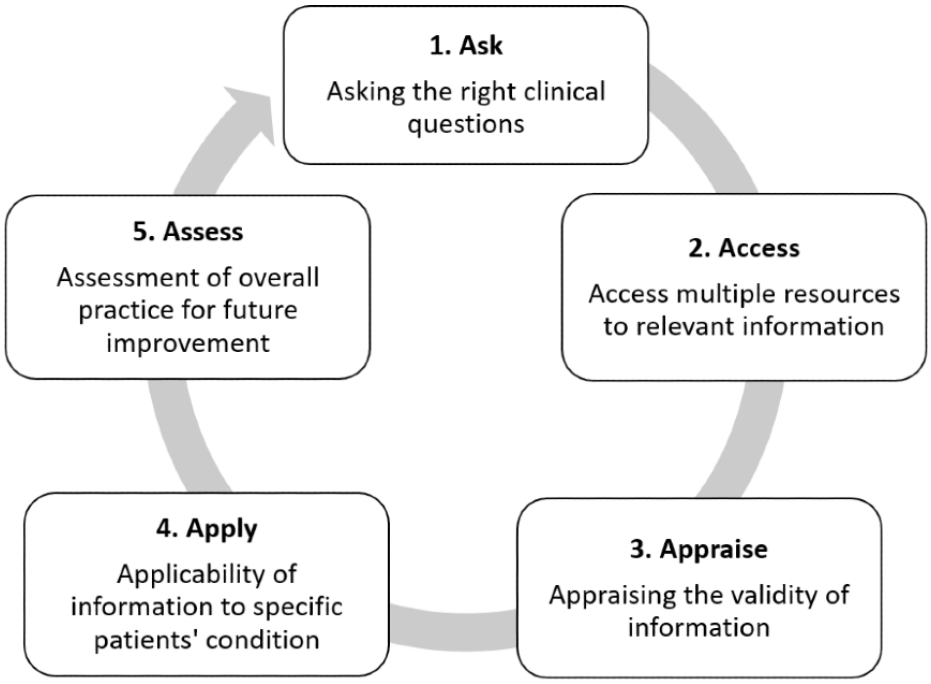

Figure 2. Information searching process model (adapted from Kuhlthau [42]).

Model of the Information Search Process

	Initiation	Selection	Exploration	Formulation	Collection	Presentation	Assessment
Feelings (Affective)	Uncertainty	Optimism	Confusion frustration doubt	Clarity	Sense of direction/ confidence	Satisfaction or disappointment	Sense of accomplishment
Thoughts (Cognitive)	Vague →			Focused →		Increased interest	Increased self-awareness
Actions (Physical)	Seeking relevant information			Seeking pertinent information			
	Exploring →				Documenting		

Previous Studies on Querying Behavior and Result Viewing Behavior

A few previous studies reported on querying behavior during the EBM practice [44-47]. These research studies were conducted on a single search domain and were based on self-perception of the search process. These studies did not include equally important aspects of querying behavior, such as the number of queries issued and query reformulation. According to the findings of research studies examining results viewing behavior during the practice of EBM, challenges are also encountered in this stage of the information seeking process [5,44,48,49]. Therefore, this study aims to explore and describe the online information-seeking behavior of EBM practitioners at the point of care where information-seeking activities were documented. Findings from this study can be used to design initiatives to improve the online searching process during the EBM practice.

Methods

A cross-sectional study was conducted from 2015 to 2018 at the University of Malaya Medical Center, a tertiary teaching hospital in Malaysia.

Setting

This study was conducted in the neonatal intensive care unit (NICU). The unit admitted 30 newborn infants per month on average, all of whom required critical care and constant monitoring. A clinical team of consultants, specialists, medical officers, science officers, nurses, and medical students will conduct clinical rounds at the NICU twice a day, every day (morning and evening). Two portable laptops were placed on a mobile trolley inside the NICU for use during clinical rounds. A few stationary desktop computers were also provided to aid in the search for clinical information. When a clinical question arose, members of the clinical team searched for answers using laptops or desktop computers preloaded with electronic databases such as the Cochrane Library and PubMed. The clinical team was told to search these electronic databases whenever they needed to for clinical queries.

Ethics Approval

This study was approved by the Monash University Human Research Ethics Committee (project ID 4690). Further, the data collection methods for this research study were approved by the medical ethics committee of the University of Malaya Medical Council (MEC ID No. 201311-0506).

Participants

A total of 47 participants were recruited from clinical teams that made clinical decisions for their patients' care by constantly referring to the best empirical evidence. They were routinely involved in online search activities that took place during the study period between December 2015 and December 2018. A research assistant was present during these online activities.

Data Collection

A standardized questionnaire containing information on the demographic characteristics of the participants was used to collect data. The questionnaire also included a structured observation involving the length of the search, time of the search, and method of search (either advanced or simple search) for 2 electronic databases. Before analysis, all data were deidentified. The process was documented through video recordings of the computer screen made with the Morae Manager (TechSmith Corp) key-logging recorder, and search terms were transcribed to a spreadsheet. Whenever a query was entered into the search field (eg, infan* or newborn or neonat* or premature or preterm or very low birth weight or low birth weight or VLBW or LBW) of the web browser or the search field of the search engine, the queries were observed and recorded using the Morae recordings. For both databases, a search strategy was developed. The keywords were identified before the search based on the clinical queries of participants/problems, interventions, comparisons, and outcomes (PICO). Using advanced search and Medical Subject Headings (MeSH) terms, similar terminology for each PICO will be identified. The literature search identified the information in all languages. The information collated included the number of queries, keywords used, length of the query (determined by calculating the number of terms/words used in a single query), use of Boolean operators (such as AND, OR) in queries, proportion of queries with typing and other errors, and the proportion of repeat queries to answer the same clinical question. For postsearch interviews, voice recordings were made and transcribed verbatim using NVivo (version 10, QSR International) software.

Data Analysis

The data were analyzed for descriptive statistics using SPPS (version 22, IBM Corp) software for participant characteristics and online search, including querying pattern, resulting viewing pattern, and search duration. We presented the data collected from postsearch interviews narratively.

Results

Participant Characteristics

The characteristics of the participants are shown in Table 1. The participants included medical students, house officers, medical officers, and specialists.

Table 1. Demographic details of participants.

Variable	MS[a] (n=15)	HO[b] (n=19)	MO[c] (n=8)	Specialist (n=5)
Gender, n (%)				
Female	6 (40)	12 (63)	7 (88)	4 (80)
Male	9 (60)	7 (37)	1 (123)	1 (20)
Age (years), mean (SD)	23.4 (0.6)	26.4 (1.9)	31.8 (4.1)	35.2 (5.7)
Age (years), range	23-24	24-32	26-39	28-41
First language spoken, n (%)				
English	1 (5)	7 (40)	2 (25)	4 (80)
Malay	6 (40)	10 (50)	3 (38)	1 (20)
Chinese	7 (50)	2 (10)	2 (25)	0 (0)
Tamil	1 (5)	0 (0)	1 (13)	0 (0)

[a]MS: medical student.

[b]HO: house officer.

[c]MO: medical officer.

Reason for and Manner of Searches

Of the 99 searches, house officers conducted the most (51/99, 52%), followed by medical students (32/99, 32%), medical officers (10/99, 10%), and specialists (6/99, 6%). Most search activities were directed at junior members of the team, such as medical students and house officers, and self-initiated searches increased with seniority. Most of the search activities were carried out individually, with only a few carried out collaboratively (Table 2). Many participants used simple search strategies that consisted of one or more keywords entered alongside each other without the use of synonyms or any type of Boolean operator.

Table 2. The reason for and manner of searches.

Search type	MS[a] (n=32), n (%)	HO[b] (n=51), n (%)	MO[c] (n=10), n (%)	Specialist (n=6), n (%)
Search initiation				
Self-initiation	10 (31)	10 (20)	4 (40)	5 (83)
Instructed	22 (69)	41 (80)	6 (60)	1 (17)
Search activities				
Individual	30 (94)	46 (90)	8 (80)	5 (83)
Collaborative	2 (6)	5 (10)	2 (20)	1 (17)

[a]MS: medical student.

[b]HO: house officer.

[c]MO: medical officer.

Querying Activity

The querying activity represented the participants' querying patterns during the search sessions. Whenever a query was entered into the search field of the web browser or search engine used to find information, the Morae recordings were observed and recorded. The querying activity's results were presented in terms of participant categories and search types (foreground [FG] or background [BG]). FG refers to the user application and BG refers to the programs that are behind the scene. The results were further classified according to the number of queries issued, average query length, use of medical terms in queries, use of stop words and operators in queries, queries with spelling errors, issuance of ineffective queries, and reissuance of the same query. Table 3 shows the total number of queries issued and average query length.

Table 3. Number of queries issued and average query length of the queries issued.

Query	MS[a] (n=15)		HO[b] (n=19)		MO[c] (n=8)		Specialist (n=5)	
	BG[d] (s=26)	FG[e] (s=6)	BG (s=45)	FG (s=6)	BG (s=8)	FG (s=2)	BG (s=3)	FG (s=3)
Queries issued								
Sum	54	11	160	30	28	7	9	12
Mean (SD)	2.08 (1.1)	1.83 (1.17)	3.56 (3.2)	5 (2.8)	3.5 (2.3)	3.5 (2.1)	3 (2)	4 (4.4)
Range	1-5	1-4	1-14	2-9	1-7	2-5	1-5	1-9
Query length, average								
Sum	98.6	42	159.1	23.4	28.7	9	18.2	14.6
Mean (SD)	3.8 (1)	7 (2.6)	3.5 (1.4)	3.9 (1)	3.6 (2.3)	4.5 (2.1)	6 (1)	4.9 (4.4)
Range	2-6	5-12	1.5-8	2.6-5	1.7-6	3-6	5-7	1-9.6

[a]MS: medical student.
[b]HO: house officer.
[c]MO: medical officer.
[d]BG: background.
[e]FG: foreground.

Use of Medical Terms

Cross-checking the terms with medical terms in the MeSH library revealed the number of medical terms issued within a query. According to the results, 70.1% (218/311) of the queries issued were medical queries that included some medical terms. The participants used 307 medical terms, with an average of 1.4 medical terms per medical query recorded. The results also revealed that participants who frequently used medical terms in the queries were the house officers, who used an average use of 3.7 medical terms in the queries issued, as opposed to the medical students, medical officers, and specialists, who used a mean number of 2.3, 3.5, and 2.3 medical terms, respectively. The evidence from the participants' verbal utterances suggested that they had included medical terms in their queries to retrieve more relevant results. Table 4 contains information on the medical terms used in the participant queries.

Table 4. Details of the use of medical terms in the queries issued.

Variable	MS[a] (n=15)		HO[b] (n=19)		MO[c] (n=8)		Specialist (n=5)	
	BG[d] (s=26)	FG[e] (s=6)	BG (s=45)	FG (s=6)	BG (s=8)	FG (s=2)	BG (s=3)	FG (s=3)
Medical terms								
Sum	59	7	166	28	28	4	7	8
Mean (SD)	2.3 (2.2)	1.2 (0.9)	3.7 (4.2)	4.7 (4.9)	3.5 (4.2)	2 (1.4)	2.3 (3.2)	2.7 (3.8)
Range	0-8	0-3	0-16	0-13	0-12	1-3	0-6	0-7
Queries with medical terms								
Sum	35	5	125	19	18	3	5	8
Mean (SD)	1.4 (1.1)	0.8 (0.4)	2.8 (2.8)	3.2 (2.8)	2.3 (2.1)	1.5 (0.7)	1.7 (2.1)	2.7 (3.8)
Range	0-4	0-1	0-11	0-7	0-6	1-2	0-4	0-7
Queries with medical terms, n (%)								
Yes	29 (73)	5 (83)	39 (87)	4 (67)	7 (88)	—[f]	2 (67)	2 (67)
No	7 (27)	1 (17)	6 (13)	2 (33)	1 (13)	—	1 (33)	1 (33)

[a]MS: medical student.
[b]HO: house officer.
[c]MO: medical officer.
[d]BG: background.
[e]FG: foreground.
[f]Not applicable.

Use of Stop Words and Boolean Operators

According to the results of the analysis, stop words were used in only 65% (17/26) of the searches. The findings of this study differed from those of previous studies [45,46], which found that stop words were used in 80% of the searches conducted. The remaining searches lacked stop words in their queries, and the vast majority were BG-type searches. When examining the number of stop words used in the queries, FG-type searches had more stop words (1-4 stop words) than BG-type searches (1-3 stop words). The stop words used in this study were "in," "of," "on," "is," "for," "and," and "with." The participants in this study did not frequently use Boolean operators in their queries (Multimedia Appendix 1). Only 4 of the searches had queries issued with Boolean operators, which were issued by the house officers. In this study, the operators used were the double quotation mark, bracket, and AND operator.

Search Activities

A total of 311 queries during 99 search sessions were issued by the participants, with a mean of 3.14 (SD 2.6) queries. Participants who were house officers issued the most queries (51/99, 52%), followed by medical officers (10/99, 10%), medical students (32/99, 32%), and specialists (6/99, 6%). The participants spent an average time of 2.3 hours per day searching for medical information, with a single medical information search lasting 21 minutes on average. The average number of queries issued by all participants ranged between 2 and 4 queries. The mean number of queries issued in the BG- and FG-type search categories differed slightly, with FG-type searches recording 3.5 (SD 2.7) queries, slightly higher than BG-type searches, which recorded 3 (SD 2.6) queries.

In total, 307 distinct medical-related keywords were used in the searches. The length of the participant queries were then checked. The length of a query was calculated based on the number of terms/words used in a single query. The average query length in this study was 3.9 (SD 1.76) words. Specifically, the mean query length for FG-type searches was 5.2 (SD 2.6) words, which was higher than the mean query length of BG-type searches, 3.71 (SD 1.4) words. Query length averages issued by house officers and medical officers were comparable, at 3.6 and 3.7 terms, respectively. Multimedia Appendix 2 depicts the issuance of queries with spelling errors, ineffective queries, and the reissuance of the same query. A total of 4% (4/99) of searches used Boolean operators, with "AND" being the only one. Spelling errors were found in 6.8% (21/311) of the queries. Participants were aware of the errors made after the search and reran the searches with the correct spelling.

Result Viewing Activity

The number of results and sublinks clicked, number of tabs used to view results, and control functions used in searches were used to analyze participant result viewing activity. When participants used the search engine to access a specific link or webpage after the queries were issued, the number of results clicked was displayed (Multimedia Appendix 3). According to the findings of this study, 377 results were clicked when looking for information. Of these, 302 came from BG-type searches and the rest from FG-type searches. The mean number of results clicked in this study was 3.81 (SD 3.11). According to the data, the mean number of results clicked in FG-type searches was 4.41 (SD 3.043), while the mean number of results clicked in BG-type searches was 3.68 (SD 3.13). This indicates that there was a higher level of result viewing activity when searching for FG-related information.

When participants proceeded to click on the links presented in the result clicked/webpages visited, the number of sublinks clicked was recorded. In this study, the mean number of sublinks clicked was 1.27 (SD 2.43), with the mean value being higher in FG-type searches (1.82, SD 3.067) compared to BG-type searches (1.16, SD 2.29). The participants' verbal utterances revealed that they clicked on the sublinks during the FG-type searches because of progressive searching within a result/webpage to gain a better understanding of the subject matter being searched.

An interesting pattern in the use of multiple tabs during searching was discovered during the analysis of the result viewing activity (Multimedia Appendix 4), which depicts the number of tabs opened and control functions used by participants. Of the total searches observed, 65.6% of participants viewed their results in more than one tab. The mean number of tabs used was 3.15 (SD 2.86). The mean number of tabs in FG-type searches was 4.29 (SD 3.53) compared to 2.91 (SD 2.66) in BG-type searches. This indicates that more tabs were opened during the result viewing process in FG-type searches than in BG-type searches. Participants who used control functions indicated that they were successful in finding the information they were looking for.

The analysis of the result viewing activities of the participants revealed the use of control functions when viewing results or webpages. In the postsearch interview, participants who had used control functions in their searches were asked why they had done so. Their responses were: "to improve the searching process" and "to skim through important content only." In their result viewing activity, only 4 BG searches by a medical officer and 3 by medical students used control functions. CTRL-F (in 2 searches) and CTRL+ were the control functions used in this study. The CTRL-F function was used to search the information on the results page for terms like "defin," "1P," "size," "mm," and "pda." In the results presented, the CTRL+ function was used as a zoom-in function to improve the viewing of images and text.

Discussion

Principal Findings

Previous studies evaluating search practices in health care trainees and practitioners relied heavily on participant perceptions of previous searches [13,23,44-47,50-52]. There have been no studies that have assessed search activities in an acute clinical setting based on direct observation of real-time searches as far as we are aware. Despite limitations in the period of engagement due to restrictions related to the nature of the NICU and disruption of the study period, our observations yielded useful information. The majority of those who took part were house officers who had been ordered by their superiors to

conduct searches, usually alone. There were 3 queries per search session on average, with 4 words used in each query. Relevant evidence appeared to be found in more than three-quarters of cases, and in roughly two-thirds of cases, there was more than one source of relevant evidence. Junior members of the clinical team who were tasked with conducting searches to answer multiple questions posed by senior team members in a short time may encounter difficulties in locating the best evidence. This included ownership of queries, content expertise, search techniques, and the absence of another person to provide input into the search process. Due to time constraints or a lack of clarity in terms of the questions posed, the challenges may have resulted in errors and ineffective searches that were not followed up on. Identifying the best evidence among multiple sources could also be difficult, although this study did not assess how the searchers dealt with this. It has been demonstrated that increasing the use of medical terms in queries increases the likelihood of retrieving the desired information [45,46]. If well chosen from a focused clinical question, the average query length of 4 words in this study was usually sufficient for an effective quick search to retrieve some relevant evidence, either in a repository of primary studies such as PubMed or in preappraised resources such as the Cochrane Library [53].

There have been no previous studies that have reported findings on the result clicking behavior among medical students in terms of result viewing activity. In this study, the medical students used search tabs more frequently when looking for FG-related information. In addition, when compared to house officers, medical officers, and specialists, medical students used the most tabs while searching. When viewing the results of the click, the control functions were also used. In terms of the number of sources accessed, medical students accessed the fewest in the BG-type searches. The medical students indicated PubMed and MEDLINE as their preferred sources of information based on the searches they conducted.

In this study, house officers demonstrated the most active search behaviors. When compared to medical students, medical officers, and specialists, they conducted the most overall searches (54.5% of the total searches recorded in this study). During searches, house officers had the most querying activity (the highest average number of queries issued, the highest number of stop words used in queries issued for FG-type searches, the highest number of queries issued with spelling errors, and the most ineffective queries). The findings of this study contradict previous findings, which indicated a lower number of queries issued when participants searched for EBM-related information [44,45,47].

The medical officers' search behaviors in this study were straightforward. They had completed 10.1% of all recorded searches, with 80% yielding successful outcomes. In their querying activity, they demonstrated simple search behaviors by issuing a higher average number of queries and a longer average query length. They also used the fewest stop words in both their FG- and BG-type searches, had no spelling errors in their queries, and included medical terms in all of their FG-type searches. Although the simple search behaviors demonstrated by medical officers were effective in producing successful outcomes, the findings of this study do not agree with previous research findings. Previous research found that the number of queries issued was lower and the average query length was shorter [44,45,47].

In this study, the specialists displayed 2 types of searching behaviors: uncertain and expert. The specialists' uncertain behavior was mirrored in their querying activity. Specialists issued the most queries in FG-type searches compared to BG-type searches, the longest average query length in BG-type searches, the fewest medical terms used in FG-type searches, and the most stop words used in all BG-type searches. In addition, specialists issued a greater number of ineffective queries in their BG-type searches than in their FG-type searches. Such behaviors by specialists were classified as uncertain and differed from previous studies, which reported fewer queries issued, a greater number of medical terms used, and the use of stop words to prevent the searcher from searching for their desired information [44-47,54]. This uncertain behavior of the specialists indicates the need for better information retrieval strategies to improve their online searching behaviors during the EBM practice. The findings point to a possible focus on training to improve the effectiveness of searches. These include the target participants of junior doctors and medical students, techniques for converting clinical encounter queries into well-constructed questions with relevant keywords, recognition of types of research that are most likely to answer specific questions, ranking of keywords to determine their order in searches, and appropriate use of Boolean operators.

Limitations

Our study has some limitations. First, our findings may not be generalizable because they were conducted in a clinical practice setting with a specific team structure and facilities. Although most hospitals have a hierarchical structure like the one used in our study, the nature of task delegation, particularly in information retrieval, may differ across countries. Furthermore, because the search sessions recorded in this study were limited to selected morning clinical rounds, the information gathered over a very limited cumulative engagement period may not represent the participants' true search behaviors. The type and amount of prior training received by the searchers may differ, which may result in different search patterns and results. On the other hand, as part of evidence-based practice, the NICU studied was provided with devices conducive to online searching and such facilities may not be widely available in places with limited resources.

Conclusion

In conclusion, our study found that junior doctors were the primary individuals tasked with searching for clinical evidence in the NICU of a tertiary hospital in Malaysia. They mostly searched on their own, using simple, quick search strategies based on a few keywords. In three-quarters of the cases, they recovered what appeared to be relevant evidence, failing in one-quarter of the cases. This suggests that different search behavior profiles are required among the various types of EBM practitioners. The searches recorded in this study were based on clinical problems encountered by the EBM practitioners to reflect the participants' true search behaviors. According to the findings of this study, different online searching behaviors were

observed during the practice of EBM among different types of EBM practitioners. More research should be conducted on the facilitators and challenges of real-time searches in clinical settings, types of questions asked, and quality of evidence retrieved, as well as the association between effective evidence retrieval and the provision of best evidence in guiding care and improvement in patient-important outcomes.

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Authors' Contributions

NAM, VS, and AD designed the study, performed the data collection, and wrote the first draft of the manuscript. NAM, AI, NSMD, and NC performed the data analysis and wrote the first draft of manuscript. NML supervised the study and wrote the first draft of manuscript. All authors have reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The use of stop words and operators in the queries issued.
[DOCX File , 15 KB - formative_v6i4e30687_app1.docx]

Multimedia Appendix 2
The issuance of queries with spelling errors and ineffective queries.
[DOCX File , 14 KB - formative_v6i4e30687_app2.docx]

Multimedia Appendix 3
Details of the number of results clicked and the number of sublinks clicked during result viewing activity.
[DOCX File , 14 KB - formative_v6i4e30687_app3.docx]

Multimedia Appendix 4
Details of the number of tabs opened and control functions used during result viewing activity.
[DOCX File , 14 KB - formative_v6i4e30687_app4.docx]

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Abbreviations

BG: background
EBM: evidence-based medicine
ICT: information and communication technology
ISP: information searching process
FG: foreground
LBW: low birth weight
MeSH: Medical Subject Headings
NICU: neonatal intensive care unit
PICO: participant/problems, interventions, comparisons, outcomes
SEA-ORCHID: Southeast Asia—Optimizing Reproductive and Child Health in Developing Countries

VLBW: very low birth weight

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Original Paper

Linking Individual-Level Facebook Posts With Psychological and Health Data in an Epidemiological Cohort: Feasibility Study

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Abstract

Background: Psychological factors (eg, depression) and related biological and behavioral responses are associated with numerous physical health outcomes. Most research in this area relies on self-reported assessments of psychological factors, which are difficult to scale because they may be expensive and time-consuming. Investigators are increasingly interested in using social media as a novel and convenient platform for obtaining information rapidly in large populations.

Objective: We evaluated the feasibility of obtaining Facebook data from a large ongoing cohort study of midlife and older women, which may be used to assess psychological functioning efficiently with low cost.

Methods: This study was conducted with participants in the Nurses' Health Study II (NHSII), which was initiated in 1989 with biennial follow-ups. Facebook does not share data readily; therefore, we developed procedures to enable women to download and transfer their Facebook data to cohort servers (for linkage with other study data they have provided). Since privacy is a critical concern when collecting individual-level data, we partnered with a third-party software developer, Digi.me, to enable participants to obtain their own Facebook data and to send it securely to our research team. In 2020, we invited a subset of the 18,519 NHSII participants (aged 56-73 years) via email to participate. Women were selected if they reported on the 2017-2018 questionnaire that they regularly posted on Facebook and were still active cohort participants. We included an exit survey for those who chose not to participate in order to gauge the reasons for nonparticipation.

Results: We invited 309 women to participate. Few women signed the consent form (n=52), and only 3 used the Digi.me app to download and transfer their Facebook data. This low participation rate was observed despite modifying our protocol between waves of recruitment, including by (1) excluding active health care workers, who might be less available to participate due to the pandemic, (2) developing a Frequently Asked Questions factsheet to provide more information regarding the protocol, and (3) simplifying the instructions for using the Digi.me app. On our exit survey, the reasons most commonly reported for not participating were concerns regarding data privacy and hesitation sharing personal Facebook posts. The low participation rate suggests that obtaining individual-level Facebook data in a cohort of middle-aged and older women may be challenging.

Conclusions: In this cohort of midlife and older women who were actively participating for over three decades, we were largely unable to obtain permission to access individual-level data from participants' Facebook accounts. Despite working with a third-party

developer to customize an app to implement safeguards for privacy, data privacy remained a key concern in these women. Future studies aiming to leverage individual-level social media data should explore alternate populations or means of sharing social media data.

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KEYWORDS

social media; cohort; psychological factors; recruitment; feasibility; middle-aged and older adults; women

Introduction

Substantial research has demonstrated that psychological factors (eg, depression and optimism) and their related biological and behavioral responses are associated with physical health and the risk of chronic diseases of aging [1-3]. The majority of research in this area relies on self-reported assessments of psychological factors, which can be difficult to scale because they can be expensive to administer and time-consuming to complete, and therefore impose substantial burdens on participants and investigators. As a result, investigators are increasingly interested in social media as a novel and convenient platform for obtaining information efficiently in large populations. Developing such low-cost low-burden methods for unobtrusively obtaining assessments of psychological factors at the individual level, which can then be linked with individual health and other types of data, may expand capacity and efficiency for examining how psychological factors impact health.

A small but growing body of research suggests that various psychological factors can be measured using machine learning–derived algorithms that harness social media "big data." For example, a recent study leveraged text from 5100 public Facebook status updates and built models to assess an individual's level of psychological well-being (characterized by positive emotions and meaning/purpose in life) embedded within any particular Facebook status update. When comparing algorithm-derived scores with scores annotated by human raters, investigators found moderate correlations of 0.4-0.6 [4]. In another study of 66,732 Facebook users using anonymous data, researchers created an algorithm to estimate other psychological factors similar to Big 5 personality measures; correlations between self-reported and algorithm-based scores derived from social media similarly ranged from 0.4 to 0.5 [5]. Moreover, research has suggested that measures of psychological functioning derived from social media can be used to predict health status. One study examined Twitter posts in 1347 US counties, covering 88% of the US population, and derived measures of psychological functioning using machine learning [6]. Each county was then scored according to levels of negative and positive psychological factors (eg, anger, anxiety, positive emotions, and engagement), and cross-sectional analyses evaluated if these factors were related to county-level rates of heart disease mortality. The psychosocial measures derived from Twitter language were strongly associated with heart disease mortality rates.

However, most studies using social media data to assess psychological functioning in relation to health are ecological (eg, county-level psychological and health data) and cannot link individual-level psychological measures derived from social media to individual-level health outcomes [7,8], a critical methodological element for making causal inferences. Thus, it is important to test the use of social media platforms for individual-level research in cohort studies, where information on demographics and lifestyle, as well as longitudinal data on chronic diseases are available, and enable both the identification of direct relationships and control of potential confounding factors. In particular, Facebook is the most widely used social media platform in the world, with over 2.7 billion users [9]. It has the potential to provide a substantial amount of data on individuals who are posting large quantities of text over extended periods. Moreover, while the majority of Facebook users are young adults, 22% of users are over 45 years of age [10]. To our knowledge, social media approaches to psychological measurement have not been applied in prospective cohort studies of midlife and older adults. Linking psychological factors derived from social media with rich epidemiological data from large prospective studies of midlife and older adults could enable the rigorous and efficient understanding of new perspectives on psychological factors and health outcomes. Therefore, we leveraged the Nurses' Health Study II (NHSII), an ongoing cohort study of women aged 56 to 73 years in 2020, to examine the feasibility of obtaining participant Facebook data to derive measures of psychological factors.

Methods

Study Population

The NHSII is a prospective cohort study that was launched in 1989 among 116,429 US female nurses aged 25 to 42 years at the study onset. At baseline, all participants completed a questionnaire including basic sociodemographic characteristics, lifestyle factors, and medical conditions. The cohort was originally followed using biennial mailed questionnaires to update information on these factors and further assess psychosocial factors. Approximately 60,000 of the women now complete questionnaires online; the follow-up rate since study inception is nearly 90% [11].

The 2017-2018 online questionnaire assessed psychosocial factors, such as optimism, depression, and social support. Items also requested information regarding participants' use of social media. Specifically, the questionnaire included the following items: "Do you regularly post updates or information on social media (rather than just viewing or *liking* posts)?" Among women who answered "yes," a follow-up question asked which of the following sites participants used: (1) Facebook, (2) Instagram, (3) Twitter, and (4) other. Ultimately, 18,519 participants reported regularly posting on Facebook. Very few (7%) reported

using other social media outlets. Thus, in April 2020, we initiated the study to request Facebook data.

Protocol

Obtaining Facebook Data

When collecting any type of individual-level data, privacy is an important concern, and this concern is potentially magnified when collecting information on individuals that was not originally intended for use in a scientific study. At the time this study was initiated, Facebook was not sharing personal data for investigators to use in the context of scientific research. Thus, such data could only be obtained directly from participants. To reduce privacy concerns, we chose to ask participants only for text from Facebook posts they wrote and did not ask for any other content, including photos, links, or posts written by friends. We worked with third-party software developers at Digi.me to modify a program that would enable participants to obtain their own Facebook data and then to send the text of their posts only to our research team securely. The original Digi.me app enables individuals to obtain and store their own digital content from various sources (eg, finances, health, and social). For our study, we customized the original app, including a process by which Facebook text could be securely transferred from each participant to the NHSII server. We also developed simple instructions for use. The NHSII Digi.me app transferred only the text of participants' Facebook posts.

Ethics Approval

The Brigham and Women's Hospital Institutional Review Board and Information Security Office conducted an ethical review and a security review of the modified app, as well as the research protocol, and granted approval for the study (2018P002265).

Participant Recruitment and Consent

An email invitation was sent to a random subset of the women who reported being regular Facebook users in 2017-2018. The email included a brief description of the study and an informed consent form. If consent was given, participants received an email with instructions for using the NHSII Digi.me app. The app enabled them to (1) securely and privately download their individual Facebook posts, and (2) encrypt and securely send their Facebook text to NHSII servers, to be stored behind a firewall. Participants were informed that Digi.me only enables the secure transfer of information and does not see data at any point.

Recruitment Waves

We conducted 3 waves of recruitment. In the initial data collection (Wave 1) occurring in April 2020, we invited a random subset of 40 eligible participants by email. We began the work slowly by inviting a small random subset of eligible participants instead of inviting all participants at once because the Facebook study involved new technology (eg, Digi.me) and potentially large amounts of data transfer. In the second data collection wave (Wave 2), occurring between June and September 2020, we sent the invitation email to a further 269 randomly selected eligible women. In a separate step in September 2020 (Wave 3), we sent an email to participants who had consented to provide their Facebook text but had not transferred their data. The email contained information describing how we had fixed a technological issue, simplified the instructions for the use of Digi.me, and explained that anyone still interested could try to send their Facebook text.

Measures

Our primary outcomes were the following 2 feasibility measures: the percentage of invited participants who consented to share their Facebook data, and the percentage of invited participants who ultimately provided their Facebook posts. We also conducted an exit survey for eligible women who declined to participate in the Facebook study. These women received a single multiresponse question by email. Women were asked to indicate the reasons why they refused to participate with the following 5 response options: (1) lack of time due to increased work responsibilities, (2) lack of time overall, (3) discomfort using Digi.me because of privacy concerns, (4) discomfort using Digi.me because of dislike of technology/apps, and (5) discomfort about sharing Facebook posts. An open-ended response option was also provided. We chose to do an exit survey to gather data on recruitment and participation in the least burdensome way possible for participants.

Statistical Analysis

We conducted descriptive analyses (ie, percentages, means, SDs, and frequency tables) examining the demographic characteristics of participants who were eligible for the study, the percentage of women who consented to send Facebook data, the percentage of women who provided Facebook posts, and the responses to the exit survey.

Results

Descriptive Data

Among the 18,519 women who reported regular Facebook use (Table 1), ages ranged from 56 to 73 years, with a mean age of 65 years (SD 4.7 years). Overall, 93.8% (17,361/18,519) were White, 73.2% (13,549/18,519) were married, and 82.4% (15,261/18,519) lived in an urban area. The median census home value was US $165,000 (SD US $115,000).

Table 1. Characteristics of women eligible for the study to collect Facebook posts (Nurses' Health Study II, 2020; N=18,519).

Characteristic	Value
Age (years), mean (SD)	65.4 (4.7)
Race, n (%)	
White	17,361 (93.8)
African American	160 (0.9)
Other	998 (5.4)
Marital status, n (%)	
Married	13,549 (73.2)
Divorced/separated	3,506 (18.9)
Widowed	739 (4.0)
Missing	725 (3.9)
Median home value (census tract; US$), mean (SD)	165,000 (115,000)
Urbanicity of residence, n (%)	
Urban	15,261 (82.4)
Suburban	1,830 (9.9)
Small town/rural	1,424 (7.7)
Missing	4 (0.0)

Wave 1 Data Collection

Of the 40 women invited, only 4 (10%) participants signed a consent form. Given the low initial participation rate, we paused recruitment to consider potential reasons and modify our strategy accordingly. We identified several possible concerns regarding the initial lack of participation: (1) the first surge of cases due to the COVID-19 pandemic crisis was occurring at the time, and this may have impacted participation among our nurse participants, and (2) the brief invitation email may not have adequately addressed possible participant concerns regarding the technological burden and personal data sharing involved in the Facebook study. Thus, we modified the study in several ways. First, we excluded women who reported on the 2019 NHSII questionnaire that they were active health care workers. Second, we developed a Frequently Asked Questions factsheet and included it as a link in the invitation emails; this factsheet included more detailed information regarding the steps required to use the technology and the actions we had taken to maximize data security and privacy (eg, encryption). Finally, as described previously, we also included the exit survey inviting women who did not want to participate to provide their primary reasons for not participating.

Wave 2 Data Collection

Of the 269 randomly selected participants invited in Wave 2, 48 women (17.8% of Wave 2 invited participants) completed a consent form to participate in sharing their Facebook posts. Among these 48 women, 3 used the Digi.me app to send their Facebook posts (1% of Wave 2 invited participants). Further, 23 women who did not complete the consent form responded to the brief exit survey describing their concerns about participation (Table 2). Each participant could provide more than one response. Of the 23 women, 3 (13.0%) noted that they did not have time to participate, 8 (34.8%) indicated they had concerns regarding privacy, 1 (4.3%) indicated not liking the use of apps, and 12 (52.2%) indicated they did not want to share all the information in their Facebook posts. In addition, 6 women (26.1%) provided written comments in the space for "other concerns;" these mostly involved comments that they had stopped using Facebook or used it only in a very limited way. Further, on receiving the Facebook text from 3 participants, we identified some problems in the data transfer; the 3 women also emailed that they found the directions for using Digi.me somewhat complex. Thus, before initiating a third wave of invitations, we fixed the data transfer issue and also simplified the instructions for using Digi.me.

Table 2. Reasons for choosing not to participate in the study to send Facebook text (Nurses' Health Study II; N=23).

Reason provided in the survey[a]	Value, n
I am working more than usual and do not have time	2
I would have been interested in participating if I had more time	1
I don't feel comfortable using digi.me because of privacy concerns	8
I don't feel comfortable using digi.me because I do not like technology/apps	1
I don't feel comfortable sharing my Facebook posts	12
Other	6

[a]Women were requested to mark all responses that were relevant to them.

Wave 3 Data Collection

In the third data collection that occurred in September 2020, we sent an email to a total of 49 women (15.9% of all invited participants) who had consented to provide their Facebook text but had not transferred the data. The email explained that we had fixed a technological issue and simplified the instructions for use of Digi.me, and that anyone still interested could send their Facebook text. However, we received no additional data transfers.

Of the 309 participants invited overall, 52 consented (16.8%) and 3 attempted to transfer data (1.0%). On carefully considering the low rate of participation, we decided to end the Facebook study and did not send invitations to the remaining eligible women.

Discussion

The goal of this study was to examine the feasibility of using social media data to assess psychological factors, and ultimately examine if these passively measured factors were associated with health outcomes. We queried middle-aged to older women in an ongoing cohort study, the NHSII, on their use of social media. A substantial number reported regularly posting on Facebook (approximately 28%), and few reported using other platforms (eg, 5% Instagram and 2% Twitter) [12]. Working with an industry partner, we developed a customized app to enable participants to download their Facebook data and to transfer Facebook text to the cohort servers using highly secure processes. However, despite providing information about their health and behavior for over three decades on biennial questionnaires and giving biospecimens (eg, blood and toenails) on more than one occasion, very few women agreed to share their Facebook data for cohort research. On exit surveys, women noted that the key issues were concerns about sharing social media data and worries about privacy.

Much of the research to date considering social media data in relation to health has relied on ecological-level data, namely using county-level aggregated social media data from Twitter and linking the data to measures of health status from the same counties [6,13]. Other work has used a computational approach to identify publicly available social media data from the profiles of users who self-disclose health status information in some way, without any means to verify the health information [14,15] and with little available information on other potential confounding factors (eg, sociodemographics, health status, and lifestyle factors). Such work can provide important insights and novel strategies for identifying public health concerns (eg, rising rates of depression) [16]. However, additional insights may be gained by linking social media–derived measures of psychological or behavioral functioning with individual-level health outcomes.

The few early studies seeking to collect this type of data seemed encouraging. For example, in a study of patients in an emergency department, researchers approached individuals over a 26-month period to invite participants to share Facebook postings as well as data from medical records [17]. Of 11,224 individuals who were approached, 2903 consented and were eligible. Among these, 1175 participants (44%) were able to log into their Facebook accounts and share their data with the investigators through an app. Notably, the mean age of consenting individuals was 29 years, and the majority were Black women. Another study recruited 223 participants, primarily psychiatric patients, to participate in a study examining if Facebook data could differentiate participants with different psychiatric diagnoses, drawing on individual-level psychiatric data from medical records [14]. The mean age of the participants was 24 years, with majority being female and White individuals. In a similar study, other authors recruited participants from an emergency room to obtain social media data and access to their electronic health records. Of the 5256 individuals approached, 2717 (52%) were Facebook and/or Twitter users, and among the social media users, 1432 (53%) agreed to participate in the study. Of these participants, 1008 (71%) consented to share their social media data for the purpose of comparing the data with their electronic medical records [7]. Participants who were willing to share their social media data were younger (29.1 years among sharers vs 31.9 years among nonsharers), more likely to be Black, less likely to be White or Asian, and more likely to frequently post on social media. Clearly, there are many differences between these studies and our study, from the average age of participants to the very short-term requirements and data storage of these studies (ie, in contrast to NHSII research in which data are continually stored and utilized for decades).

In a recent study seeking to characterize the willingness of individuals to share 19 different types of digital data (eg, email, fitness tracker, voting history, and Google search) [8], of 595 individuals at an academic urban emergency department who were invited to participate, 206 consented and about half of

these expressed willingness to share some form of digital data. The majority of participants were young (70% were less than 44 years old), female, and Black. However, it is worth noting that among those who did participate, fewer than 50% of participants reported current willingness to share Facebook (or similar) digital data, and many identified substantial concerns around potential data and privacy breaches related to sharing digital data in general. As noted in this study, concerns about privacy may have been exacerbated after 2018, when the public learned that some companies were able to access the data of many millions of individuals' Facebook accounts without their permission.

In this study, many of the women who did consent to provide Facebook data subsequently did not download and send their data to the cohort. In the typical NHSII protocol, women provide data by filling out a detailed questionnaire every other year, which can be sent via mail or completed online. In the substudy, women needed to engage in multiple steps to provide their data, including downloading an app, creating an account on a cloud provider, linking this account to the app, and downloading and then transferring their data to the NHSII servers. Thus, the process for participating in this study required comfort with digital interfaces more than most prior data collection activities in the cohort.

In addition, women identified privacy concerns as a barrier to participation. Prior to conducting this research, we were highly sensitive to potential concerns women in our cohort might have about data privacy, particularly in the aftermath of reporting on breaches of data privacy in the context of Facebook in 2018. To reduce concerns about breaches, we worked with Digi.me, a company dedicated to facilitating individuals' control and use of their own digital data with safeguards for privacy. The app made it possible for women to download their Facebook data and then to securely transfer the relevant data to our research database. As noted above, to reduce concerns about privacy, we committed to obtaining only text, rather than images or posts from friends. Together with Digi.me, we invested substantial time and effort to customize the app to make it possible to curate the data we obtained, as well as to provide simple instructions and maximize data privacy and security. Despite these efforts, the participation rate in our study was low. Thus, it is possible that social media research may be better suited to populations who more frequently use digital apps, which may explain the higher participation rates in previous studies of younger populations [7,14,17].

The limitations of this study include the potential lack of generalizability of our findings to other populations. Our study population was made up of women who were 56 to 73 years of age, primarily white, and educated professionals. Therefore, care should be taken in extrapolating our results to other demographic groups. In addition, the potential participants were members of a long-term cohort, who have provided a large amount of personal and health data to the study previously, which may have influenced their willingness to contribute Facebook data. However, as the participants, who have developed a relationship of trust with the research for decades, did not feel comfortable sharing their Facebook data, the results would plausibly be worse in newer cohorts. Our exit survey was brief and therefore somewhat limited in that we could not tease out the exact or specific reasons why participants did not feel comfortable sharing their Facebook posts. Eventually, in this type of research, one limitation of deriving psychological factors from Facebook data is that Facebook, or other organizations, may commoditize the data for uses that are not directed toward benefitting society, for instance, targeted advertising. Although our study protocol was not successful in obtaining Facebook data or developing algorithms for deriving psychological factors using Facebook data, other researchers should be aware of the potential ethical implications of building these tools and using these data for research. Finally, another limitation of our approach is that recruitment took place during the COVID-19 pandemic. That said, the study protocol was entirely web-based, and we excluded nurses who were active health care workers, so it is unclear how the pandemic might have affected participation.

The question remains as to the range of paths for scientific research to leverage individual-level social media data to inform our understanding of health and well-being among midlife and older individuals. Future work seeking to leverage social media data to understand health will need to carefully consider the populations under study, especially barriers in recruiting older individuals who may be less familiar with such technology, and solutions for enhancing participation. In addition, researchers should conduct qualitative work to understand better how participants interact with social media, including what type of information they are willing to disclose and how they might curate their image on social media. Besides the challenges we identified, social media platforms and apps are changing rapidly, and the frequency of use and the tools developed for accessing platforms may evolve quickly. This is an area of research that must be fast-paced by definition, while infrastructure (especially processes for ensuring ethical research practices) for conducting medical research necessarily moves much more slowly. In conclusion, individual-level research using social media data will best proceed with a clear understanding of the barriers and challenges existing in specific populations and in doing research in a rapidly changing data environment.

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Conflicts of Interest

None declared.

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Abbreviations

NHSII: Nurses' Health Study II

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Original Paper

A Personalized Smartphone-Delivered Just-in-time Adaptive Intervention (JitaBug) to Increase Physical Activity in Older Adults: Mixed Methods Feasibility Study

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Abstract

Background: Just-in-time adaptive interventions (JITAIs) provide real time *in-the-moment* behavior change support to people when they need it most. JITAIs could be a viable way to provide personalized physical activity (PA) support to older adults in the community. However, it is unclear how feasible it is to remotely deliver a PA intervention through a smartphone to older adults or how acceptable they would find a JITAI targeting PA in everyday life.

Objective: The aims of this study are to describe the development of *JitaBug*, a personalized smartphone-delivered JITAI designed to support older adults to increase or maintain their PA level, assess the feasibility of conducting an effectiveness trial of the JitaBug intervention, and explore the acceptability of JitaBug among older adults in a free-living setting.

Methods: The intervention was developed using the Behavior Change Wheel and consisted of a wearable activity tracker (Fitbit) and a companion smartphone app (JitaBug) that delivered goal-setting, planning, reminders, and JITAI messages to encourage achievement of personalized PA goals. Message delivery was tailored based on time of day, real time PA tracker data, and weather conditions. We tested the feasibility of remotely delivering the intervention with older adults in a 6-week trial. Data collection involved assessment of PA through accelerometery and activity tracker, self-reported mood and mental well-being through ecological momentary assessment, and contextual information on PA through voice memos. Feasibility outcomes included recruitment capability and adherence to the intervention, intervention delivery *in the wild*, appropriateness of data collection methodology, adverse events, and participant satisfaction.

Results: Of the 46 recruited older adults (aged 56-72 years), 31 (67%) completed the intervention. The intervention was successfully delivered as intended; 87% (27/31) of the participants completed the intervention independently; 94% (2247/2390) of the PA messages were successfully delivered; 99% (2239/2261) of the Fitbit and 100% (2261/2261) of the weather data calls were successful. Valid and usable wrist-worn accelerometer data were obtained from 90% (28/31) of the participants at baseline and follow-up. On average, the participants recorded 50% (7.9/16, SD 7.3) of the voice memos, 38% (3.3/8, SD 4.2) of the mood assessments, and 50% (2.1/4, SD 1.6) of the well-being assessments through the app. Overall acceptability of the intervention was very good (23/30, 77% expressed satisfaction). Participant feedback suggested that more diverse and tailored PA messages, app use reminders, technical refinements, and an improved user interface could improve the intervention and make it more appealing.

Conclusions: This study suggests that a smartphone-delivered JITAI is an acceptable way to support PA in older adults in the community. Overall, the intervention is feasible; however, based on user feedback, the JitaBug app requires further technical refinements that may enhance use, engagement, and user satisfaction before moving to effectiveness trials.

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KEYWORDS

mobile health; mHealth; sedentary lifestyle; digital health intervention; intervention design; feasibility study; aging; mobile phone

Introduction

Background

The importance of physical activity (PA) for healthy aging is well recognized. Alongside a reduced risk of mortality [1], cardiovascular disease [2], and metabolic disease [3], engagement in PA and exercise has been linked with lower levels of depression [4] and elevated quality of life and well-being [5]. Long-term PA has been shown to protect against vascular decline in old age [6], and there is convincing evidence that PA can reduce risk of falls [7] and prevent osteoporosis [8] in older adults. Despite these wide-ranging health benefits, approximately 1 in 4 adults is insufficiently physically active [9]. Given that PA levels tend to decline with age [10], older adults are among the least physically active segments of the population, leaving them at greater risk of chronic conditions and disability.

Interventions designed to promote PA in community-dwelling older adults are effective in increasing PA as well as improving self-efficacy and quality of life [11,12]. Most interventions have incorporated lifestyle counseling and health education elements, typically delivered face-to-face in the home, general practice, or community setting and supported by scheduled remote contact to encourage further involvement in PA [11]. However, such approaches are resource intensive, likely inaccessible to those from remote communities, and cannot fully support the dynamic nature of PA behavior. Furthermore, the recent COVID-19 pandemic has highlighted the need for scalable interventions that do not rely on face-to-face delivery.

Digital health behavior interventions have emerged as a solution to some of these challenges. Early internet-based studies have demonstrated some success in increasing PA and reducing sedentary behavior in both adults [12,13] and older adults [14]. More recently, focus has shifted to mobile health (mHealth) interventions, which offer additional advantages, including on-demand tailored support and the potential for broad reach, scalability, and cost-effectiveness in comparison with face-to-face approaches [15]. Just-in-time adaptive interventions (JITAIs) are a type of mHealth intervention that provide real time *in-the-moment* behavior change support to users when and where it is needed and depending on an individual's changing needs [16]. The principle is that JITAIs can be more effective than standard mHealth approaches by addressing the dynamic nature of behavior and capitalizing on the changing states of *vulnerability* (need), *opportunity* (namely heightened susceptibility to positive behavior change), and *receptivity* (when someone is able and willing to receive and process just-in-time support) [17]. To do this, JITAIs typically rely on data from the Internet of Things, sensors, connected smartphone apps, or other environmental or contextual inputs.

In the context of PA, JITAIs use activity-tracking data collected through smartphones or wearables to deliver personalized PA prompts at the right time. However, an effective JITAI requires continuous updates from an activity tracker, which represents a significant technical challenge. Currently, only commercially available activity trackers can meet this need. Although activity data can be leveraged from consumer-grade devices such as smartphones, smartwatches, and activity trackers [18], modification of proprietary algorithms is not usually possible. As such, researchers are often forced to develop interventions that match the app's features, rather than developing an evidence-based intervention and then planning features to align with the intervention [19]. To use data from consumer-grade devices in a theoretically robust mHealth intervention, it is necessary to build a stand-alone but complementary mode of intervention delivery, such as a smartphone app.

Research on JITAIs has, to date, been limited to young or middle-aged populations and community settings such as the workplace, universities, and secondary care [16]; none has targeted older adults in a free-living setting. To address this, as well as the aforementioned issues, we developed a JITAI delivered through a bespoke companion mobile app to help older adults increase or maintain PA levels. This was particularly pertinent because we developed the app in response to the first COVID-19 pandemic–induced lockdown in the United Kingdom, and older adults were identified as being at higher risk from COVID-19 complications than their younger counterparts.

Objectives

The aims of this paper are three-fold: to (1) describe the development of the *JitaBug* app and intervention, (2) examine the feasibility of conducting a larger definitive trial on the effectiveness of the JitaBug intervention, and (3) explore the acceptability of the intervention among older adults in a free-living setting. We hypothesized that it would be possible to use a commercial app for continuous activity–monitoring purposes, while also being able to deliver our own JITAI, grounded in behavior change theory, with custom messaging, and tailoring variables through our companion app.

Methods

Development and Design

The JitaBug intervention was developed during the COVID-19 pandemic in 2020 to maintain or improve PA behaviors in at-risk older populations. The intervention was developed using the

Behavior Change Wheel [20], a theory-driven framework based on several models of health behavior that facilitates the systematic development of behavior change interventions. It is underpinned by the *COM-B model*, which is based on 19 existing frameworks of behavior and consists of three necessary conditions for a given behavior to occur: (1) capability, (2) opportunity, and (3) motivation. The development process involved six steps: (1) defining the problem (in this case reduced PA in older adults because of COVID-19–related restrictions), (2) selecting and specifying the target behavior (increasing daily PA levels at home), (3) identifying the COM-B components and psychological determinants to be addressed for behavior change (behavioral diagnosis), (4) using the APEASE (Acceptability, Practicability, Effectiveness, Affordability, Side-effects, and Equity) criteria to identify appropriate intervention functions, (5) selecting appropriate behavior change techniques (BCTs) by using the BCT Taxonomy (version 1) [21] to deliver intervention functions, and (6) identifying the mode of delivery for the intervention. Following these steps, we designed an intervention incorporating a bespoke smartphone app (JitaBug) combined with a wearable activity tracker (Fitbit [Google LLC]) that would allow users to (1) set PA or exercise goals, plan activities, and set reminders; (2) self-monitor PA levels and receive feedback on behavior; and (3) receive just-in-time adaptive prompts (push notifications) with personalized and actionable messages using motivational language to encourage users to meet PA goals. We chose to use a Fitbit device, given Fitbit's popularity with consumers and therefore the increased potential for future scalability of the intervention and because of the availability of an application programming interface (API), allowing remote data tracking (described in the following sections).

Intervention Components

Using a combination of self-regulatory BCTs, including goal setting, prompting self-monitoring, providing feedback on performance, and reviewing goals, has been shown to increase the effectiveness of PA behavior change interventions [22].

Goal Setting

Goal setting is considered a fundamental component of successful behavior change and is the most frequently used component in health behavior interventions [23]. Evidence from systematic reviews and meta-analyses has shown goal-setting interventions to have small [24] to moderate [25] positive effects on PA. As part of the initial *onboarding* of the JitaBug app, we implemented a goal-setting feature that allowed participants to choose a step count or activity minutes goal depending on their preference. In total, three options were offered—500, 750, or 1000 steps more per day—relative to baseline step count. These targets were informed by evidence that pedometer-based studies typically elicit an increase of 775 steps per day (or effect size of 0.26) in older adults [26]. The activity minutes goal also offered three options—10, 20, or 30 minutes more per day—relative to baseline activity. These goal options were offered to allow participants to gradually increase their PA levels in a realistic and achievable way. Once a goal was selected, participants could rate their level of self-efficacy in achieving their goal by responding to the following question: "On a scale of 1-10, with 1 being not very and 10 being very, how confident are you that you can make some good progress toward your goal?" In addition, participants could review and revise PA goals and reassess their self-efficacy in achieving their goal at any point on the app home screen and were prompted to review their goals every 2 weeks.

Planning and Reminders

Action planning, or prompting the user to make specific plans about when and where they will increase their activity, has been suggested as a useful tool to motivate people to change PA behavior [27]. Evidence from systematic reviews has shown action planning to be one of several effective BCTs in increasing both self-efficacy and PA [28,29]. However, experimental evidence concerning the impact of specific BCTs or combinations of BCTs on PA has suggested that action planning only increases PA when combined with coping planning [30]. A planning feature within the JitaBug app allowed participants to plan activities and when and where to perform them. Participants could log activities for a specific date and time, and the app would deliver an activity reminder as a notification. Given that weather is a common barrier to PA [31], a scrollable 7-day weather forecast (presented in 3-hour blocks) was made available on the same planning screen, using the GPS location of the smartphone to assist participants with coping planning; for example, planning indoor or outdoor activities.

Self-monitoring and Feedback on Behavior

Self-monitoring is considered an essential technique for PA behavior change and is more effective when combined with one or more other techniques derived from control theory (eg, goal setting, feedback on performance, and reviewing goals) [32]. PA interventions with self-monitoring are more effective than those without and more effective again when combined with action planning and coping planning [30]. We designed the JitaBug app to work alongside a wrist-worn Fitbit activity tracker to allow users to self-monitor PA and progress toward activity goals by viewing summary feedback on the device and on the associated Fitbit app.

We included a *snippets* feature within the app that allowed participants to record voice memos concerning PA behavior using the smartphone microphone. Participants were first asked to indicate ("Yes" or "No") if they had engaged in PA that day. Depending on the option selected, participants were given guidance on what to record in the snippet, such as the type, duration, and location of PA, as well as reasons for being active or not, feelings about their PA, and any PA barriers experienced.

JITAI Messaging

Personalized PA messaging was delivered by the JitaBug app to encourage participants to meet their daily PA goal. Messages were tailored to participants' context based on (1) real time PA level (from Fitbit data repository), (2) chosen activity goal (step count vs exercise), (3) time of day (anytime, 12:30 PM, 5:30 PM, or 8:30 PM), and (4) good weather versus bad weather from the *OpenWeather* API (good weather defined as <50% chance of rain). A set of 13 decision rules linked to 3 possible intervention options (Table 1) were developed to dictate what message the participant received and when. A total of 136

unique messages were developed (10-14 for each of the 13 decision rules), and depending on whether the participant chose a *step* goal or *activity minutes* goal, they could receive up to 75 unique messages across the intervention period. The time points incorporated into the decision rules were chosen as possibly opportune times to make PA suggestions (ie, to encourage an activity break around mealtimes or to plan an activity for the following day). Once a JITAI message was received by a user's device, a notification was shown on the lock screen (if locked) or home screen (if unlocked). Clicking on this notification would open the JitaBug app and present the message screen to the user. The message screen displayed the text, any images, and any hyperlinks to resources included in the message. The message screen also included a message-rating question, *Was this useful?*, whereby users could respond by clicking on either a thumbs up or thumbs down image (but not both).

Table 1. Just-in-time adaptive intervention option examples.

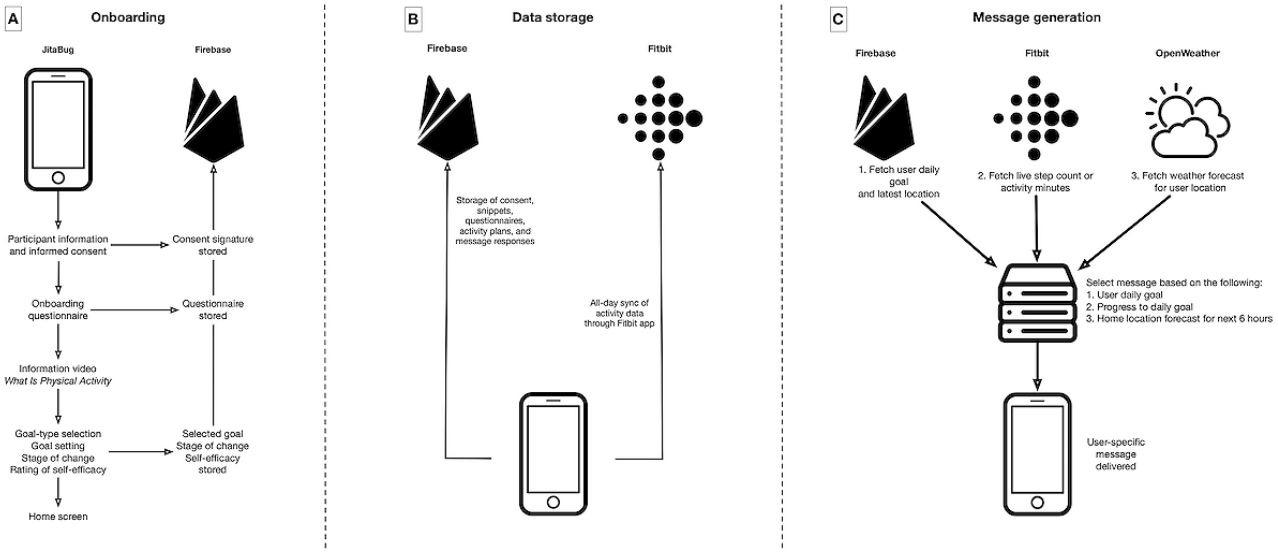
Scenario	Goal of message	Example
Intervention option 1		
When a participant meets their daily step or activity minutes goal	Provide positive feedback and encouragement to repeat the behavior	Well done [NAME]! You reached your goal for today! Aim for the same again tomorrow .
Intervention option 2		
When a participant has not yet reached their daily step goal and the time is between 12:30 PM and 5:30 PM or between 5:30 PM and 8:30 PM and the weather is good	Provide a brief update on goal progress and a message that (1) highlights the benefit of taking an activity break and (2) suggests an activity	You've not reached your step goal for today yet, but there's still time! The weather looks good for this afternoon . How about a brisk walk?
When a participant has not yet reached their daily activity minutes goal and the time is between 12:30 PM and 5:30 PM or between 5:30 PM and 8:30 PM and the weather is bad	Provide a brief update on goal progress and a message that (1) highlights the benefit of taking an activity break and (2) suggests an activity	Don't forget that building muscle strength is just as important as aerobic activity; it helps to maintain functional fitness and prevent falls. How many times can you stand up and sit down from a chair during TV ad breaks?
Intervention option 3		
When a participant did not meet their daily step goal and the time is later than 8:30 PM and the weather is bad	Provide a brief update on goal progress and a prompt that encourages them to plan activity for the following day to meet the goal	The weather is pretty bad tomorrow. But there's some great online workouts available to try. Does anything take your fancy? [33]
When a participant did not meet their daily activity minutes goal and the time is later than 8:30 PM and the weather is good	Provide a brief update on goal progress and a prompt that encourages them to plan activity for the following day to meet the goal	Let's make sure you reach your step count target tomorrow . It's going to be dry so why not plan something outdoors?

Technical Implementation

The technical implementation of the mobile app is depicted in Figure 1. The app was developed using the Dart programming language and the Flutter development framework. This framework has the advantage of enabling apps to be compiled for both Android and iOS platforms with a substantial amount of shared code. Consequently, the final app *JitaBug* was released onto the Apple App Store and Google Play Store shortly before the start of the study intervention (September 2020).

To deliver personalized JITAI messages to each user, we used a separate remote server to automate messaging. This was written using the Python programming language (version 3.7; Python Software Foundation), the Firebase Admin Python package [34], and an open access Fitbit API package [35]. Personalized messages could be compiled by accessing three data sources for each user: (1) a Firebase repository that held data, including the user's first name, home postal code, chosen activity goals, and mobile phone unique ID; (2) a Fitbit data repository that held the user's current activity metrics; and (3) the *OpenWeather* API that pulled the weather forecast for the next 4 hours at the user's home location (based on home postal code). The messaging algorithm ran in 2 parts. Every hour, between 9 AM and 8 PM, the server would check the Fitbit repository to determine whether the user had met their daily activity goal; if yes, it would process and send a motivational *congratulations* message (Intervention option 1; Table 1). In total, three times per day (12:30 PM, 5:30 PM, and 8:30 PM), the server would access the 3 aforementioned data sources and send a personalized message based on the decision rules.

Figure 1. Technical model of the JitaBug intervention, summarizing (A) the onboarding process, (B) how data were stored, and (C) the generation of just-in-time adaptive physical activity messaging.



Feasibility Study Design

We tested the feasibility and acceptability of the JitaBug intervention in a 6-week 1-group pretest-to-posttest trial using a mixed methods approach. The study was conducted entirely remotely across the United Kingdom between September 2020 and November 2020. Participants completed a 7-day monitoring period (baseline), a 4-week intervention (weeks 2-5), and a follow-up 7-day monitoring period. As this was a feasibility study, a sample size calculation was not necessary [36]. Sample size targets were defined by practical and resource considerations, limiting us to recruit 40 older adults.

Ethics Approval

The study was approved by the Health and Life Sciences Research Ethics Committee of the University of the West of Scotland (13212).

Participants

Participants were ambulatory, community-dwelling older adults who use a smartphone but not a wearable activity tracker. They were recruited through social media posts from the research teams' personal accounts (Twitter and Facebook), university newsletter, research recruitment websites [37], community groups (Men's Shed), and word of mouth. Those interested were emailed a participant information sheet, including contact details for the study team in case they wished to ask questions, and a consent form. After informed consent, participants were asked to provide contact details so that a member of the research team could arrange for the delivery of the study equipment through courier (accelerometer, Fitbit activity tracker, and accessories). In addition, they were sent study enrollment videos and user manuals describing each stage of the study onboarding process.

Procedure

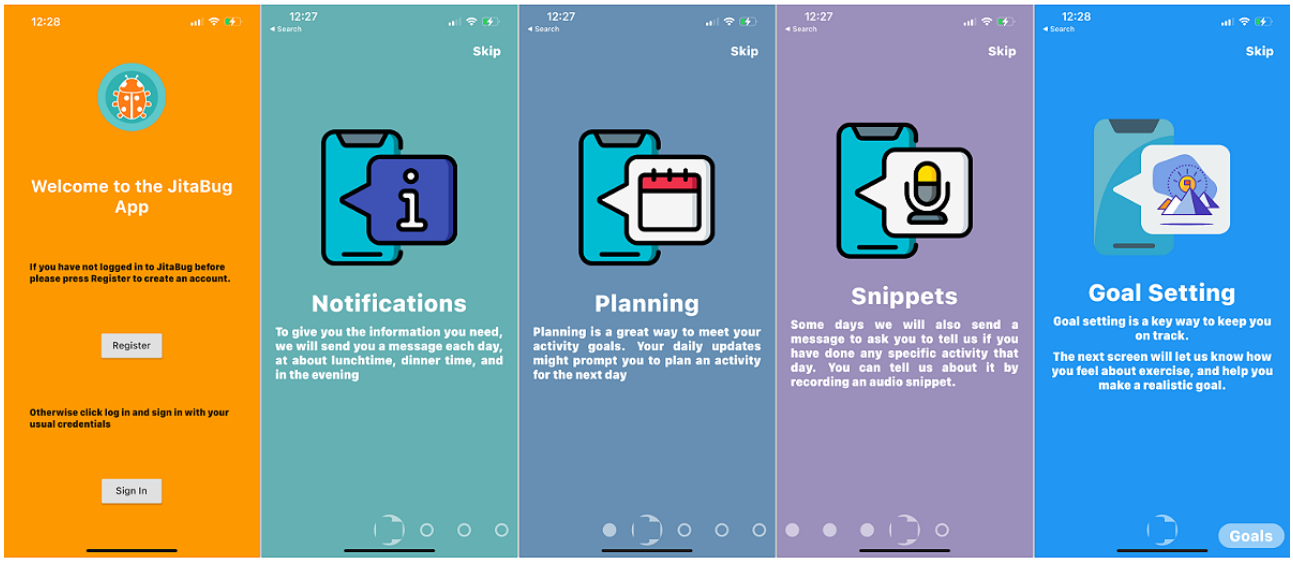
Fitbit Onboarding

Participants were couriered a Fitbit activity tracker (Fitbit Charge 4) for use during the study. The Fitbit trackers were preregistered so that the Fitbit user ID for each device was available to the research team. Notifications were turned off on the Fitbit tracker, the *do not disturb* mode was enabled, and all *exercise* options were removed from the tracker, with the exception of *walk*, before sending to participants to avoid contamination with the JitaBug intervention. Participants were asked to download the Fitbit app and log in using the study username and password provided to them. After logging in, participants were guided to turn off all push notifications and to connect the Fitbit tracker to their smartphone through Bluetooth. They were required to keep Bluetooth turned on for the duration of the study to ensure uninterrupted data upload to the Fitbit data repository (approximately every 15 minutes). This allowed our server to access each participant's most recent activity data to inform the JITAI decision rules. All participants inputted their date of birth, height (cm), body mass (kg), and sex (male or female) into the *personal* profile section of the Fitbit app.

JitaBug Onboarding

Upon downloading the JitaBug app, participants were asked to reconfirm consent to participate in the research study and log in using the study username and password. Participants then completed a survey to provide personal, anthropometric, demographic, and socioeconomic information. They were then guided through a summary of the app and its key features (Figure 2) including notifications (prompts), planning, the *snippets* feature (described in the following section), and goal setting.

Figure 2. JitaBug onboarding screenshots.



Main Intervention

After onboarding, participants were directed to the *goal-setting* feature. First, they were shown a short in-app video clip to describe what PA is, what the current PA guidelines are, and how to distinguish between intensity levels. The key message of the video was *any activity is better than none and more is better still* [38]. After they had watched the video, participants were asked to indicate their stage of change [39] with respect to PA from a list of five options:

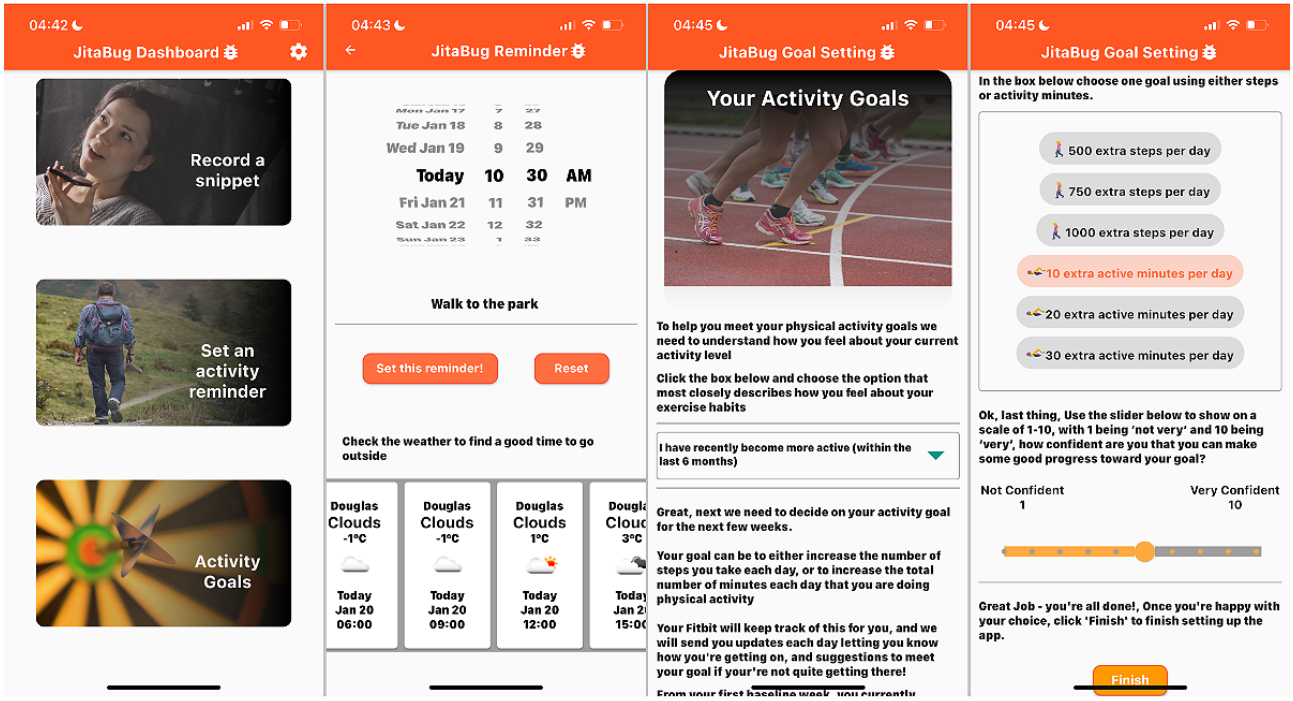
1. I've been physically active for more than 6 months and I am maintaining my activity level (maintenance).
2. I have recently become more active (within the last 6 months; action).
3. I have definite plans to improve my physical activity level in the next month (preparation).
4. I'm seriously intending becoming more physically active in the next 6 months (contemplation).
5. I know I should improve my physical activity level, but I don't intend to (precontemplation).

Next, participants were shown their average step count and activity minutes from the previous week (baseline). They were then asked to choose either a personal step count goal (500, 750, or 1000 more steps than the average step count during the preintervention period) or an activity minutes goal (10, 20, or 30 more *active minutes* than during the preintervention period) based on their baseline activity level. Finally, self-efficacy in achieving the selected goal was assessed with the following question: "On a scale of 1-10, with 1 being not very and 10 being very, how confident are you that you can make some good progress toward your goal?"

The JitaBug app was designed to mainly run *in the background* with minimal user input. The app automatically delivered PA message prompts (push notifications), in line with the predefined JITAI decision rules, to encourage the participant to meet their goal. Some message prompts encouraged participants to use the activity-planning feature, but they could also access this feature at any point during the intervention. At certain time points throughout the intervention, participants were also prompted to record ecological momentary assessment (EMA) *snippets* to reflect on their progress and describe contextual aspects of their physical activities. After 2 weeks and again after 4 weeks, participants were prompted to review and revise their activity goal or continue with their original goal. Screenshots of the app's main screens, including the dashboard, planning feature, and goal setting, are shown in Figure 3.

On completion of the study and after safe return of all devices, participants were provided with a £20 (approximately US $26.80) voucher from a reputable retailer as a thank you for their time and effort during the study.

Figure 3. JitaBug app screenshots.



Outcome Measures

Proximal Outcome

The proximal outcome of interest was defined as daily PA goal achievement measured using the Fitbit tracker. The Fitbit tracker was worn throughout the entire study on the nondominant wrist and only removed for charging purposes.

Distal Outcome

The main distal outcome of interest was change in time spent in low-, moderate-, and vigorous-intensity PA (minutes per day) and sedentary activities (minutes per day) between baseline and postintervention follow-up. Given the current limitations with wearable activity tracker validity [18] and the need to accurately measure intervention effectiveness in a later definitive trial, we chose to measure PA at baseline and follow-up by research-grade accelerometer. Participants were provided with an ActiGraph wGTX3-BT accelerometer (ActiGraph LLC) and instructed to wear it on their nondominant wrist, distal to the Fitbit tracker when both were worn, for 8 consecutive days, 24 hours per day, during the baseline and follow-up periods, removing it only for bathing or showering. The accelerometers were synchronized with GMT, initialized to capture data at 100 Hz, and programmed to commence data collection at 6 AM on the day after delivery. Participants were instructed to wear the accelerometer on the day it was received to ensure full data capture.

Other Outcomes

Sociodemographic and anthropometric characteristics, including gender, age, location within the United Kingdom (postcode), marital status, employment status, key worker status, number of people in the household, household income, education level, number of dependents, dog ownership, bicycle ownership, past activity tracker ownership, and PA preferences, were obtained by means of a survey during the onboarding process to describe the sample recruited.

Self-reported contextual information on PA types, locations, domains, reasons for being active, and barriers experienced was gathered throughout the intervention using the snippets feature that doubled as a voice-based EMA approach. Participants were sent notifications to *record a snippet* at two time points (12:30 PM and 5:30 PM) on two random days of the week (1 weekday and 1 weekend day) each week of the 4-week intervention (16 in total).

We also explored mental well-being and mood responses to the intervention using this approach. On the same day the snippet notifications were delivered, participants were also prompted in the evening (8:30 PM) to complete two questionnaires: the short Warwick-Edinburgh Mental Wellbeing Scale [40] and the short version of the Multidimensional Mood State Questionnaire [41]. The questionnaire screen used a touch interface 6-point (Multidimensional Mood State Questionnaire) or 7-point (Warwick-Edinburgh Mental Wellbeing Scale) Likert scale with a visual indicator of the selected response.

Finally, participants completed a postintervention user experience survey to assess overall experience, app usability and satisfaction with the technology (using relevant questions from the mHealth App Usability Questionnaire [42]), perceived effect on behavior, and views on the intervention as a whole.

Data Processing

ActiGraph data were downloaded using ActiLife (version 6.14.3; ActiGraph) and saved in raw format as .gt3x files. The files were subsequently converted to time stamp–free .csv files and

exported into R (version 3.6.3; The R Foundation for Statistical Computing) for processing using the GGIR package (version 2.1.0) [43]. Briefly, this processing method detected nonwear time as well as abnormally high values and autocalibrated the raw triaxial accelerometer signals using local gravity as a reference [44]. As this was a feasibility study, we were interested in reporting the number of participants who met our proposed wear time inclusion criterion of 4 days, including 1 weekend day, of valid wear (defined as ≥16 hours per day) [45].

Analysis

The analyses reported here focus on the trial feasibility and acceptability of the intervention. Feasibility outcomes include (1) recruitment and retention within the study; (2) intervention delivery in the wild; (3) completion rates and usable data from the app, the Fitbit wearable activity tracker, and the ActiGraph accelerometer; and (4) adverse events. Results are summarized narratively and descriptively (means, SDs, and proportions) based on data from researcher notes, app analytics, and the user experience survey.

Acceptability outcomes are summarized descriptively based on data from the user experience survey and include three categories: (1) satisfaction with the research overall; (2) satisfaction with the technology (JitaBug app and Fitbit tracker together); and (3) satisfaction with, and usability of, the JitaBug app itself. Likert-scale responses were scored (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree). An overall score for each acceptability category (research overall, technology components, or app components) was calculated by summing the mean score for each question within the respective category. Open-ended responses were coded and categorized into themes. Data are presented as mean (SD), unless otherwise stated.

Results

Feasibility

Recruitment and Retention

Recruitment advertisements resulted in 75 people contacting the research team about the study. Participants responded through Twitter (2/75, 3%), a research recruitment website [37] (41/75, 55%), existing contact lists (6/75, 8%), or after hearing about the study through word of mouth (26/75, 35%).

After they were provided the study details, 64% (48/75) of the respondents volunteered to participate. Of these 48 volunteers, 46 (96%) met the study inclusion criteria and provided informed consent to participate (exclusion reasons: residing outside the United Kingdom, 1/48, 2%, and current knee injury, 1/48, 2%). Of the 46 participants who consented to participate, 5 (11%) withdrew from the study before receiving the study equipment (Fitbit tracker and accelerometer). Reasons for withdrawal at this point included family emergency (1/46, 2%), other commitments (2/46, 4%), deciding not to take part (1/46, 2%), and unable to download the JitaBug app to an older iPhone (iPhone 5; 2012; 1/46, 2%). Of the remaining 41 participants, 8 (20%) either withdrew or dropped out from the study after having received the equipment. Reasons included no response to study emails/unable to contact the participant (4/41, 10%), issues setting up the JitaBug app (1/41, 2%), did not like the look of the ActiGraph accelerometer (2/41, 5%), and deciding not to take part (1/41, 2%). After completion of the baseline monitoring week, of the 33 remaining participants, 2 (6%) withdrew because of Fitbit syncing issues with their smartphone. Therefore, of the 46 older adults initially recruited, 31 (67%) participants aged 65.5 (SD 5.4) years started and completed the feasibility study. Table 2 summarizes the sociodemographic profile of the final sample.

Table 2. Participant characteristics (N=31).

Characteristics	Participants, n (%)
Sex	
Male	14 (45)
Female	17 (55)
Location (country in the United Kingdom)	
Scotland	20 (65)
England	7 (23)
Wales	4 (13)
Northern Ireland	0 (0)
Marital status	
Married or cohabiting	21 (68)
Single	2 (7)
Widowed	1 (3)
Divorced	3 (10)
No response	4 (13)
Employment status	
Employed full time	8 (26)
Employed part time	1 (3)
Self-employed	1 (3)
Retired	16 (52)
No response	5 (16)
Education level	
Postgraduate	7 (23)
College graduate or undergraduate	15 (48)
School	4 (13)
No response	5 (16)
Household income, £ (US $) per year	
<40,000 (<53,651)	2 (7)
40,000-59,999 (53,651-80,475)	13 (42)
>60,000 (>80,475)	6 (19)
No response	10 (32)
Previous tracker use	4 (13)
Dog ownership	6 (19)
Key worker (performing essential services during the COVID-19 pandemic)	7 (23)
Stage of change	
Precontemplation	1(3)
Contemplation	0 (0)
Preparation	8 (26)
Action	10 (32)
Maintenance	7 (23)
No response	5 (16)

Intervention Delivery

All participants received the study equipment through courier within 2-5 days of dispatch without issue. All participants were able to download the JitaBug app from the relevant app store (Apple App Store or Google Play Store) independently, but 3% (1/31) of the participants required further assistance from the research team because their device used an operating system that was older than the one the initial design of the app would work with (JitaBug was initially only compatible with Android software development kit version 23 onward). To retain the participant in the study, the research team developed a bespoke version compatible with Android software development kit version 21.

Of the 31 participants, 27 (87%) were successfully onboarded, chose an activity goal, and completed goal self-efficacy at baseline. Goal self-efficacy ratings were generally high (median 8, range 2-10), suggesting that participants were confident in achieving their chosen goal. Of the 31 participants, 14 (45%) reviewed and changed this goal at least once during the intervention period, whereas 4 (13%) required assistance from the research team with onboarding because of lack of mobile data access at the time of onboarding.

Of the 2390 JITAI messages sent throughout the intervention, 2247 (94%) were delivered successfully; of these, 188 (8.37%) were goal-achievement messages from Intervention option 1 (Table 1). To send the right type of message at the right time, the 13 decision rules relied on accurate and up-to-date data from the Fitbit activity tracker and the weather API. Overall, 99% (2239/2261) of the Fitbit, and 100% (2261/2261) of the weather, data calls were successful. Of the 31 participants, 3 (13%) reported that they either “did not receive any notifications” or “received very little information” during the intervention, suggesting that some did not receive this intervention component. These participants were likely those who had difficulty with onboarding because, on investigation, it became apparent that if the process was interrupted or not completed (eg, by closing the app halfway through), then the decision rules would not function because of missing information, namely the activity goal choice. As a result, the participant would not receive any PA messages. The issue was identified and resolved for these participants during the intervention.

Data Collection and Missing Data

In terms of accelerometer data, valid and usable data were obtained from 90% (28/31) of the participants at baseline and follow-up. At baseline, of the 31 devices, 30 (97%) were returned for processing, with 29 (97%) files subsequently processed; we were unable to process 1 (3%) device for an unknown technical reason, and 2 (6%) participants failed to meet the minimal wear time criterion. At follow-up, of the 31 devices, 30 (97%) were returned and 30 (100%) files were successfully processed; 3 (10%) files were removed from subsequent analysis for not meeting the minimal wear time criterion. Researcher notes indicated that 6% (2/31) of the participants did not wear the accelerometer while sleeping. The average number of valid days of data was 7.1 (SD 0.5) at baseline and 7.9 (SD 0.7) at follow-up.

Of a possible 496 snippet recordings, 212 (43%) valid recordings were obtained. On average, participants recorded 50% (7.9/16, SD 7.3) of the snippets, 38% (3.3/8, SD 4.2) of the mood assessments, and 50% (2.1/4, SD 1.6) of the well-being assessments through the app. The user experience survey distributed at the end of the study had a 97% (30/31) response rate.

Adverse Events

There were no adverse events reported during the study.

Acceptability

Acceptability data are available in Multimedia Appendix 1.

Satisfaction With Research Process

The overall acceptability score for the research process was very good (4.00/5.00, SD 0.73; 80% satisfaction). Most of the participants (27/30, 90%) agreed or strongly agreed that they were satisfied with the research conducted. Most (21/29, 72%) were satisfied with the measurements taken and the amount of data gathered.

Satisfaction With Technological Components

The overall acceptability score for the technology components of the intervention was very good (3.86/5.00, SD 0.59; 77% satisfaction). Most of the participants agreed or strongly agreed that they felt comfortable using the technology (21/30, 70%), that it required little effort to use (23/30, 77%), and that it was easy to learn how to use (25/30, 83%). Very few participants agreed that using the technology caused them embarrassment (2/29, 7%). Participants were moderately satisfied with the usefulness of the technology (15/30, 50%) and the accuracy of the data provided by the technology (18/30, 60%).

Satisfaction With App Components

The overall acceptability score for the JitaBug app components was good (3.36/5.00, SD 0.72; 66% satisfaction). Most of the participants agreed or strongly agreed that the app was easy to use (22/30, 73%), that the amount of time involved using the app and answering questions within the app was reasonable (18/30, 60%), and that the app’s PA goals were realistic (20/30, 67%). Overall, 59% (17/29) of the participants said that they were satisfied with the app; however, only 43% (13/30) of the participants agreed that they would use the app again. Lower satisfaction (agreement) was also observed with respect to the interface of the app (12/29, 41%), frequency of notifications (16/30, 53%), relevance of notifications (12/30, 40%), usefulness of the information presented within the app (12/30, 40%), and appropriateness of the notification timing (13/30, 43%). Of the 19 questions, 2 (11%) scored high *neutral* responses—satisfaction with the way the app presented feedback and information (17/30, 57%) and satisfaction with the time interval between setting new goals (16/29, 55%)—suggesting that several participants may not have received these aspects of the intervention. Finally, only 33% (10/30) of the participants agreed that the app had all the expected functions and capabilities.

Satisfaction With the Intervention

Responses from the open-ended questions of the user experience survey are summarized in Table 3. The feedback identifies potential improvements to the intervention and recommends specific elements that could enhance user engagement in mobile app–based behavior change interventions for older adults going forward. The collective feedback is categorized into themes and links to positive and negative outcomes.

Table 3. Summary of qualitative feedback from the user experience survey (N=30).

Theme and positive comments, n (%)	Negative comments, n (%)
Goals	
Motivated to do more, 2 (7)	—[a]
Felt good when achieving goals, 1 (3)	—
Self-monitoring and feedback	
Receiving feedback on behavior, 8 (27)	Fitbit did not track low-intensity activities, 1 (3)
Tracking and visualizing behavior patterns, 7 (23)	Unreliable and inaccurate, 1 (3)
Comparing with past performance, 4 (13)	Dislike wearing a second watch, 1 (3)
Raised awareness, 6 (20)	—
Prefer passive data collection, 1 (3)	—
JITAI[b] messages	
Took on advice and formed a new habit, 1 (3)	Ignored, 1 (3)
—	Annoying, 1 (3)
—	Too many, 1 (3)
—	Repetitive, 3 (10)
—	Irrelevant, 1 (3)
—	Too simple or patronizing, 4 (13)
—	Inappropriate times, 3 (10)
Setting activity reminders	
Established a new routine so no longer needed reminders, 1 (3)	Not useful, 3 (10)
—	Felt bad when unable to follow through with plans, 3 (10)
—	Too time consuming, 1 (3)
—	Most difficult part, 1 (3)

[a]None reported.

[b]JITAI: just-in-time adaptive intervention.

Participants liked using the Fitbit tracker the most (22/30, 73%), followed by receiving feedback on their activity (5/30, 17%). Participants liked using the Fitbit tracker and its associated app to track data on their activity and sleep patterns and visualize their progress over time. This seemed more useful than receiving feedback on behavior through the JITAI messages. Participants felt that the intervention raised their awareness of their PA level and gave them encouragement to be active and meet their goals. There was a suggestion that the passive activity detection offered by the Fitbit tracker was preferred over self-reporting through *snippets*; however, a limitation is that some lower-intensity physical activities are either not detected or do not contribute to steps or activity minutes. Example quotes are as follows:

> *I think that wearing a tracker automatically makes you more aware of periods of inactivity and progress towards goals, even though it was at times unreliable and didn't record activities such as tai chi and yoga towards my daily goal.* [Participant 2]

> *Fitbit provides immediate feedback on a wide range of health metrics, so enabling more direct tracking of progress, if not against targets, then against historic data.* [Participant 4]

> *I was able to see what I was doing and compare days and what my sleep pattern was like. It reported to me on the activity I was doing and my sleep rather than asking me to report what I was doing and then suggest options.* [Participant 21]

Some participants commented that they found the PA message content to be repetitive and the timing of the messaging was not always appropriate. For example, some reported receiving a message to be active immediately after an activity bout and some mentioned that they were not able to act on the message *in the moment*, which made them feel bad:

> *They never came in at the right times usually after I had been exercising.* [Participant 30]

> *I couldn't always guarantee to do it and there wasn't anything I could do about it. So it made me feel bad about myself.* [Participant 22]

In addition, some mentioned that the language used in the messages was too simplistic and, at times, *patronizing*, and they may be more suited to very inactive people:

> *...I enjoyed all the information, goals and targets provided with the Fitbit app, so that the JitaBug was really not necessary. One night it did tell me to get out for a walk in the dark, which I did and have continued to do so if I haven't got my steps in through the day. That was one definite piece of advice from the JitaBug that I responded to. A lot of it was a bit lightweight for me, I feel. I can see that it would be appropriate for some people though (possibly older and less able).* [Participant 13]

Improvement Suggestions From Users

Participants offered several suggestions for improvements to the JitaBug app, predominantly centered around usability. They advised that the PA message notifications should be more obvious (eg, adding a red dot to the app icon on the home screen when a new notification is received) and accessible because messages were not always seen in the notification center. It was suggested that reviewing and setting PA goals should be easier and that there should be more flexibility with the app features (eg, avoid forced completion of EMA questionnaires). Participants suggested that having more content and resources would encourage people to use the app more and that PA messages should be used as an opportunity to provide educational content. Finally, participants suggested that the app should integrate with, and offer more than, existing health apps.

Discussion

Principal Findings

This study demonstrates for the first time that a smartphone-delivered JITAI using data from a wearable activity tracker is an acceptable approach to increase PA in older adults in a free-living setting. A main finding is that by using a companion app (and server), it is feasible to leverage the technical benefits of commercial activity trackers and still deliver a theory-led JITAI with bespoke tailoring variables and messaging. Overall, the acceptability of the intervention was very good (23/30, 77% expressed satisfaction). Participants were comfortable with the technology and found the app easy to use. Furthermore, given the intervention completion rate of 67% (31/46), the successful delivery of the intervention *in the wild* as intended, the acceptable levels of accelerometer data collection, and the absence of adverse events, we propose that after some minor usability improvements, the JitaBug intervention is feasible to run in a larger, fully powered trial to ascertain its effectiveness in changing PA behavior and improving health and well-being.

Concerns regarding the acceptability of mobile technology in studies with older adults are largely historical, and our data on the acceptability of the JitaBug intervention confirm what has been reported elsewhere. Hawley-Hague [46] assessed the acceptability of a mobile app to support falls rehabilitation, reporting that older adults had few issues with the technology and were comfortable with using it for exercise advice. Similarly, several studies have reported that older adults find wrist-worn activity trackers acceptable [47,48]. Nevertheless, it is worth noting that the evidence to date is likely subject to sampling bias, given the need for people to own an up-to-date smartphone capable of running new apps and syncing with wearable devices. Indeed, our participants were predominantly well educated, retired, and with reasonable household income. Therefore, more research is needed, across a wider demographic, to understand whether mHealth solutions can truly reach harder-to-reach groups such as those from lower socioeconomic backgrounds and therefore achieve their full potential.

Overall, the JitaBug intervention was well received, the app was easy to use, and participants were comfortable with the technology. However, we noted that participants were less satisfied with the features and content within the JitaBug app and the PA messages in terms of timing, relevance, and repetitiveness. We propose that this was partly due to disparity between the study aims and participants' expectations of the app. The JitaBug app was designed to run in the background with minimal user input to reduce user burden and limit intervention fatigue [17]. However, participants reported that they wanted more content and interaction and felt that they often had little reason to open the JitaBug app. We intended to avoid recreating the Fitbit app; therefore, we did not include updates on activity minutes or step count within JitaBug. However, to ensure fidelity to the JITAI messaging and BCT approaches, we also requested participants turn off notifications from the Fitbit app. Consequently, participants felt that the JitaBug app offered insufficient information regarding progress toward their goals each day. Future studies should address this and include some feedback on activity data within the companion app if the Fitbit (or another proprietary) app might compromise study fidelity.

Regarding timing, relevance, and repetitiveness of PA messages, specific tailoring variables within decision rules may have influenced delivery of appropriate messages. For example, time lags between the Fitbit wearable activity tracker syncing with the JitaBug servers may have resulted in incongruence between real time PA and the message received concerning current PA. The JitaBug app called the Fitbit server every hour, but this was dependent upon an internet connection and the frequency with which the phone synced data with the Fitbit server. Another variable that could influence message content was weather conditions. Given that the study was delivered in the autumn in the United Kingdom when average rainfall is at its highest and the decision rules determined good versus bad weather depending on rainfall, it is likely that far fewer message options were delivered than intended. Thus, the geographical location and season in which an intervention is delivered may have profound implications for intervention delivery and user acceptability. Finally, we used predefined windows of time, chosen as possible opportune moments to intervene on PA behavior, to send JitaBug notifications. However, event-based timing, for example, when someone has been sedentary for a prolonged period of time, might be a more effective approach

[17]. Furthermore, the timing of JITAI messages may be enhanced by detecting a user's state of receptivity [49] with additional data inputs such as location, device interaction, and battery level [50]. Future studies should expand on the number and type of tailoring variables relevant to PA, which in turn will facilitate the development of more intuitive and nuanced messaging rules.

We anticipated at the outset that creating PA messages that are equally meaningful to participants with different backgrounds, reading abilities, and expectations was likely to be one of the most challenging parts of the study. The language used in our messaging was aimed at a reading level equivalent to 6th grade (12 years of age) in line with guidance on the reading level of patient education and health literacy materials [51]. Nevertheless, participants commonly described the messages as overly simplistic and occasionally patronizing. The same feedback has been reported in another JITAI study targeting substance abuse in adolescents and young adults [52]. Developing meaningful messages is complex, multidimensional, and requires the incorporation of a variety of concepts and theories [53]. It is possible that co-designing messages with intended users might increase satisfaction with this aspect. Moreover, it may be possible to target messages to specific user groups, for example, based on demographics or further tailor messages for individual users based on preferences, baseline activity levels, and even personality traits [54]; however, this would inevitably require significantly greater resource commitment.

In terms of feasibility, web-based, email, and referral recruitment strategies were successful in reaching 75 people over a 9-week period, with 48 (64%) of them then volunteering to participate. Of the 46 volunteers who were eligible, 31 (68%) enrolled onto the study, suggesting a good level of interest in the intervention. These recruitment and retention findings are similar to other PA-focused mHealth studies using apps and commercially available activity trackers in adults [55,56]. Given that the apps used in these previous studies have undergone extensive testing and development over several years to maximize engagement, finding comparable recruitment and retention rates with the JitaBug intervention is promising and further supports the feasibility of the intervention. Furthermore, this study was conducted in the context of COVID-19 restrictions, which required us to develop an intervention that could be delivered wholly remotely. Thus, unlike earlier work, our retention data did not benefit from face-to-face induction of participants onto the study. Indeed, critical aspects of the intervention, including the aims and functionality, which might usually be undertaken by the research team, had to be incorporated into the app *onboarding* process. Nevertheless, retention was relatively unaffected; therefore, the encouraging recruitment and retention data suggest that a high proportion of older adults can feasibly use the JitaBug app remotely.

The feasibility of PA data collection by accelerometer and wearable activity tracker was excellent. We also assessed the feasibility of collecting longitudinal changes in participants' mood and well-being using an EMA-based questionnaire and contextual information about PA behavior using a voice-based EMA approach, both integrated within the JitaBug app. According to a recent systematic review of smartphone-based EMAs [57], this is the first study to combine qualitative data collection with an EMA approach and only the second to evaluate the feasibility of EMA in older adults. de Vries et al [57] report that although compliance in EMA studies is infrequently reported, it ranges between 43% and 91%, with longer studies trending toward lower compliance. Our compliance of between 38% and 50% is relatively low and is perhaps not surprising, given the length of EMA collection. Nevertheless, our qualitative EMA approach through audio snippets provides a novel and feasible way to gather contextual information about PA behavior, which is currently lacking in device-based PA measurement studies [18]. It is also worth noting that additional reminders when participants miss EMA recordings have not previously been feasible because researchers had to wait until the end of the study to retrieve the EMA data. However, we have demonstrated herein that it is feasible to remotely collect and store snippets, making them immediately accessible by researchers; therefore, EMA reminder notifications are possible and could further increase the feasibility of this data collection method.

Limitations

There are several limitations of this study that should be noted. Our proximal outcome was achievement of daily PA determined by the Fitbit tracker. This was because the JITAI component of this study was dependent on continuous activity–updating of Fitbit servers to enable remote tracking, a feature not available on research-grade accelerometers. Although validity and reliability of commercial activity trackers for step counting in older adults have been reported as good to excellent [58,59], they are still considered less valid than research-grade accelerometers in measuring PA of different intensities [18,60]. We sought to overcome the limitations with the measurement device by simultaneously determining the feasibility of remote deployment and recovery of research-grade accelerometers in the week before and the week after the JITAI. The accelerometer data loss of 10% (3/31) is encouraging, suggesting that it is feasible to measure PA using ActiGraph in community-dwelling older adults; therefore, this approach can be used to strengthen the validity of efficacy data. A second limitation is that muscle-strengthening activities are not accurately captured through device-based measurement, particularly when step counting is used over heart rate–based activity goals [61]. The importance of muscle-strengthening activities in addition to aerobic PA has been well established, but fewer older adults meet the daily recommendations [62]. Thus, including a means for recording muscle-strengthening activities in the JitaBug app is an area for consideration. Third, we did not collect location data or use other contextual data (such as calendar appointments, device use, and battery status) within our decision rules. These data may improve the timing of, and receptivity to, JITAI messages [50] and should be considered in future versions of the intervention. Finally, the participants recruited were predominantly well educated, retired, and with reasonable household income; therefore, the feasibility of the intervention in other population groups, including those from lower socioeconomic backgrounds, may be required before implementation.

Conclusions

This study demonstrated that a smartphone-delivered JITAI using a wearable activity tracker (JitaBug) is an acceptable way to support PA in older adults in a free-living setting. Moreover, the intervention was feasible, although the app will undergo further technical refinements that may enhance use, engagement, and user satisfaction before effectiveness trials. Finally, we present a novel and feasible approach to capture qualitative insights into PA behavior alongside quantitative measurement, which may advance the PA measurement capabilities of future smartphone-delivered mHealth approaches.

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Authors' Contributions

NS and JLM conceived of the study and designed the intervention. NS developed the app and managed the technical implementation of the app. AKC recruited participants and collected the data. JLM analyzed the data and wrote the manuscript. LDH and NS contributed to the manuscript writing. DSB analyzed the ActiGraph data, and both DSB and CE provided methodological guidance and reviewed the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Acceptability data.
[DOCX File , 28 KB - formative_v6i4e34662_app1.docx]

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Abbreviations

APEASE: Acceptability, Practicability, Effectiveness, Affordability, Side-effects, and Equity
API: application programming interface
BCT: behavior change technique
COM-B: capability, opportunity, motivation–behavior
EMA: ecological momentary assessment
JITAI: just-in-time adaptive intervention
mHealth: mobile health
PA: physical activity

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Original Paper

Feasibility of a Digital Patient–Provider Communication Intervention to Support Shared Decision-Making in Chronic Health Care, InvolveMe: Pilot Study

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Abstract

Background: Enhanced communication with health care providers (HCPs) can improve symptom management and health-related quality of life (HRQoL) for patients with chronic health conditions. Access to appropriate communication venues is needed to improve communication, however. As such, digital communication interventions mediated by patient portals carry the potential to support patient-provider communication and interaction and through this, also facilitate shared decision-making (SDM). The *InvolveMe* intervention was designed to provide patients with the opportunity to communicate symptoms and informational needs prior to consultation via digital assessment, including prioritizing what is most important to discuss with their HCPs, as well as to interact with HCPs through secure messages between outpatient visits.

Objective: The aim of this study was to assess the feasibility of the *InvolveMe* intervention by investigating acceptability, demand (ie, system use), and limited efficacy.

Methods: The study was designed as a single-arm, pre-post feasibility study combining quantitative and qualitative methods for data collection. Patients from an endocrine outpatient clinic were invited to use the *InvolveMe* intervention for 3 months, and HCPs administering *InvolveMe* were invited to participate in a focus group. Guided by descriptions of how to design feasibility studies by Bowen et al, feasibility was tested by exploring (1) acceptability, using data collected during recruitment from patient participants and nonparticipants (ie, declined to participate or did not meet study requirements), HCP experiences with recruitment, and the System Usability Scale (SUS); (2) demand via exploration of system use through extraction of system log data and HCP experiences with system use; and (3) limited efficacy testing, via exploration of potential effects from the Short-Form Health Survey (RAND 36), Hospital Anxiety and Depression Scale, and Health Literacy Questionnaire.

Results: Patient participants (N=23) were a median 54 (range 26-78) years old and primarily male (14/23, 61%). Nonparticipants (N=16) were a median 73 (range 55-80) years old and primarily male (12/16, 75%). The average SUS score was 72.2, indicating good system usability. Assessments were completed by 8 participants from home prior to outpatient visits. The assessments entailed various bodily symptoms and needs for information. Participants sent 17 secure messages related to patient administrative matters, symptoms, and challenges. Focus group participants (N=4) were all female and registered nurses. Data were analyzed

in 2 predefined themes: Acceptability and Demand. Acceptability included the subthemes intervention attractiveness and intervention suitability. Demand included the subthemes elements of SDM and intervention challenges and opportunities. All patient participants completed outcome measures at baseline, and 19 (19/23, 83%) completed outcome measures at 3 months. These preliminary efficacy findings were mixed and inconclusive.

Conclusions: The study design provided findings from both patient and HCP perspectives and supported feasibility of the *InvolveMe* intervention. The investigation of acceptability and demand supported the potential for remote SDM mediated by patient portals using assessments and secure messages.

Trial Registration: ClinicalTrials.gov NCT NCT04218721; https://www.clinicaltrials.gov/ct2/show/NCT04218721

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KEYWORDS

digital assessment; secure messages; patient portal; remote shared decision-making; chronic health conditions; assessment; portal; decision-making; chronic condition; chronic; communication; intervention; feasibility; pilot; acceptability; usage; demand; patient-reported outcome measures; PROM; outcome

Introduction

Living with a chronic health condition is demanding, as chronic health conditions often cause a variety of symptoms (eg, anxiety, depression, fatigue, loneliness, and sleeping problems) that may negatively affect health-related quality of life (HRQoL) [1-4]. In order to manage the various symptoms they experience, patients need to be able to communicate and interact with health care providers (HCPs) [5,6]. However, experiences with poor communication and interaction between patients and HCPs are common, which may interfere with symptom management and help-seeking [7,8]. Shared decision-making (SDM) may, with its focus on the patient and HCP working together to understand and address the patient's situation, carry the potential to improve patient-provider communication and interaction [9-11]. Traditionally, SDM has taken place in physical patient-provider encounters. However, information and communication technology (ie, eHealth) has provided new opportunities for SDM to be explored by improving access to care, enabling information exchange, supporting patient-provider communication, and building relationships [12].

Remote SDM may provide benefits by helping HCPs to understand which aspect of the patient's problem requires action and, together with the patient, identify the action required to solve the problem [13]. Patient portals present one way to engage patients and providers in remote SDM [14]. A patient portal provides patients with secure online access to their own health information, such as HCP's journal notes, medication lists, and opportunities for communication with their HCPs via secure messaging [15]. A review of patient portals [14] found that use of portals supported information sharing, improved preparation before visits, and supported patient-provider communication. Furthermore, portal use was found to encourage engagement in self-management of chronic disease [14,16] and empower patients in SDM [14]. However, the review rated the evidence related to portal use for improved communication, information sharing, and patient-provider relationships as low [14]. Secure messaging was identified as the most commonly reported portal feature, with patient-generated data by remote patient-reported symptoms (ie, assessments tools) less frequently reported [14].

Secure messages can also be an integral part of SDM, providing patients and HCPs with opportunities for contact, and benefits to patient-provider communication from using secure messages have been implied [17-19]. A review identified patients' main triggers for sending secure messages as accessibility to HCPs, self-management, and unmet needs [20]. Furthermore, the review highlighted that consequences of patient-provider secure messaging included patient empowerment, health promotion, and acquisition of uncertain answers [20]. Another review, focusing on use of secure messages, reported improved or comparable patient health outcomes for patients with chronic conditions when using secure messages compared with in-person care, describing quality of care as equivalent or improved for chronic conditions [21]. Use of secure messages among cancer patients has also been associated with improved survival and reduced treatment-related admissions, as well as reduced emergency visits [22]. In addition, the use of secure messages has been associated with improved glycemic level among patients with diabetes [23].

Remote assessment in preparation for health care visits can support symptom management [24], which is an important and integral part of chronic health care. Collecting patient-reported symptom data remotely can provide an opportunity to address the individuality and variability in symptoms over time among patients. Remote collection of patient-reported symptoms can also make the clinical workflow more efficient by not requiring patients to complete assessments in the waiting room or report symptoms within the limited time for consultation with HCPs [24]. A recent review found that there were few published studies examining integrated systems (ie, more than one system act together as one) for remote patient-reported symptoms, primarily feasibility and pilot studies, and subsequently limited evidence exists related to care and outcomes from using such integrated systems [24]. However, results from standalone systems (ie, a system that functions independently of other systems) for remote patient-reported symptoms are promising. The use of such systems has been reported to reduce symptom burden [25-27] and decrease emergency visits and in-hospital admissions [28]. Also, a review found improved symptom control, HRQoL, patient satisfaction, and patient-provider communication when patient-reported symptoms were used in feedback to patients [29]. A review on the effectiveness of

digital assessment tools to improve SDM [12] also found that communication, especially information sharing related to the patient's HRQoL and social aspects, as well as provider management of the patient's condition, improved through use. The review highlighted that digital assessment tools can be especially important for people with chronic health conditions [12].

Even though benefits of patient-provider communication and patient outcomes from the use of secure messages and remote patient-reported symptoms have been reported, research examining digital interventions combining secure messages and remote patient-reported symptoms through patients' portals to facilitate SDM is scarce. There are also patient barriers to the use of patient portals, such as lack of user-friendliness, technical support, education, and access to the internet [16,30]. Patient age may also play a role [30], and tailoring digital patient-provider communication interventions through the involvement of stakeholders representing end users (eg, patients or HCPs) appears crucial [31,32]. Stakeholders can provide insight to help tailor interventions to suit the local context (eg, hospital setting) and thus make interventions more acceptable, user-friendly, and less complex [31,32]. There are several factors that may impact intervention implementation, both relating to population and individuals [33]. For example, adaptation and tailoring to context are acknowledged as important implementation strategies [34], and creating an understanding of the context in which the intervention will be used can hence help avoid development of interventions that may fail during evaluation [33].

Seeking to address some of the issues raised by existing research, the current research team designed and developed a digital patient-provider communication intervention, called *InvolveMe*, aiming to support patients living with chronic health conditions, such as patients with nonfunctioning pituitary adenomas (NFPA) [35]. This single-arm pilot study aimed to assess the feasibility of the *InvolveMe* intervention by exploring acceptability, demand (ie, system use), and limited efficacy using a combination of qualitative and quantitative methods.

Methods

The *InvolveMe* Intervention

The *InvolveMe* intervention was developed to support SDM in the follow-up of patients with chronic health conditions, by being tailored to suit the patient group [35]. The intervention was further tailored to suit the intended context (ie, endocrine outpatient clinic) [36], in this study, patients with NFPA. *InvolveMe* provides patients with the opportunity to remotely report symptoms, needs, and preferences for care by completing an assessment (ie, predefined symptom list) in the hospital's patient portal. In addition, patients can use the secure messaging feature in the patient portal to interact with HCPs about symptoms and needs between hospital visits [35]. To allow for integration in patient portals, the *InvolveMe* assessment feature was developed as a Single Page Application (ie, web-technology) in line with the HL7 FHIR standard (ie, a specification for health care interoperability) [37]. The assessment part of *InvolveMe* is organized in 4 categories: (1) *bodily symptoms* (eg, pain, fatigue), (2) *psychosocial challenges* (eg, anxiety, loneliness), (3) *the need for work-related support* (eg, work-related understanding, whether the job exacerbates health), and (4) *the need for information* (eg, medication side effects, treatment change). The system allows for all symptoms and needs to be marked. In the first 3 categories, patients can rate how bothersome they find the symptom, while in *The need for information* category of the assessment, patients can request information from a predefined list. All symptoms and needs can be prioritized according to patients' preferences for care, on a scale from 0 to 10. The completion of the assessment generates a summary that is sent to the patients' HCPs (ie, as an attachment via the secure message feature).

In this study, the assessment was used as preparation prior to upcoming in-person outpatient consultations, as well as for feedback during the consultations. Secure messages were sent from, and received in, a shared message inbox managed by a dedicated moderator (ie, registered nurses). Routines for the moderator were established in dialog with the registered nurses to suit daily clinical workflow. The moderator would send a secure message through the patient portal approximately one week prior to the planned visit with an invitation for patients to complete an assessment (See Figure 1). *InvolveMe* was accessed by patient participants through the hospital patient portal and could be used on smartphones, tablets, or PCs. The shared message inbox had an automated message response, providing patients with contact information in case of medical emergency, response time, and contact information for the endocrine outpatient clinic. See Figure 2 for selected screenshots of the *InvolveMe* assessment feature from the patient interface. HCPs accessed the shared message inbox through hospital computers. See Figure 3 for screenshots showing the HCP interface of a completed, received assessment. The *InvolveMe* intervention was provided as an addition to standard care.

Figure 1. Invitation to complete the *InvolveMe* assessment from the patient interface.

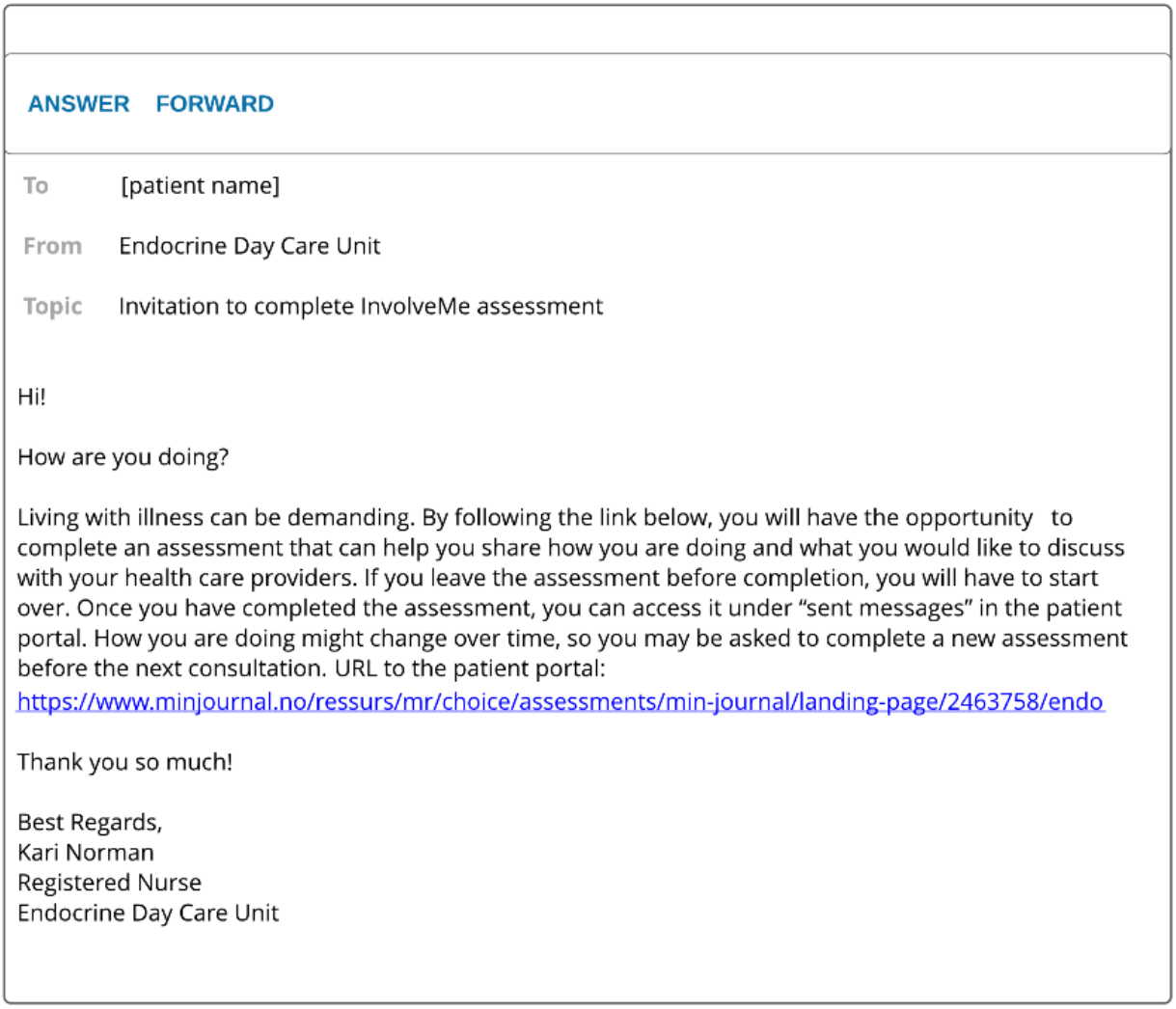


Figure 2. Screenshots of the *InvolveMe* assessment feature from the patient interface.

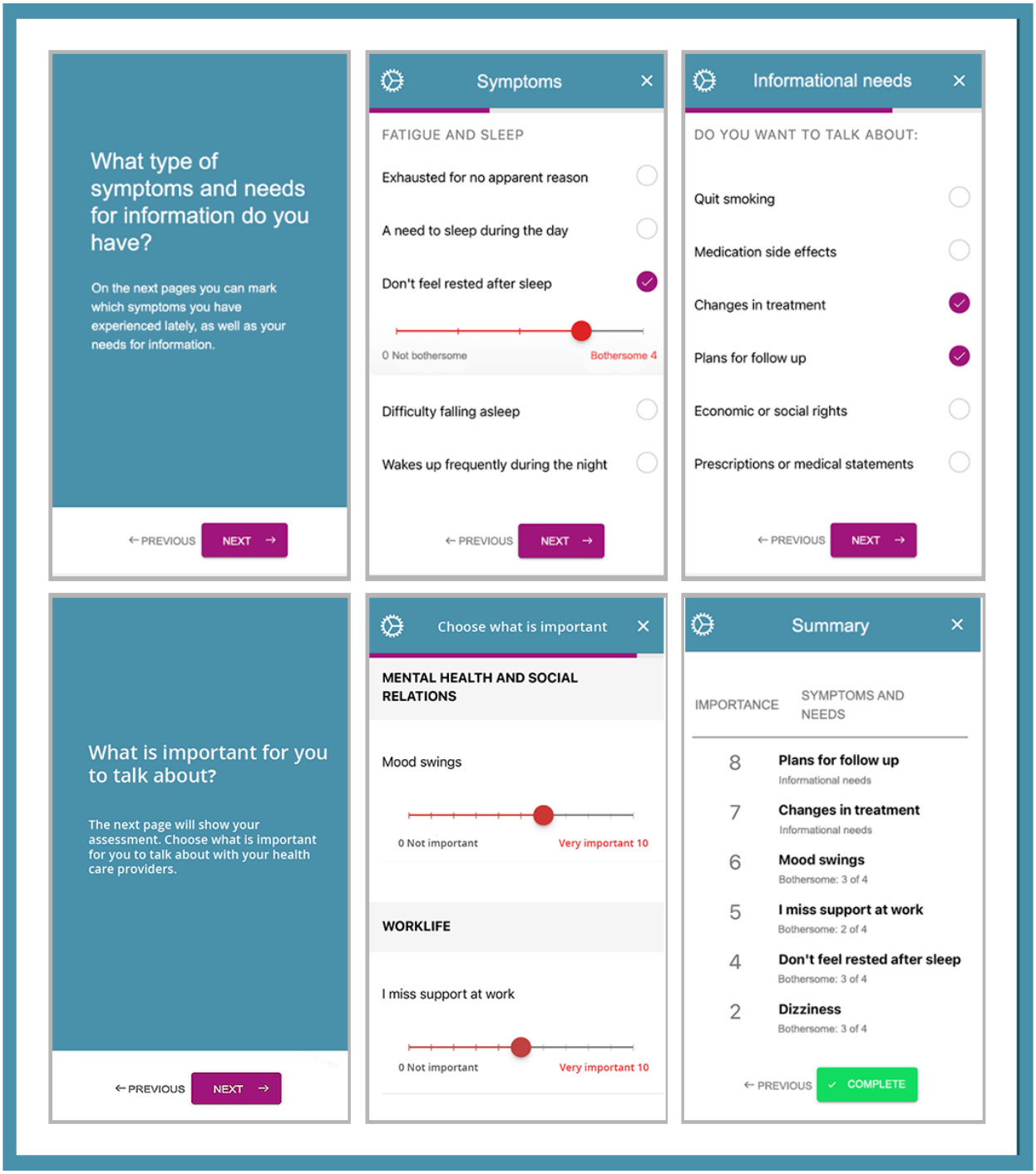
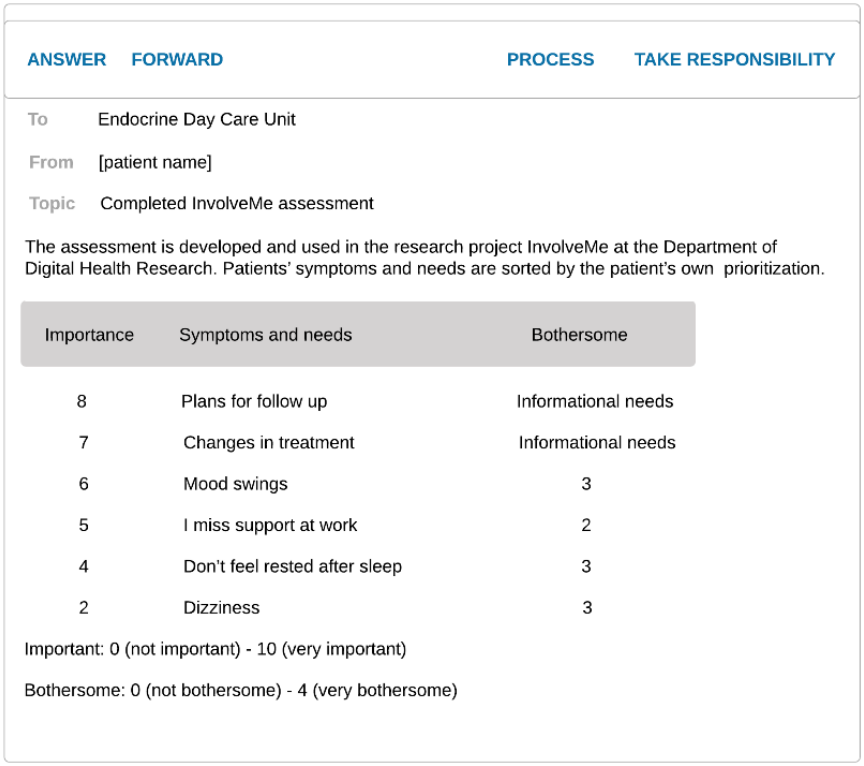


Figure 3. Completed assessment received from the health care professional (HCP) interface.



Study Design

In order to evaluate the effectiveness of complex interventions, initial testing and refinement of the intervention to ensure its feasibility are recommended [38]. Feasibility studies are important for producing findings that can be used to tailor interventions and examine recruitment settings [39]. This study was therefore designed as a pre-post feasibility study, with all patient participants receiving the *InvolveMe* intervention. In addition to the perspective of patients, the perspective of nonparticipants (ie, patients who declined to participate or did not meet study requirements) was included in this study to elaborate on potential barriers for use of eHealth interventions, which are of special interest for universal health care delivery, as provided in Norway. In addition, the perspective of HCPs was included to gain an understanding of intervention delivery and use in clinical practice. Feasibility conceptualization was guided by Bowen et al [39], exploring (1) acceptability (To what extent is *InvolveMe* judged as suitable, satisfying, or attractive?), (2) demand (Exploration of the actual use of the *InvolveMe* intervention and experiences with use from the HCP perspective), and (3) limited efficacy testing (Does the tool show promise of being successful with the intended population?) [39]. For the study purpose, this study combines quantitative and qualitative methods for data collection.

Setting, Participants, and Recruitment

The participants in this study were patients with NFPA and HCPs recruited from an endocrine outpatient clinic at a university hospital in Norway. NFPA are benign pituitary tumors, with which patients frequently experience a long period of slow deterioration of their health status before undergoing surgery, and they usually experience a variety of symptoms in the aftermath [40-42], which negatively impacts HRQoL [41,42]. Patients experience individuality and variability in symptoms, including pain, fatigue, sleeping problems, anxiety, and depression, and they may also face challenges related to visual limitations, fear of recurrence, distressing thoughts, loneliness, and frustration [41,43]. Patients with NFPA need and receive long-term follow-up in outpatient care after surgery. The initiative to include this patient group came from the endocrine outpatient clinic participating in this study, which recognized a need to improve patient follow-up after surgery.

Eligibility criteria for inclusion of patients in the study were (1) a diagnosis of NFPA (anywhere in the disease trajectory); (2) receiving treatment and follow-up from the study endocrine outpatient clinic; (3) ≥18 years of age; (4) able to understand oral and written Norwegian; (5) access to a smartphone, tablet, or personal computer; (6) access to the internet with a secure access key (BankID).

Participating HCPs were registered nurses responsible for care and follow-up of NFPA patients at the endocrine outpatient clinic. Some of them had previously participated in studies related to the development and intervention tailoring of *InvolveMe* [35,36].

Ethical Considerations

The study was approved by the Regional Committee for Medical and Health Research Ethics (2018/2201) and the Oslo University Hospital Institutional Review Board equivalent function (2017/9223). Informed consent was obtained from all participants.

Study Procedure

Registered nurses and physicians at the endocrine outpatient clinic identified eligible patient participants based on study inclusion criteria, and the registered nurses asked if these

patients were interested in receiving information about the study. Some of the patients were contacted and asked prior to upcoming consultations; others were asked during consultations. Those interested in receiving more information were contacted by the first author (BS) by phone and provided with information about the study purpose and procedures. Those interested in study participation signed a digital information and consent form. Patient-reported outcome measures were collected online through a secure server at Services for Sensitive Data (TSD; University of Oslo). After completing baseline outcome measurements, patient participants were contacted by the first author and informed how to register and log into the patient portal to access the *InvolveMe* features. After the first log on, HCPs sent a welcome message with information about the project to the patient participant. Patient and HCP participants could contact the first author by phone during the day on weekdays in case of questions. All contacts with participants were logged. The patient participants were informed to direct emergency issues or non-study-related questions to their primary care team or the nearest hospital or urgent care treatment unit.

HCPs at the endocrine outpatient clinic were provided with information about the study, and those willing to participate were included.

Data Collection and Outcome Measures

Timeframe

Data collection from patient participants was carried out from April 2020 until October 2020, when an unexpected incident led to the closure of the hospital patient portal and subsequently closure of the study before the planned study period completion. Outcome measures were collected from patient participants prior to them receiving access to *InvolveMe* and after 3 months of access. Numbers of assessments and secure messages, as well as the content in the secure messages, were also collected. Data from HCP participants were collected through a digital focus group in December 2021.

Sociodemographics and Disease-Related Measures

Information about patient participants' age, sex, level of education, work, income, and year of diagnosis and whether participants had received surgery were collected at baseline. HCP participants were all female registered nurses working in the endocrine outpatient clinic.

Acceptability—Patient Perspective

To explore to what extent the intervention was judged as satisfying or attractive, the first author's experiences from introducing patient participants to the *InvolveMe* intervention, including registration and login procedures in the patient portal, were written down. In addition, patient participants completed the System Usability Scale (SUS), a 10-item survey that provides a comprehensive assessment of subjective usability [44], at the 3-month follow-up. The SUS is a widely used subjective rating tool with acceptable reliability and validity [45-47]. Data from patients who declined to participate in the study (ie, nonparticipants), including age, sex, and reason for not participating in the study, if given unsolicited, were collected.

Demand (System Use)—Patient Perspective

Details of actual system use of the *InvolveMe* intervention were extracted from the patient portal. These data included the number and content of secure messages sent by patient participants, number of assessment invitations sent from HCPs, and number of and content in the assessments completed by patient participants. In addition, reasons for noncompletion of assessments were collected by the first author by phone (ie, written down).

Acceptability and Demand—HCP Perspective

The HCP participants were invited to share their experiences in a focus group that was conducted digitally due to national in-person meeting restrictions during the COVID-19 pandemic. The focus group interview guide consisted of open-ended questions based on operationalization of acceptability and demand [39] after dicussions and consensus of the research team. To explore to what extent the intervention was judged as attractive, suitable, and satisfying (ie, acceptability), participants were asked questions about experiences with recruitment and system usability. To explore experiences with system use (ie, demand), participants were asked questions about the use of secure messages and assessments. The focus group was facilitated by the first (BS) and last (EB) authors, lasted 45 minutes, was recorded with a digital voice recorder, and was transcribed verbatim by the first author.

Limited Efficacy Testing

To explore the feasibility of outcome measures and whether *InvolveMe* could show promise of being successful with the intended population, as well as explore preliminary indications of the potential impact of using *InvolveMe*, participants completed the following outcome measures: anxiety and depression, HRQoL, and health literacy.

Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS), a 14-item measure of anxiety and depression [48]. Items were rated on a 4-point scale (0-3), with a total score ranging from 0 to 42. The HADS is divided into 2 subscales: anxiety (HADS-A; 7 items) and depression (HADS-D; 7 items).

HRQoL was measured with the noncommercial RAND 36 survey, a 36-item HRQoL measure of physical, emotional, cognitive, role and social functioning, physical health, and general and global health [49,50]. Scores can range between 0 and 100 for all subscales, with lower scores indicating higher disability (0=maximum disability, 100=no disability).

Health literacy was measured with the Health Literacy Questionnaire (HLQ) [51]. The 44-item questionnaire includes 9 independent scales, with each scale including 4 to 6 items. The first 5 scales (Part 1 of the HLQ) are scored using response options indicating the level of agreement to items (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree), while the 4 remaining scales (Part 2 of the HLQ) report on the capacities to undertake different tasks (1=cannot do or always difficult, 2=usually difficult, 3=sometimes difficult, 4=usually easy, 5=always easy) [51].

Statistical Analysis

Statistical analyses were completed using SPSS version 25 (IBM Corp, Armonk, NY). Data on baseline characteristics and perceived usefulness are presented as medians and ranges for continuous variables and as proportions with percentages for categorical variables. Dependent paired *t* tests were used to analyze pre-post intervention changes. All tests were 2-sided, and *P* values <.05 were considered statistically significant.

Qualitative Analyses

Data from secure messages sent by patient participants and data from the focus group with HCP participants were analyzed using thematic analysis inspired by Braun and Clarke [52]. The analysis process was led by the first author (BS) in close collaboration with the last author (EB). Data from 17 secure messages (ie, written text) were read by the first and last authors and coded inductively by the first author [52]. Quotes (ie, written text) to illustrate the content of the secure messages were then chosen by the first and last authors and discussed within the research team.

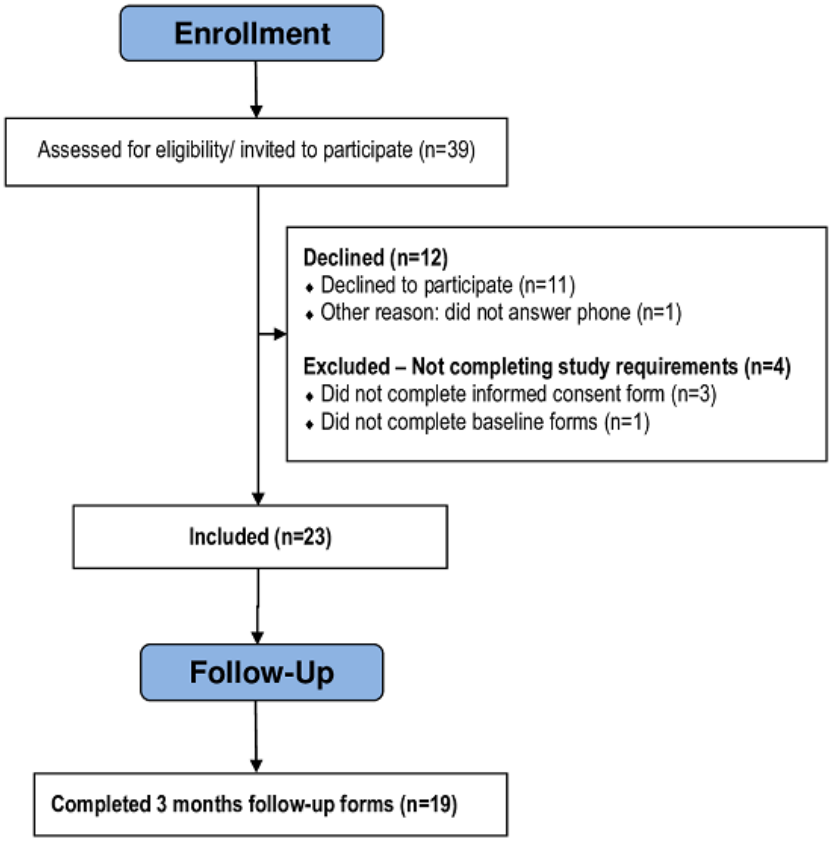
The first and last authors read the transcript from the HCP focus group to become familiarized with the data [52]. Then, the 2 authors used the interview guide to code the transcript deductively into 2 predefined codes: (1) acceptability and (2) demand. Next, subthemes within each main theme were identified. Themes and subthemes were then re-examined, and quotes to illustrate each subtheme were finally chosen and discussed within the research team [52].

Results

Recruitment, Participant Flow, Sample Description

Of 39 patients with NFPA who were assessed for eligibility, 23 (59%) agreed to participate (ie, patient participants), and 16 (41%) declined or did not meet study requirements (ie, nonparticipants). The 23 participants who were included in the study completed baseline measures and received the *InvolveMe* intervention. Of these, 19 participants completed the 3-month follow-up outcome measures. Due to technical issues with the hospital patient portal, the study closed after 6 months, which meant that 4 of the final included participants had limited time (ie, 1 to 4 weeks) to use *InvolveMe*. These 4 were hence not invited to complete the 3-month follow-up outcome measures. One of these participants completed and returned a secure assessment, but none of them used the secure message option in *InvolveMe*. Figure 4 provides details of the study recruitment and participant flow.

Figure 4. Recruitment flowchart.



Patient participants (N=23) were a median 54 (range 26-78) years old at inclusion. Of these, 17 (74%) had completed surgery. Participants were mostly male (14/23, 61%), and almost one-half (10/23, 44%) noted elementary school as their highest level of education (see Table 1 for details). The nonparticipants (N=16) were a median 73 (range 55-80) years old and mostly male (12/16, 75%). HCP participants (N=4) were all female and registered nurses working at the endocrine outpatient clinic.

Table 1. Patient participants' baseline demographics and illness characteristics (N=23).

Characteristics	Results
Age (years), median (range)	54 (26-78)
Sex, n (%)	
Female	9 (39)
Male	14 (61)
Marital status, n (%)	
Married/cohabitating	15 (65)
Single/divorced	8 (35)
Education, n (%)	
Elementary/high school	10 (44)
University/college ≤4 years	7 (30)
University/college >4 years	6 (26)
Employment status, n (%)	
Full-time/part-time work	7 (30)
Sick leave/disability benefits	10 (44)
Retired/other	6 (26)
Income (NOK[a]), n (%)	
200,000-399,999	6 (26)
400,000-599,999	7 (30)
600,000-799,999	0 (0)
800,000-1,000,000	2 (9)
>1,000,000	8 (35)
Surgery, n (%)	17 (74)
Months since surgery[b], median (range)	11 (1-39)

[a]NOK: Norwegian krones; a currency exchange rate of NOK 1=US $0.90 is applicable.

[b]n=17.

Acceptability—Patient Perspective

Among the 23 patients receiving the *InvolveMe* intervention, 7 (30%) needed additional technical support and assistance beyond the 2 planned contacts during study inclusion to be able to complete study requirements (ie, to complete the digital consent form, complete the digital baseline forms, or register in the patient portal). There were no questions from participants related to completing outcome measures after the initial guidance on how to complete the digital forms. At the 3-month follow-up, the 19 participants also completed the SUS. Mean system usability (ie, SUS) score was 72.2 (SD 14.6), which equals good system usability [44]. Of the 16 nonparticipants, 4 (25%) were positive toward participating but did not complete study requirements such as informed consent or baseline outcome measures. Reasons for declining were mainly described as not having a smartphone (7/16, 44%), feeling overwhelmed (2/16, 13%), or that they thought the intervention would be difficult to use (2/16, 13%). Some stated that it could be challenging to participate in a digital intervention, and some were not familiar with certain terms such as “smartphone.”

Demand (System Use)—Patient Perspective

During the 3-month study period, 43% (10/23) used the *InvolveMe* intervention (ie, used the secure message, completed the assessment, or both) before study closure.

Secure Messages

Of the included patient participants, 4 (4/23, 17%) sent a total of 17 secure messages (ie, assessments not included) during the study. HCPs responded to all, mainly by messages, some by phone or in-person in the upcoming consultation. The content of the messages from participants were sorted into 2 codes: (1) Patient Administrative Matters and (2) Symptoms and Challenges.

For the “Patient Administrative Matters” code, the 9 secure messages mainly concerned a change in the scheduled time of a hospital appointment, prescriptions for medications, or other practical matters. One participant wrote:

> *I have called the pharmacy for a while, but they have not received my medicine. Think the medicine is called something like [medication name]. I was advised by*

> *the doctor to take it during my appointment in May. Have called you too, but no answer.* [Participant 11]

For the "Symptoms and Challenges" code, the 8 secure messages concerned various symptoms and challenges experienced by the participants. The messages centered on a need for guidance (ie, including information and advice) regarding how to manage various symptoms and how to live with the chronic health condition. One participant wrote:

> *What should I feel or look for when I work with challenging things over time, or to see the degree to which I can work-out. Previously I have been told to double the dose of [medication] when needed, but when is that? What are the risks associated with the procedures that have been performed?* [Participant 5]

Another participant wrote:

> *I am still on sick leave, as I feel VERY and UNUSUALLY tired. I get easily tired after doing something. Have also had strict restrictions about making sure I take it easy, not bending forward, sleeping in at least a 30 degrees upwards position, not just showering hot, not eating hot/spicey food etc. (...) Have today raised hemoglobin to [X], as I have lost a lot of blood which may have affected the situation? (...) I'm not quite sure what to do to feel better?* [Participant 16]

Assessments

HCPs sent invitations to complete intervention assessments to all patients with upcoming consultations. Of the 13 invitations sent, 8 (62%) participants completed the assessments prior to the scheduled consultation. In a phone conversation, 1 patient said about the assessment:

> *So incredibly beneficial to be enabled to meet prepared.* [Statement, Participant 17]

Patient participants marked their symptoms and needs in all 4 assessment categories. The categories *Bodily symptoms* and the *Need for information* were marked in all assessments. The most prevalent need for information was about the disease trajectory, marked by 7 (7/8, 88%) participants. The number of marked symptoms and needs varied from 3 to 17 (median 6.5). See Table 2 for an overview of content in the completed assessments.

Table 2. Overview of the content in completed assessments (n=8).

Assessment main categories	Completed individual assessments							
	1	2	3	4	5	6	7	8
Bodily symptoms	Y[a]	Y	Y	Y	Y	Y	Y	Y
Psychosocial challenges	N[b]	Y	Y	Y	Y	N	Y	Y
The need for work related support	N	N	Y	N	N	N	Y	N
The need for information	Y	Y	Y	Y	Y	Y	Y	Y

[a]Y: yes.

[b]N: no.

Reasons for not completing the assessment varied: The upcoming consultation was rescheduled; the assessment was not received by the user due to technological difficulties; and one participant "felt fine" and felt no need to complete an assessment. Two participants did not receive an assessment notification in the patient portal and were therefore not aware of the assessment invitation. Patients had to register their contact information in the hospital patient portal in order to receive notifications there, and a failure to do so could potentially explain why these participants did not receive a notification.

Acceptability and Demand—HCP Perspective

Findings from the focus group with HCP participants were analyzed into the 2 predefined themes of Acceptability and Demand.

Acceptability

Participating HCPs provided a variety of feedback on the intervention, constituting 2 subthemes: (1) Intervention Attractiveness and (2) Intervention Suitability.

In the Intervention Attractiveness subtheme, HCP participants described their experience with the intervention in favorable words and phrases. They described the availability that the intervention provided for the patients as favorable, being able to contact HCPs when they needed to. They also stated that the intervention provided a unique option, especially for patients with complex health issues or heavy symptom burden. They stated that they would have liked to use the intervention for a longer period than the actual study period and said they would like to be a part of and use the intervention in a potential future clinical trial. Regarding recruitment of patient participants, the HCPs described most patients as interested and easy to recruit for this study. As one HCP stated: "...it was not difficult to recruit patients at all, they were, many were positive..."

In the Intervention Suitability subtheme, participating HCPs described the need for a secure and safe place for patients and HCPs to be able to communicate digitally and stated that the intervention was suited for this purpose. They highlighted that their, as well as the patient participants', previous involvement in the process of intervention development and tailoring was an important factor to make the intervention suited to purpose. However, based on experiences of recruiting participants for the pilot study, the HCPs were not entirely convinced that the intervention was suitable for older patients. One HCP stated

that older patients sometimes lacked the necessary equipment (eg, a smartphone) to participate, and reflecting on this, other HCPs contemplated whether a pre-educational group could be useful for eligible patient participants that needed guidance on how to use the intervention. The participating HCPs described themselves and the participating patients as satisfied with the *InvolveMe* intervention and described how patients had provided positive feedback to them about the intervention. One HCP stated that "...the participating patients gave the impression of being very satisfied, they thought it was exciting, and nice, that they could send questions."

Demand

The participating HCPs described the actual use of the *InvolveMe* intervention, and findings constituted 2 subthemes: (1) Elements of SDM and (2) Intervention Challenges and Opportunities.

In the Elements of SDM subtheme, HCPs described how the assessment helped patient participants sort their thoughts before the hospital visits and stated that it acted as a way of providing information about common symptoms and needs. One HCP described the assessments completed prior to consultation as making it easier to address sensitive topics in in-person conversations with patients. This was supported by the other participating HCPs. Some of them described how patients' identification and prioritization of topics important to them contributed to a focus in the consultation conversation, centering around what was most important to discuss for the patients. The HCPs described how the assessments had contributed to change their perspective on what was important to discuss with patients and said that, through this information exchange focusing on patients' current situations, a more individualized follow-up was facilitated based on the patient's needs. As described by one of the HCPs:

> *...the most important thing is that it is user centered, that patients dare to raise issues that are important to them, so that we can focus on what is important, for them to benefit the most from the health care service, this is very important and very rewarding.*

Also, one HCP described how the intervention provided support and contact for patients who felt unprepared for the aftermath of surgery. This was also supported by the other participating HCPs.

In the Intervention Challenges and Opportunities subtheme, participating HCPs described the intervention as time-consuming initially, as they had to learn a new system (ie, hospital patient portal) and develop new routines to be adapted into the daily clinical workflow. However, they stated that, after having learned to use the system, it was no longer time-consuming but rather something that could be executed in between other daily tasks. As stated by one HCP:

> *...we had to learn a new system, which we spent some time on, but I think it was quite easy to learn the system, and it quickly became the routine.*

One participating HCP also stated that they spent some time between themselves discussing potential responses to patients before replying to the secure messages from patients. They reported considering this as something positive, providing quality-assured responses to patients and also contributed to the development of care though contributing to professional discussions. One participant stated that the assessment could potentially even provide support for new HCPs with little prior knowledge about the patient group. They also highlighted, based on feedback from patients, that access to the intervention was valued, even by the patients not using the intervention (ie, participating nonusers), stating that interventions were often used the most by those with complex health issues or heavy symptom burden.

Limited Efficacy Testing: Pre-Post Intervention Results

Pre-post intervention findings at the 3-month follow-up revealed statistically significant increases in symptoms of anxiety (mean difference [MD] 3.9, 95% CI 2.3-5.5) and depression (MD 2.7, 95% CI 0.9-3.8) for the participating patients. Time since surgery had no impact on these results. HRQoL findings indicated a statistically significant improvement for the "Role Physical" subscale (MD 25.0, 95% CI 3.0-47.0) but not for the 7 other subscales. There was a high degree of heterogeneity in the data, with large variance and subsequently broad CIs for the HRQoL subscales (eg, the "Role Emotional" subscale improved by 17.5, but due to the large variance, the findings were not statistically significant). Scores related to health literacy remained stable, with no statistically significant changes from baseline to follow-up. See Multimedia Appendix 1 for details.

Discussion

Principal Findings

Findings from this feasibility pilot study gave insights related to the acceptability and demand of the *InvolveMe* intervention. Exploration of intervention acceptability identified good system usability, and the findings also provided insights regarding patients' reasons for not participating, as well as demographic factors impacting intervention participation (eg, older age among nonparticipants). Furthermore, some participants appeared to struggle with understanding terms used to describe study participation. The examination of demand (ie, system use) suggests that completed assessments and use of secure messages may respectively act as preparation for upcoming visits and provide patients with the opportunity to request guidance on symptom management. The limited efficacy testing showed mixed findings in terms of HRQoL, anxiety, and depression but indicated a study population with high health literacy.

This study provided insight into opportunities for remote SDM through use of secure messages and digital assessments mediated by a patient portal. During the study period, only 17% of participants used the secure message feature. However, simply having the access and opportunity to communicate with HCPs may be of benefit to patients, even without using this option [53]. This was as expected and also suggested in focus group with HCPs. About half of the secure messages sent in the study contained questions related to symptom and treatment complication guidance, which may indicate that the secure messages were used by those who experienced a heavy symptom burden at the time. This was also pointed out by the HCPs during the focus group.

Existing research has found patients to be interested in using secure messages with their HCPs and that patients prefer the convenient and asynchronous aspects provided by secure messaging through portals [14]. The modest use of secure messages in the current study could have been due to the brief study timeframe, and providing patient access over a longer period of time could have provided increased knowledge and experience related to the use of secure messages. Some patients may also lack interest in communicating through portals as they are satisfied with the existing in-person communication [14]. Health literacy is another factor that may play a role in patient portal use, as research has pointed to patients with lower literacy skills as being less likely to use patient portals [14]. However, the participants in this study did not have low literacy skills, quite the contrary.

The assessments collected prior to consultation in this study revealed a wide range of symptoms and needs experienced by the patient participants, which may help identify important topics and priorities for patient-provider discussions and SDM, as also pointed out in the focus group with HCPs. Such assessments may address the individuality and variability in symptoms, aiding patients with communicating their symptoms, needs, and preferences for care to their HCPs [54,55]. In all completed assessments, the study participants used the opportunity provided to request information. This could help improve the provision of tailored information to suit the patients' situations and thus support patients in making choices about their lifestyle, when ready to do so. It has been suggested that, when patient preferences are asserted, HCPs may manage patient concerns and health conditions more effectively [12]. In line with SDM, the *InvolveMe* assessment feature, providing insight into patients' current situations, may facilitate collaboration between the patient and provider to mutually understand and address the patient's situation [9-11].

In this study, 41% of the eligible patients declined to participate or did not complete study requirements (ie, nonparticipants), which is a low percentage of people declining compared with similar studies examining eHealth interventions (ie, 60%-68%) [56,57]. However, evidence on how patients accept eHealth interventions is limited [58], and increasing knowledge related to reasons for nonparticipation (eg, user friendliness, complexity) is necessary in order to improve intervention acceptance.

Nonparticipants in this study were older (median 73 years) than the participants (median 54 years), corresponding with findings from existing research [56,59]. Increased age has been described as contributing to lower levels of digital skills [60,61], a known barrier for adopting new technology [30,62]. Along these lines, a review pointed to substantial health equity disparities in patient portal use, where older persons, persons with low socioeconomic status, persons with low health literacy, and persons with chronic health conditions appear to use portals less often [62].

In this study, some of the eligible patient participants struggled to understand some of the terms used to describe the study participation in detail. Use of technology may inadvertently create health equity concerns by not paying sufficient attention to the social determinants of health during the implementation process [62]. Instead of focusing on barriers for portal use, which may place responsibility on patients already experiencing health disparities, one should focus on developing interventions that are easy to use in order to reduce disparities [62,63]. Findings from this study, as well as existing research on strategies to minimize potential disparities in use [14,63,64], point to the need to develop strategies to increase the number of participants in future studies.

System usability was rated as good but not excellent in this study, which indicates room for intervention improvement. However, using the SUS [44] to measure usability may not have been ultimate in this study, as participants most likely rated the overall system usability, including all the features of the hospital patient portal, not the specific features of the *InvolveMe* intervention alone. When aiming to measure usability and evaluate features integrated into an existing system, the SUS may not be specific enough, and other or additional usability measures should be considered.

The psychosocial outcome measures in this study were primarily included to test feasibility of the measures (eg, are they easy to answer digitally, do they capture changes). Even though some participants initially struggled with completing the outcome measures, all 19 participants receiving the 3-month follow-up measures completed these. There were no questions from the participants related to outcome measures after the initial guidance on how to complete these, indicating satisfactory study routines for this aspect. The noted statistically significant increases in anxiety and depression during the 3-month study period were unexpected. These findings could however be related to the ongoing pandemic during this study, and a recent study revealed that the general population was almost 3 times more likely to suffer from symptoms of anxiety and depression due to the pandemic [65]. The current study period coincided with a national decrease in COVID-19 cases around baseline (ie, May 2020 to June 2020) and a national increase in cases around the 3-month follow-up (ie, August 2020 to September 2020), which might explain the pre-post increase in symptoms of anxiety and depression. However, given the feasibility nature as well as the limited number of participants in the study, efficacy conclusions cannot be made.

Compared with indicators of health literacy (ie, *Active engagement with HCPs* and *Read and understand health information*) from a population-based survey (ie, including people with chronic health conditions) [8] as well as general population participants [66], health literacy scores from this study indicate a study population with high health literacy. Reasons for these findings are not evident, although participants in this study were younger compared with nonparticipants, and higher age has been associated with lower health literacy [60,67].

Even though the closure of the hospital patient portal during this study caused premature study closure, the software development of the *InvolveMe* assessment feature is in accordance with a standard enabling the completed assessment to be sent as an attachment via the secure message feature in the national patient portal [68] as well. Use of standards for provision of eHealth systems has been recognized as a key factor

for successful implementation [31,32], and the importance of developing new software features and systems according to established standards are clearly emphasized through this feasibility pilot study.

The COVID-19 pandemic brought an urgent need for remote care through secure, technical systems and as such, boosted the use of the national patient portal [68] in various ways. For example, as of March 2020, all COVID-19 test results were accessible to Norwegian citizens through the national patient portal, and a number of HPCs, including general practitioners, began using the national portal for most nonurgent care and follow-up. This increase in use of eHealth systems as a consequence of the pandemic has also been identified through a recent review, highlighting how the transformation of care from in-person to virtual or remote accelerated during this time [69]. The *InvolveMe* intervention, incorporated into the national patient portal, may provide features currently not used in the national portal, further promoting patient-provider communication and interaction and serving the need for remote care systems.

Study Limitation and Strengths

This study has several limitations. First, the study was designed to assess the feasibility of a digital patient-provider communication intervention to support patients with NFPA. All patient participants received access to the intervention, without randomization, and statements regarding the effectiveness of the intervention cannot be made. Efficacy testing was however not a major part of this feasibility pilot study. Second, the participants were recruited through a collaborating partner (ie, endocrine outpatient clinic), and it may therefore be assumed that the participating sample were highly motivated and the study cannot conclude whether patients with NFPA in general would be interested in, or benefit from, such an intervention. Indications on feasibility are however promising. Third, the urgent closure of the hospital patient portal led to an unpredictably shortened study period, which might have affected study outcome. Fourth, the focus group with HCPs was conducted 1 year after the pilot study was finished, and all HCP participants were registered nurses. This might have affected recall of experiences, and other additional professionals could have elaborated even more on questions asked in focus group.

This study also has several strengths. First, both patient and HCP perspectives are included in the study, underlining the importance of stakeholder involvement when aiming for real world implementation [30-32]. Second, all eligible patients were invited for participation. This provided insight into who would be interested in the opportunity to assess symptoms and information needs prior to consultations and use secure messages to communicate digitally with HCPs between consultations, as well as reasons for nonparticipation. Such information could be used to tailor educational material and study routines for participant follow-up during the study. Third, the data collection related to acceptability and demand provided essential information for tailoring of the *InvolveMe* intervention as well as study routines in preparation for a future clinical trial.

Future Directions

Through exploration of acceptability, demand (ie, system use), and limited efficacy testing, this study established feasibility of the digital patient-provider communication intervention *InvolveMe*. Findings provided ideas and suggestions for further tailoring in order to prepare for a future clinical trial, such as the development of study-specific questions (ie, in addition to SUS) [44]; use of simple, plain language in the recruitment processes and patient education material; as well as having a dedicated support person involved in the study. In the study, some participants struggled with completing study requirements. Future research should aim to incorporate ways to help adults not familiar with technology to become familiar with and adopt digital interventions.

The increasing number of persons living with chronic health conditions entails, in addition to individual personal challenges, increases costs and demands for resources, representing a major challenge for health care services. Therefore, future research should continue to explore how assessments and secure messages mediated through patient portals can promote and support remote SDM in a variety of chronic health conditions.

Finally, in order to examine actual effects of digital patient-provider communication interventions such as *InvolveMe*, larger-scale clinical trials are needed.

Conclusions

This feasibility pilot study explored how a digital patient-provider communication intervention, *InvolveMe*, could be of use for patients living with chronic health conditions, such as patients with NFPA. Feasibility was established, and the importance of developing software according to given standards was highlighted. Given the findings showing that patient participants used the secure assessment and messages to communicate about bodily symptoms, needs for information, and challenges they experienced, the use of patient-provider interventions such as *InvolveMe* has the potential to facilitate SDM by enhancing accessibility and information exchange and to strengthen the patient-provider relationship for patients living with chronic health conditions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Pre-post intervention changes.
[DOCX File , 16 KB - formative_v6i4e34738_app1.docx]

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Abbreviations

HADS: Hospital Anxiety and Depression Scale
HCP: health care provider
HLQ: Health Literacy Questionnaire
HRQoL: health-related quality of life
MD: mean difference
NFPA: nonfunctioning pituitary adenomas
SDM: shared decision-making
SUS: System Usability Scale

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Original Paper

Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study

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Abstract

Background: Digital health technologies such as continuous remote monitoring and artificial intelligence–driven clinical decision support systems could improve clinical outcomes in intensive care medicine. However, comprehensive evidence and guidelines for the successful implementation of digital health technologies into specific clinical settings such as the intensive care unit (ICU) are scarce. We evaluated the implementation of a remote patient monitoring platform and derived a framework proposal for the implementation of digital health technology in an ICU.

Objective: This study aims to investigate barriers and facilitators to the implementation of a remote patient monitoring technology and to develop a proposal for an implementation framework for digital health technology in the ICU.

Methods: This study was conducted from May 2018 to March 2020 during the implementation of a tablet computer–based remote patient monitoring system. The system was installed in the ICU of a large German university hospital as a supplementary monitoring device. Following a hybrid qualitative approach with inductive and deductive elements, we used the Consolidated Framework for Implementation Research and the Expert Recommendations for Implementing Change to analyze the transcripts of 7 semistructured interviews with clinical ICU stakeholders and descriptive questionnaire data. The results of the qualitative analysis, together with the findings from informal meetings, field observations, and previous explorations, provided the basis for the derivation of the proposed framework.

Results: This study revealed an insufficient implementation process due to lack of staff engagement and few perceived benefits from the novel solution. Further implementation barriers were the high staff presence and monitoring coverage in the ICU. The implementation framework includes strategies to be applied before and during implementation, targeting the implementation setting by involving all ICU stakeholders, assessing the intervention's adaptability, facilitating the implementation process, and maintaining a vital feedback culture. Setting up a unit responsible for implementation, considering the guidance of an implementation advisor, and building on existing institutional capacities could improve the institutional context of implementation projects in the ICU.

Conclusions: Implementation of digital health in the ICU should involve a thorough preimplementation assessment of the ICU's need for innovation and its readiness to change, as well as an ongoing evaluation of the implementation conditions. Involvement of all stakeholders, transparent communication, and continuous feedback in an equal atmosphere are essential, but leadership roles must be clearly defined and competently filled. Our proposed framework may guide health care providers with concrete,

evidence-based, and step-by-step recommendations for implementation practice, facilitating the introduction of digital health in intensive care.

Trial Registration: ClinicalTrials.gov NCT03514173; https://clinicaltrials.gov/ct2/show/NCT03514173

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KEYWORDS

digital health; patient monitoring; intensive care medicine; intensive care unit; technological innovation; user-centered; usability; implementation; implementation science; qualitative research; interview

Introduction

Background

In intensive care medicine, digital health technologies promise to improve outcomes by reducing the patients' length of stay or preventing complications [1-3]. Continuous remote monitoring allows early detection of deterioration in intensive care unit (ICU) patients and therefore rapid therapeutic intervention [4]. Algorithms used in clinical decision support systems and early warning scores can analyze the large amounts of data generated by ICU monitoring devices to decrease ICU mortality and the risk of complications such as prescription errors [5,6]. Despite the potential, the digital transformation of health care is lagging in numerous countries for reasons that can be ascribed at every level of the health care system. At the macro level, weak national internet infrastructures, high market fragmentation, and lack of legal frameworks, financing models, and interoperability play a significant role [7-9]. At the meso and micro levels, cumbersome operation, high costs, lack of interoperability, information governance uncertainty, and organizational resistance block digital health technology implementation [10-13].

Implementation science, as an increasingly evolving discipline, has brought about the publication of numerous guidelines and recommendations for the implementation of digital health technologies in health care settings by various institutions and researchers [9,14-17]. However, still scarce is the evidence regarding meso- and micro-level implementation and the guidelines for the successful integration of digital health technologies into specific clinical settings [16,18-20]. Successful and sustainable implementation in health care requires a holistic concept to be followed, applying meaningful strategies at all levels [21-23]. In particular, the implementation processes of digital health tools in German ICUs are poorly explored, apart from the concept *tele-ICU*, which involves augmenting local ICU capacity with external expertise through video consultation, remote monitoring, and web-based access to patient data management systems [1,24,25].

Five domains are essential for the implementation of digital health in various health care settings: (1) the individual digital health technology (eg, remote patient monitoring systems), (2) the outer setting (eg, external regulations, laws, and patient needs), (3) the inner setting (eg, the direct implementation environment, social factors, networks, and communication), (4) the individual health professionals, and (5) the implementation process [11]. These domains were first outlined in the Consolidated Framework for Implementation Research (CFIR), a well-proven tool to evaluate the implementation of an intervention into health care settings [12,13,26-29]. Targeting the improvement of implementation performance, the Expert Recommendations for Implementing Change (ERIC) provide a comprehensive compilation of strategies to boost implementation in clinical practice [30,31]. The CFIR domains and ERIC strategies are coherent and synergistic and provide meaningful guidance for implementation researchers and practitioners; however, they require more use cases and documentation of applications in a specific context and setting. In addition, the present literature on implementation strategies for digital health technologies in health care settings and particularly the ICU is extensive and unstructured, and the strategies reported are often poorly conceived [20,32,33].

It is unclear whether the aforementioned barriers and facilitators to digital health implementation can be transferred into the ICU context, given that it is a very specific setting: multiple professional groups work together, many different technologies are already in place, and staff stress levels are also high because of critically ill patients requiring acute treatment, high alarm frequency, and staffing and capacity constraints [34-36]. Concrete implementation strategies for digital health technologies in intensive care settings are still lacking.

Objectives

This study aims to (1) investigate barriers and facilitators to the implementation of a remote patient monitoring technology and (2) develop a proposal for an implementation framework for digital health technology in the ICU.

Methods

Overview

To assess the barriers and facilitators to implementing a remote patient monitoring system, we explored stakeholder perspectives using an abductive qualitative approach. This research design, combining inductive and deductive elements, included semistructured interviews with ICU leaders and key stakeholders in the implementation process, as well as field observations and regular feedback discussions within the research team. To develop the presented implementation framework for digital health technology in the ICU, we conducted a deductive analysis by matching the collected data to the CFIR and ERIC domains. Using the CFIR-ERIC mapping tool, we filtered out relevant strategies to improve implementation performance. In a final step, the strategies were ordered in a temporal sequence and visualized in a figure [37]. The Standards for Reporting Qualitative Research were consulted to report this research [38].

Ethics Approval and Consent to Participate

The ethical approval for this study was granted by the Ethics Commission of the Charité–Universitätsmedizin Berlin (EA1/031/18). Participation in the survey was voluntary. Before the study, all participants provided their consent.

Context and Technical Setup

We conducted this study with ICU staff from a German university hospital over the course of the implementation of the Virtual Patient Monitoring Platform Vital Sync (version 2.4; Medtronic plc). The device remotely monitored ICU patients from portable tablet computers at the hospital premises and was supplemental to the primary patient monitoring system, the IntelliVue patient monitoring system (MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04; Koninklijke Philips N.V.). The primary Philips IntelliVue monitoring system displayed the vital parameters on stationary touchscreen displays at the bedside and on a monitor at the central nurse station. COPRA (version 6; COPRA System GmbH) was used as the patient data management system (PDMS); however, no data transmission from the Vital Sync system to the primary monitoring system or PDMS occurred.

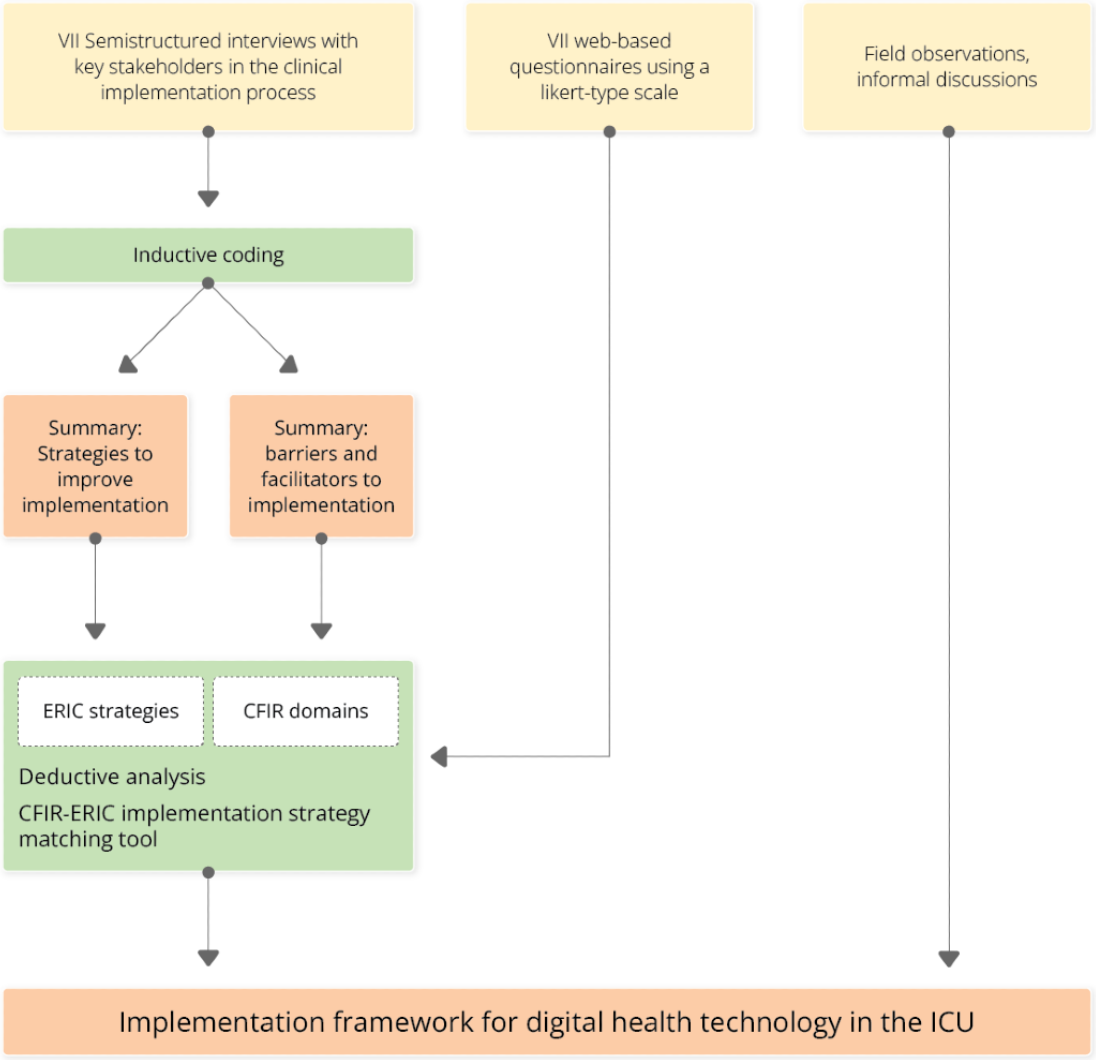
The remote monitoring system was installed between May 2018 and June 2019 in 50% (5/10) of the beds of the postanesthesia care unit, an ICU mainly for postoperative patients that need short-term intensive care treatment and monitoring. The system included 2 sensors (the pulse oximetry and the capnography) that registered peripheral capillary oxygen saturation, pulse rate, end-tidal carbon dioxide level, and respiratory rate at a frequency of 1 Hz. The vital parameters were displayed on a monitor at the central nurse station and were retrievable from 6 tablet computers (2 large 10.2“ iPad tablets [9th generation; Apple Inc], 2 iPad mini 4 tablets [Model A1550; Apple Inc], and 2 Surface Pro 4 laptops [Microsoft Corporation]). A 6-digit code protected the iPad access, and the data were accessible after logging into the Vital Sync website. A username and a password protected the access to the Microsoft Surfaces. Technical instructions of ICU staff (ie, physicians, nurses, and respiratory therapists) into the device were conducted over a period of 1 month. In addition, 2 workshops were conducted for hands-on training. Additional assistance was provided as needed. Further technical description and use of the software can be found elsewhere [39,40].

Study Design and Research Team

This qualitative exploratory implementation study is based on an abductive research approach, as described by Dubois and Gadde [41] and Zainal [42]. The abductive approach of systematic combining (containing inductive and deductive analysis methods) specifies existing theories, refining them according to the individual case and context. We considered this approach essential to derive practical recommendations for the implementation of new technology in the ICU. The transcripts of 7 semistructured interviews and web-based questionnaires with key stakeholders in the clinical implementation process, the results of field observations and informal discussions among the research group, and findings from previous explorations in the context of the implementation were analyzed and applied to the CFIR domains and ERIC strategies to develop the proposed implementation framework (Figure 1) [43].

The research team consisted of an MD candidate (LKM); a postdoctoral researcher with a background in anesthesiology, intensive care medicine, digital health, and geriatrics (ASP); a professor for digital health, who is a consultant anesthesiologist and a computer scientist (FB); a psychologist (HK); a head nurse (MS); an ICU senior consultant (SWC); and the department’s head of staff (CS).

Figure 1. Overview of the data collection and analysis for the derivation of the proposed implementation framework for digital health technology in the ICU. CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change; ICU: intensive care unit.



Data Collection

Our data included interview transcripts and quantifiable results of a questionnaire with key stakeholders in the ICU, informal meetings and discussions among the research group, field observations, and the results of previous explorations [39,43]. The outer setting and manufacturer's perspective were not part of this study because we could not evaluate these domains with the data given.

From June to November 2019, we conducted 7 semistructured interviews with ICU staff members, including 3 physicians, 3 nurses, and 1 respiratory therapist. We used purposive sampling with the aim of including all stakeholders who were closely involved in the implementation process and in leading positions in the ICU and presenting all professional groups. The identified study participants were key stakeholders (eg, head nurse, senior physician, and staff member with high working time in respective ICU) of the ICU and had closely experienced remote patient monitoring implementation, overseeing the implementation process, receiving feedback regarding the system from other staff members, and using the system in their own clinical practice.

The interview guideline was deduced on the findings of a previous study from our research group [43] and was oriented toward the categories of the CFIR (Multimedia Appendix 1 [44]). Pilot interviews with associated intensive care physicians did not alter the questions. The interviews were performed either before or after patient care and were recorded and transcribed verbatim.

The semistructured interview guideline included web-based questionnaires containing 47 items and a technology commitment scale [44]. We conducted face-to-face pilot testing with ICU staff with a focus on clarity, relevance, and order of the items. We used a 5-point Likert-type scale as an ordinal response format, with the options *not correct at all*, *not quite correct*, *partly correct*, *quite correct*, and *completely correct*. The study data were collected and managed using Research

Electronic Data Capture (REDCap) tools hosted at Charité–Universitätsmedizin Berlin [45,46]. Data resulting from the questionnaire responses were collected in an overview table.

To gain auditability and enhance reflexivity in the research process, informal meetings and discussions among the research group and field observations occurred from the start of the implementation in May 2018 until March 2020. These methods helped gain a more objective perspective and minimize potential biases that naturally arise when using a qualitative research approach, as described by Noble and Smith [47]. Results of the field research were published by Poncette et al [39].

Data Analysis

For qualitative analysis, we applied a hybrid approach combining inductive and deductive coding elements, as described by Fereday and Muir-Cochrane [48].

First, the interview transcripts were analyzed using a thematic analysis approach, applying an inductive coding process, meaning that themes and codes were iteratively developed and applied to all transcripts [49]. The resulting content of the codes was summarized to obtain the main findings and serve as the basis for the deductive analysis, as described by Crabtree and Miller [50].

Second, for deductive analysis, we used as code system templates the CFIR domains and ERIC strategies, which were grouped into 9 clusters [30,31]. Summaries from the inductive analysis and the findings of the questionnaires were coded according to templates (Multimedia Appendices 2 and 3). That is, data from the web-based questionnaires were not analyzed with quantitative methods. Specifically, the CFIR template was used to analyze the summaries regarding implementation performance, whereas the ERIC strategies served as a template for analyzing the summaries of staff's suggestions on implementation process improvements. All coding was performed using the MaxQDA 2020 qualitative data analysis software [51].

Finally, the proposal for an implementing framework for digital health technology in the ICU was derived from the results of the CFIR- and ERIC-guided analyses. The CFIR-ERIC Implementation Strategy Matching Tool supported the prioritization of the derived recommendations [52]. Findings from the informal meetings, discussions, and field observations supported in situating the results and the interview suggestions in the context of implementation and in supplementing objective characteristics. We ordered the findings into a temporal perspective.

Results

Overview

Inductive analysis of the interview transcripts revealed the two major categories *perceived performance of the implementation* and *perceived factors improving implementation*, which contained 4 and 3 subtopics, respectively. According to the interviewed stakeholders, the remote patient monitoring system's implementation was insufficient owing to a lack of staff engagement in the process and little perceived benefit from the novel solution in its current version. Factors suggested improving implementation were targeting staff training, features of the technology itself, and implementation setting.

Deductive coding revealed four major CFIR domains: *intervention characteristics*, *inner setting*, *individual characteristics*, and *process*. Regarding perceived factors improving implementation, seven clusters of the ERIC framework were mapped: *use evaluative and iterative strategies*, *provide interactive assistance*, *adapt and tailor to context*, *develop stakeholder interrelationships*, *train and educate stakeholders*, *support clinicians*, and *change infrastructure*.

Implementation Process

Staff Involvement and Training

The interviewees identified staff involvement and training as being more targeted toward nursing staff, although they were not in charge of the implementation project. According to the interviewed stakeholders, staff members of all professional groups lacked a feeling of responsibility to continuously apply the remote patient monitoring system. In addition, the staff was unable to identify a leading member in charge of the implementation process and longed for more regular staff training and information sessions. Interviewees reported that opinion leaders' communication created a negative peer pressure not to use the system.

Interviewees said that they felt well informed about the project initially; however, the information flow decreased equally. Training did not reach all staff members because of a complex shift system and a big pool of staff for 2 ICUs, whereas the system was implemented only at 50% (5/10) of bedsides on 1 ICU. Staff perceived the system as an imposition from outside the ICU and felt that it did not have any influence on the implementation.

Additional Benefit

Staff did not perceive the system's added value as high for four reasons: First, the ICU already had a monitoring system offering remote functions (eg, displaying vital parameters of different patients on all bedside monitors), although it did not offer a portable monitoring device. However, according to interviewees, this made an additional system superfluous. Second, the high staff presence in the ICU decreased the need to remotely monitor patients. Third, high patient turnover in the ICU was associated with frequent connecting and disconnecting of patients to and from the system, resulting in an increased workload for nurses. Fourth, remotely monitoring patients while being on a different ward or performing a clinical intervention would make a necessary immediate reaction to an alarm impossible.

Intervention Features

Interviewees highlighted that the limited number of vital parameters monitored by the system was not sufficient to satisfactorily evaluate the patient's condition. Furthermore, the system's dependency on a stable wireless network connection raised concerns. Interviewees perceived the tablet as too large and inconvenient to use and carry in the tunic pockets. Finally, the device would not allow patients' monitoring during their transportation.

Attitude of Staff

Interviewees said that they were satisfied with the current monitoring system and did not see the need for a change. ICU staff did not use the system because they lacked the habit and routine of using a remote patient monitoring technology. They were afraid of losing break times when applying the system and of an increased workload (eg, system setup). They feared that reduced patient contact and false alarms might increase stress levels and endanger patient safety. Overall, the staff saw no additional benefit in the technology. Figure 2 presents an overview of the factors influencing the implementation process from the perspective of interviewed staff members.

Figure 2. Implementation performance: 4 major categories were identified (inner ring), divided into themes (middle ring), and further specified (outer ring). ICU: intensive care unit.

Mapping of CFIR Domains

The summaries of the staff interview transcripts and descriptive data from the questionnaire responses were coded and assigned to four major domains of the CFIR: intervention characteristics, inner setting, individual characteristics, and process (Textbox 1 and Multimedia Appendix 2 [44]).

Textbox 1. Mapped Consolidated Framework for Implementation Research domains and subdomains.

Intervention characteristics

- Intervention source
- Evidence strength and quality
- Relative advantage
- Adaptability
- Trialability
- Complexity

Inner setting

- Structural characteristics
- Networks and communication
- Implementation climate: tension for change, compatibility, relative priority, and learning climate
- Implementation readiness: leadership engagement and access to information

Individual characteristics

- Knowledge and beliefs about the intervention
- Self-efficacy
- Individual stage of change

Process

- Planning
- Engaging: opinion leaders and formally appointed implementation leaders
- Executing

Strategies to Improve Implementation

Staff Engagement and Communication

According to the interviewed stakeholders, persistent leadership engagement and nomination of specific responsible persons for the implementation process were essential, especially in a busy environment such as the ICU. Staff training should be conducted continuously and was particularly critical in the early implementation stages. The quality of instructions was considered essential to influence the staff's opinion toward the implementation. Feedback discussions with staff, project leaders, and a well-functioning team would increase staff engagement. Communication of the project should be encouraging and motivating.

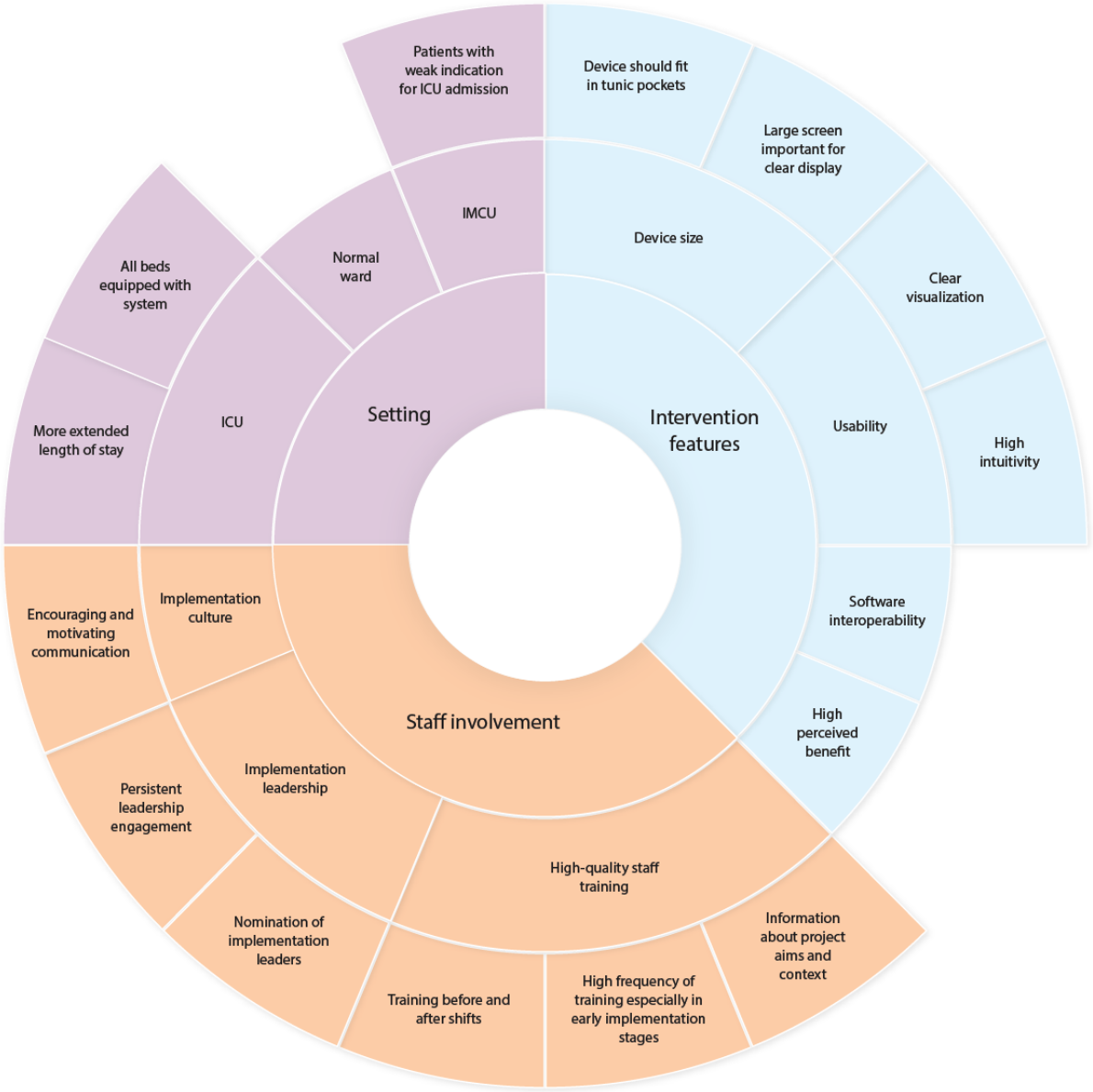
Setting

It was reported that equipping all beds in the ward with the technology and all staff members with portable monitoring devices would increase the implementation performance. A normal or intermediate care unit (IMCU) could be more suitable for a remote patient monitoring technology owing to a lower staff presence and scarcer technical facilities. Interviewees suggested that patients with a relatively weak indication for admission to the ICU could be admitted to a normal ward or IMCU and be monitored remotely. The implementation of technology concerning ICU patients would be more straightforward in a ward with more extended patient stays, as short stays imply more work to install the system.

Intervention Features

High intuitiveness would be crucial for effective implementation, as stated by the interviewees. A monitoring solution without cables would increase usability and perceived benefit. Opinions on the device size varied; a clear visualization needs a large screen, but interviewees favored a device that fits into the pocket of a tunic. Software interoperability with other devices (eg, the respirator or the PDMS) would be essential. Figure 3 presents an overview of the strategies to improve the implementation of digital health technologies according to the interviewed staff members.

Figure 3. Perceived factors improving implementation: 3 categories were identified (inner ring), divided into subcategories (middle ring), and enriched with concrete suggestions (outer ring). ICU: intensive care unit; IMCU: intermediate care unit.



Mapping of ERIC Strategies

Of the 73 ERIC strategies, 19 (26%) were mapped to the summary segments concerning staff suggestions for implementation and quantifiable questionnaire responses (Textbox 2 and Multimedia Appendix 3). The segments were assigned to 78% (7/9) of the clusters of the ERIC framework.

Textbox 2. Mapped Expert Recommendations for Implementing Change clusters and strategies.

Use evaluative and iterative strategies

- Purposely re-examine the implementation
- Develop a formal implementation blueprint
- Audit and provide feedback

Provide interactive assistance

- Facilitation
- Provide clinical supervision

Adapt and tailor to context

- Promote adaptability

Develop stakeholder interrelationships

- Identify and prepare champions
- Organize clinician implementation team meetings
- Recruit, designate, and train for leadership
- Inform local opinion leaders
- Model and simulate change
- Involve executive boards

Train and educate stakeholders

- Conduct ongoing training
- Make training dynamic
- Use train-the-trainer strategies
- Conduct educational meetings

Support clinicians

- Facilitate relay of clinical data to providers
- Remind clinicians

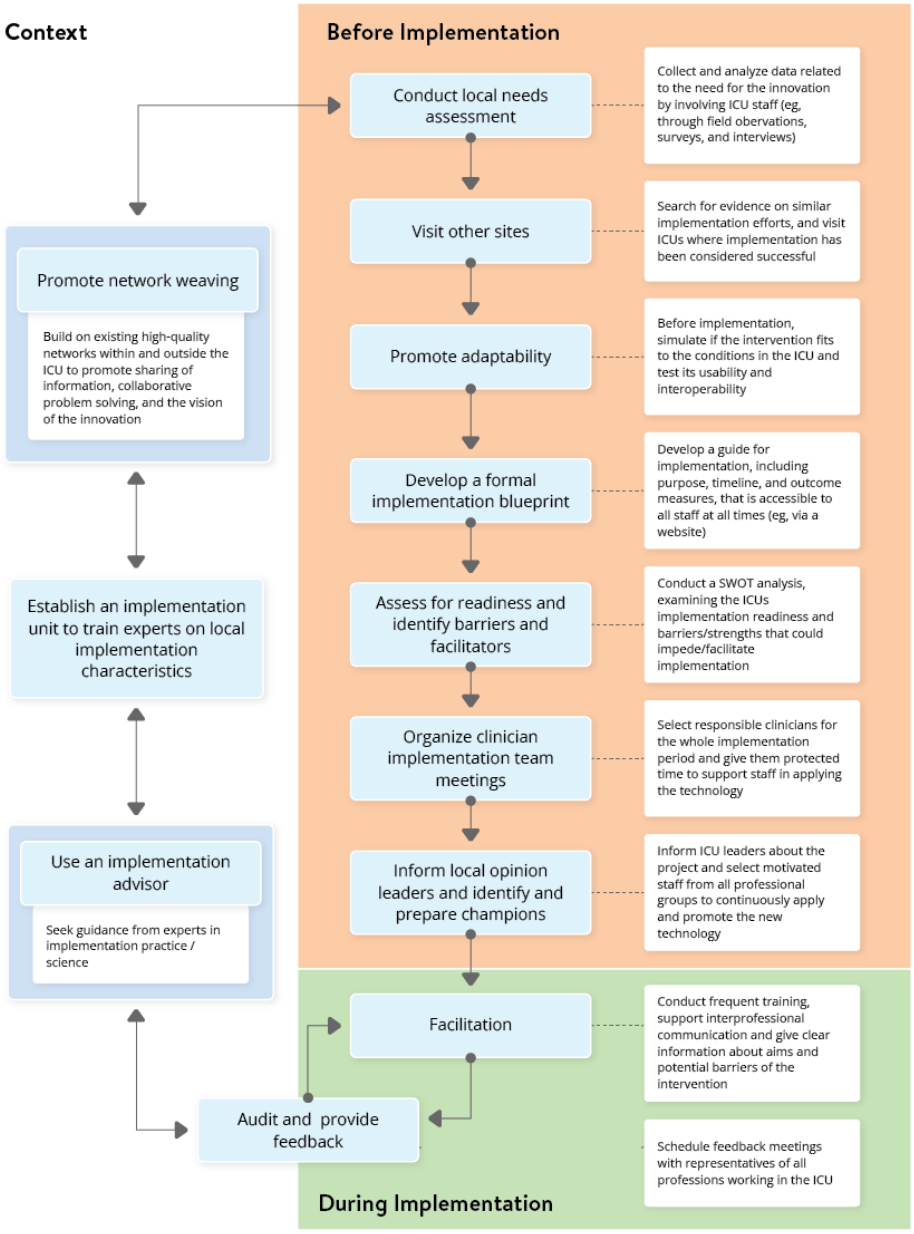
Change infrastructure

- Change physical structure and equipment
- Change service sites

Proposal for an Implementation Framework for Digital Health Technology in the ICU

The developed implementation framework includes 11 recommendations derived from ERIC strategies belonging to 4 clusters of the ERIC framework. A temporal perspective was added, and recommendations were specified to the ICU environment (Figure 4). Our recommendations are targeted toward hospital administrations, leading clinicians in the ICU, and implementation researchers—individuals responsible for the implementation process of new digital health technology in the ICU. Before implementation, 7 strategies, such as *conduct local needs assessment*, *visit other sites*, or *promote adaptability*, should be completed. During the implementation process, we recommend applying the ERIC strategies *facilitation* and *audit and provide feedback* continuously. The strategies *promote network weaving* and *use an implementation advisor* should optimize the implementation setting's context. Optimally, an implementation unit with experts for the local implementation characteristics should be established. Several factors influence the choice of the time to start the implementation process, and an implementation advisor should be consulted to adapt these factors to the context and local needs. Regular feedback by ICU staff regarding the implementation process, illustrated in Figure 4, through the feedback loop can lead to a further need for innovation and ideas to implement digital health technologies. The implementation is a circular process; therefore, we did not include an *after implementation* phase. Continuous re-evaluation triggers a new entry into the implementation strategy and thus leads to a sustainable implementation environment that is always adapted to new needs.

Figure 4. Strategies resulting from the CFIR-ERIC Implementation Strategy Matching Tool and the mapping of staff suggestions for improving implementation to the ERIC strategies before (orange) and during (green) implementation and in the general context of the implementation (yellow). CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change; ICU: intensive care unit; SWOT: strengths, weaknesses, opportunities, and threats [52].



Discussion

Principal Findings

Taking the example of a remote patient monitoring system, this study confirmed critical barriers to the implementation of new digital health technologies in the intensive care setting [11,13,53]. The proposed implementation framework for digital health technology in the ICU includes practical strategies to overcome these barriers while using facilitators from the ERIC clusters that can be applied before and during implementation and in the general context of an implementation.

Before implementation and in the general context, sharing use cases and building upon existing best practices are crucial strategies to adapt and choose the technology that best fits the local settings (ie, *visit other sites*, *promote network weaving*, and *use an implementation advisor*) [13,21]. Initiators of an implementation project should lay out its details, aim, and context before implementation (*develop a formal implementation blueprint)*. Transferable discoveries from these strategies and the strategies we propose to be applied before implementation (*promote adaptability*, *conduct local needs assessment*, *assess for readiness*, and *identify barriers and facilitators*) could be used to improve the adaptability and needs orientation of the intervention. Adaptability and user-centered design have been identified as key facilitators of digital health implementation in other settings [11,53,54]. To create the respective conditions, developers and providers of digital health technologies should actively participate in the implementation processes by taking

advantage of the valuable feedback from clinical stakeholders and adapting their products in the spirit of user-centered design [55-57]. Therefore, our proposed implementation framework suggests several strategies to enhance the involvement of clinical stakeholders directly (*organize clinician implementation team meetings*, *inform local opinion leaders*, and *identify and prepare champions*), in line with the proposed strategies for other implementation settings [58,59].

During implementation, ensuring a transparent communication of the project's aim and context (*audit and provide feedback*) is as critical as an effective *facilitation* to improve staff involvement and to promote and sustain implementation.

Sustainable implementation practice means to include the aforementioned aims and strategies in the general context of implementation practice. We propose the strategies *use an implementation advisor* and e*stablish an implementation unit* to improve the implementation environment and the local conditions for a fast, efficient, and sustainable implementation of technology that focuses on the needs of users and patients and adds value. These processes should always be re-evaluated to readapt interventions following the changing needs [58,60,61].

Implementing Technology in the ICU

For decades, the ICU has been equipped with high technology to support staff with continuous monitoring of patients' vital signs, application of medication, documentation (eg, PDMS), or diagnostics (eg, ultrasound and bronchoscopy). However, the implementation of innovative technology in a demanding and hectic environment such as the ICU is a challenge [62]. This has been prominently shown by various projects, more recently, through the rise of telemedicine in the ICU [63], necessitating frameworks for the implementation of such endeavors.

Reported digital health implementation efforts in the ICU rarely involved the use of developed implementation frameworks [64]. This could be due to a lack of both implementation expert consultation and framework transferability into clinical routine. Current frameworks for the design and implementation of digital health technologies are based on best practices and, if evidence-based, need to be validated [30,65]. Our study provides an explicit approach to target implementation challenges and optimize innovation flows and adaptability in the complex environment of an ICU. Further optimization by saturating theories with practical experiences from clinical translation is crucial for the development of a scalable and agile framework for the implementation of digital health technology in the ICU.

Internet of Things, Interoperability, and Data Security

Especially in ICU settings, where various technical devices continuously generate data, the amount of data that can be analyzed and processed is growing rapidly [66-68]. With growing amounts of data to analyze and process, the adoption of the Internet of Things (IoT) in health care is a promising approach to alleviating issues such as high staff stress levels, alarm fatigue, and even medical errors [69,70]. ICUs, in particular, use many different end devices that could be integrated into a fog-, edge-, or cloud-based IoT network for fast and efficient data processing [71,72].

To enhance the capacities of cloud systems, interoperability has become increasingly important, especially in relation to IoT infrastructures [73,74]. Holistically implemented, interoperable technologies could alleviate the burden on staff by reducing documentation time, and easier data retrieval can facilitate therapy and diagnosis [75]. The lack of interoperability of the remote patient monitoring system may have presented a barrier to its implementation. Consistent with findings from other research [55,76], our results show that health care staff support the implementation of interoperable, intelligent monitoring interfaces.

When harnessing the potential of interoperable IoT networks and implementing them in health care settings, a secure and reliable IT infrastructure is required [77,78]. Cybersecurity in health care organizations should be fostered through the definition of cybersecurity duties, sufficient funding, and the application of state-of-the-art measures to reduce the risk of cyberattacks [79,80]. For instance, blockchain technology combined with IoT-enabled smart devices using interoperable fog/edge and cloud computing networks can enable secure, instantaneous data transmission and processing while reducing costs and network delays [70,71].

Implementation Units

With aforementioned promised benefits, health care providers will experience the need to implement new digital health technology into their infrastructures in the decades to come [63,81-83]. They have to be abreast of the latest digital health technologies to select the appropriate technology for the specific area of application and to plan and execute the implementation process, requiring an effective and efficient approach to implementation.

The question arises as to which staff position is responsible for overseeing, evaluating, and adapting recent evidence and strategies in implementation science to the local context. As suggested, internal and external implementation experts should be involved as early as possible [30]. With the introduction of a unit for implementation as a central starting point for any implementation project, resources for redundant project planning or ineffective implementation could be spared and invested elsewhere. The extent to which these units will be involved in the ICU design, for example, should be assessed individually. Beyond the consultation and proposal regarding innovations, such a unit could assess the usability of devices and the adaptability of the intervention before procurement [84] or foster exnovation and deimplementation of outdated or useless technology.

Implementation Frameworks

Implementation science is a young discipline that has developed over the last 2 to 3 decades [85]. Nonetheless, numerous implementation frameworks, either for specific health care settings or for general guidelines, have been published during this period [26,64,86-88]. Other implementation frameworks and strategies for health care are nonspecific in terms of either the intervention targeted [26,64], as they refer to evidence-based

practices [89], or technology [90-92]. Looking at intensive care medicine, implementation frameworks are widely limited to the implementation of evidence-based practices [93,94]. Explicit guidelines for the implementation of novel digital health technologies in the special ICU environments are lacking.

The implementation framework at hand was developed through an interdisciplinary approach, is specific to the ICU setting, and considers relevant particularities in terms of digital health technology implementation.

Limitations

The research team was only able to obtain a limited view of the entire implementation project. The decision to implement the system was made before the study began, which prevented conducting front-end exploration of the implementation setting or evaluation of the external setting and vendor perspective. It was not possible to pursue a user-centered design and implementation in this specific context. However, our study provides valuable insights into the process of implementing digital health technology in the ICU and highlights important application strategies while planning an implementation project. In particular, we identified explicit pitfalls for implementation processes in the specific clinical environment of an ICU and solutions to overcome them.

The interpretation of the results should consider that the CFIR-ERIC mapping tool needs further validation and evidence. Thus, the mapping of strategies to the major barriers might not reflect the best strategy to tackle the respective barrier. We sought to overcome this limitation through profound discussions at meetings within the research team, extensive field research, and analysis of suggestions from staff to improve the implementation performance.

A limitation to the study's scope is that the ERIC strategies do not include changes in intervention characteristics, which would be essential when aiming to improve implementation performance in a user-centered design. ERIC only covers the last stages of implementation (planning and executing the implementation of the finalized intervention) but does not include the readaptation of the intervention as part of the development process.

Finally, the fact that every ICU has unique structural and sociotechnical features, as well as the number of interviewees, could limit the general validity of derived findings. As we investigated an explicit use case in an ICU, potential interviewees were limited because we identified and interviewed the key stakeholders throughout the study. This study depicts an implementation project in intensive care medicine that is close to the standard practice in Germany, where implementation science is still an evolving discipline. However, it is specific to the setting in which it was conducted (ICU, country, and health system), and translation of our findings to other contexts is limited and should be done with these specificities in mind. In terms of continuous reassessment, our proposed framework may need further validation and evaluation in ICU or IMCU settings to fully realize its potential for optimization of implementing digital technologies.

Conclusions

We propose an implementation framework for digital technology in the ICU, which entails practical and evidence-based strategies to improve the implementation process. The ICU provides an exceptional setting for the introduction of digital health technology: the stress level of staff is high, and the ICU team is composed of multiple different professions using the same technologies.

The proposed framework outlines strategies to be applied before and during implementation and in the general context of implementation. Before implementation, the need for innovation and potential interventions should be carefully assessed by involving all clinical stakeholders with clear implementation leadership. Interventions should be needs-oriented, user-centered, and adaptable to changing circumstances. During implementation, a clinical implementation team should ensure transparent, inclusive, and motivating staff communication regarding the project and continuous feedback through local opinion leaders and champions. To ensure efficient management of resources and time, we recommend optimizing the general context of implementation practice in the ICU and the health care institution by involving an implementation advisor, ideally in consultation with an implementation unit of the same institution. Our proposed framework should encourage health care institutions to implement modern digital technology in ICUs and facilitate clinicians and implementation advisors in the practical execution of implementation projects in ICU settings.

Acknowledgments

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Data Availability

The data sets generated and analyzed during this study are not publicly available because of data privacy; however, they are available from the corresponding author (FB) upon reasonable request.

Authors' Contributions

CS had the idea for shared decision allocation and initiated the implementation of remote patient monitoring in the intensive care unit. The study was conceived by ASP, CS, FB, and LKM. LKM conducted data acquisition and analysis, supported by ASP. LKM and ASP wrote the manuscript. HK contributed to the study's methodology and interpretation of results from a psychologist's point of view, and MS (nurses' perspective) and SWC (physicians' perspective) contributed the perspective of the intensive care unit where this study was conducted. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript.

Conflicts of Interest

CS and FB report funding from Medtronic. FB also reports grants from German Federal Ministry of Education and Research, grants from German Federal Ministry of Health, grants from Berlin Institute of Health, personal fees from Elsevier Publishing, grants from Hans Böckler Foundation, other from Robert Koch Institute, grants from Einstein Foundation, and grants from Berlin University Alliance outside the submitted work.

Multimedia Appendix 1
Interview guideline.
[DOCX File , 22 KB - formative_v6i4e22866_app1.docx]

Multimedia Appendix 2
Mapping of Consolidated Framework for Implementation Research domains to summaries of codes concerning implementation performance.
[DOCX File , 27 KB - formative_v6i4e22866_app2.docx]

Multimedia Appendix 3
Expert Recommendations for Implementing Change strategies mapped to summaries of codes concerning staff suggestions for improving implementation performance.
[DOCX File , 23 KB - formative_v6i4e22866_app3.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
ERIC: Expert Recommendations for Implementing Change
ICU: intensive care unit
IMCU: intermediate care unit
IoT: Internet of Things
PDMS: patient data management system
REDCap: Research Electronic Data Capture

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Original Paper

National Implementation of an Electronic Patient-Reported Outcome Measures Program for Joint Replacement Surgery: Pilot Study

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Abstract

Background: There is a global emphasis on expanding data collection for joint replacement procedures beyond implant attributes and progression to revision surgery. Patient-reported outcome measures (PROMs) are increasingly considered as an important measure of surgical outcomes from a patient's perspective. However, a major limitation preventing wider use of PROMs data in national data collection has been the inability to systematically collect and share electronic information with relevant stakeholders in a comprehensive and financially sustainable manner.

Objective: This study reports on the development of an electronic data capture and reporting system by a national registry for the collection of PROMs and the processes used to identify and overcome barriers to implementation and uptake. The study also aims to provide a cost breakdown of establishing and maintaining a nationwide electronic PROMs program.

Methods: Between 2018 and 2020, 3 governance and advisory committees were established to develop and implement a PROMs pilot program nested within a nationwide joint replacement registry. The program involved electronic collection of preoperative and 6-month postoperative data for hip, knee, or shoulder replacement surgery from 44 Australian hospitals. Resource requirements for the program included a project manager, software developers, data manager, and statistician. An online platform was tested, refined, and implemented for electronic PROMs collection with scalability considered for future expansion to all Australian hospitals and additional data fields. Technical capabilities included different access for multiple user types, patient registration, automatic reminders via SMS text messages and email, online consent, and patient outcome real-time dashboards accessible for different user groups (surgeons, patients, hospitals, and project stakeholders).

Results: During the PROMs pilot period there were 19,699 primary procedures undertaken with 10,204 registered procedures in the electronic system. This equated to 51.80% of people who had a joint replacement at participating hospitals during this period. Patient registration and data collection were efficient (20-30 seconds and 10-12 minutes, respectively). Engagement with the reporting dashboards (as a proportion of those who viewed their dashboard) varied by user group: 197/277 (71.1%) hospital administrators, 68/129 (52.7%) project stakeholders, 177/391 (45.3%) surgeons, and 1138/8840 patients (12.9%). Cost analysis determined an overall cost per patient of Aus $7-15 (approximately US $5-12) for 2 PROMs collections per joint replacement procedure once the program was established.

Conclusions: Successful implementation of an orthopedic PROMs program with planned scalability for a broader national rollout requires significant funding and staffing resources. However, this expenditure can be considered worthwhile, given that

collection and reporting of PROMs can drive health care improvement processes. Further consideration of strategies to improve stakeholder engagement with electronic reporting dashboards (particularly for patients and surgeons) will be critical to the ongoing success of a national PROMs program.

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KEYWORDS

cost; cost-benefit; online platform; patient-reported outcome measure; registry science; electronic data collection; electronic data; capture; joint replacement; PROMs; PROM; outcome measure; patient report; data capture; registry; surgery; operation; postoperative; surgical; data reporting; data collection

Introduction

Orthopedic registries and health care service groups around the world are gradually expanding from routinely reported surgical data to include data on the self-reported health status of patients undergoing joint replacement surgery. Patient-reported outcome measures (PROMs) provide an indicator of surgical thresholds and treatment effects, with the potential to improve health care outcomes within the health care sector for these increasingly common and resource-intensive procedures. Guidelines have been produced regarding the types of PROMs that should be collected [1,2]. However, a major limitation preventing the wider use of PROMs data in population-based studies has been the inability to systematically collect and share electronic information with all relevant stakeholders in a comprehensive and financially sustainable manner.

There are major challenges in effectively collecting and utilizing patient-reported data in a population-based setting. Timing of data collection, optimal selection of PROMs instruments, consent and data collection processes, acceptable levels of data completeness, data security concerns, approaches to delivering stakeholder feedback, and the financial implications are some of the considerations. To date, orthopedic registries that collect PROMs have implemented varying approaches to address these considerations [1-3]. To ensure the effective implementation of a national PROMs collection program, there is a need to systematically design, develop, and test an approach that addresses all of these considerations and does so in a cost-effective manner [1].

In this paper, we report on the establishment of a bespoke electronic PROMs data collection and reporting system and the processes used to overcome identified barriers. This system was developed to facilitate a PROMs pilot program nested within the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). We discuss project design, governance, resourcing, infrastructure, and multistakeholder engagement considerations. A comprehensive cost breakdown of establishing and maintaining an ongoing PROMs program nationally is provided to assist other researchers and clinicians who may be considering implementing a PROMs program in their jurisdictions.

Methods

Establishment of a PROMs Pilot Project

The primary purpose of the PROMs pilot program was to design, develop, and test a comprehensive approach to electronically collect PROMs data that could be effectively rolled out nationwide by the AOANJRR. Ongoing development of the purpose-built online platform, known as *RAPID* (Real-time Automated Platform for Integrated Data capture), continued throughout the pilot in response to learnings and stakeholder feedback. This continual refinement of processes and systems was undertaken to best position the PROMs program for a planned nationwide rollout.

Governance, Funding, and Program Approval

Establishing project governance is considered a safeguard to protect patient data and to promote efficiency in the delivery of a PROMs program [4]. For this program, 3 separate groups were established to provide oversight. A Project Steering Committee was established and met quarterly to provide support and guidance for the program. The high-level support from the committee involved a multistakeholder approach including leadership across the Australian Orthopaedic Association (AOA), AOANJRR, orthopedic surgeons, partners, consumer representation, and project funders. An International PROMs Instrument subgroup was established to provide expert advice regarding selection of PROM instruments, additional items, and the timing of data collection [1]. Lastly, a PROMs Working Group was established and met regularly to provide expert advice around project implementation and troubleshooting support for practical issues identified during day-to-day operations.

Ethical Approval

Relevant ethics and hospital governance approvals were obtained, consistent with local requirements [5]. The following Australian ethics committees approved the pilot program from which the data presented in this study were obtained: University of South Australia Human Research Ethics Committee (HREC; 200890), Sydney Local Health District Ethics Review Committee (Royal Prince Alfred Hospital Zone, HREC/18/RPAH/90), Calvary Health Care Adelaide HREC (18-CHREC-F004), Mater Misericordiae Ltd HREC (HREC/18/MHS/45), St Vincent's Health and Aged Care HREC (HREC 18/14), University of Tasmania HREC (H0017292), Calvary Health Care Tasmania HREC (010418), St John of God HREC (1408), and Calvary Health Care Australian Capital Territory (25–2018). Furthermore, licensing requirements for use of the selected PROMs instruments were addressed.

Staffing Requirements

Initially, a project manager oversaw the pilot program and a software developer commenced the design and build of the *RAPID* platform infrastructure. As data collection commenced,

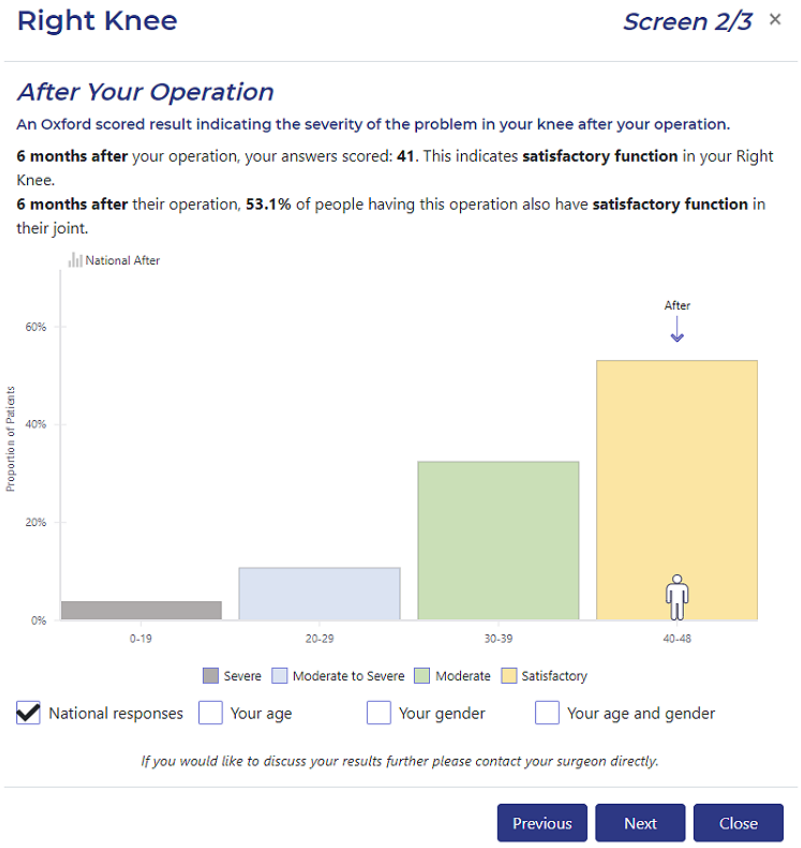
additional staffing resources were required and further team members were sourced (2 additional software developers, a data manager, and a statistician).

Infrastructure: Software Development

During the initial design phase, available off-the-shelf software solutions were deemed not fit for the purpose of the Registry's electronic PROMs collection. This was due to the lack of customizability, particularly pertaining to the layout of patient dashboards and reporting functionality, and concerns regarding ongoing costs and support. Developing the software in-house allowed for technical solutions to be developed for problems identified during the design, testing, and data collection phases. Lastly, *RAPID* was designed from the outset to be scalable for national data collection and included the capability to run multiple research projects simultaneously nested within the Registry.

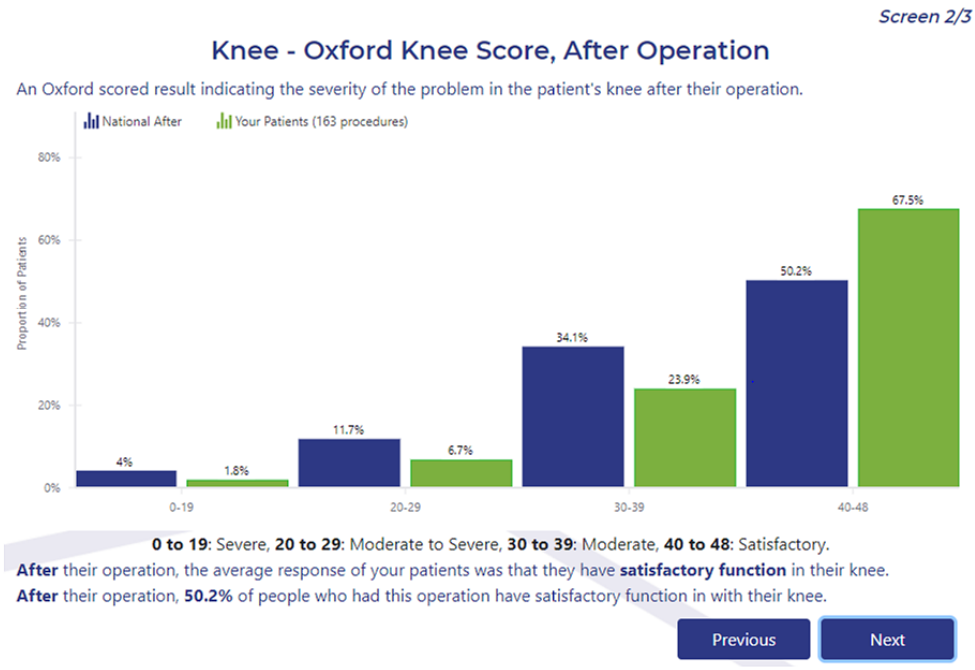
RAPID included the ability for patients to provide online electronic consent, complete their preoperative/postoperative PROMs, as well as incorporate real-time dashboard reporting for patients to view their PROMs responses to compare their own responses as well as with national averages (Figure 1). Critical to the design of *RAPID* was to make the system usable for the specific patient population undergoing joint replacement who are predominantly elderly. Therefore, it was important to make the system as simple, user-friendly, and intuitive as possible. The number of "clicks" required was minimized, 1 question was displayed at a time, and, where possible, the PROMs questions were presented without the need for scrolling (this feature also enhanced viewing ease via a smartphone or other portable devices). Patients were provided with the option to go backward and review or change their answers if they wished to do so. However, the system did not allow for responses to questions to be left blank. Screenshot examples of *RAPID* can be found in 2 published AOANJRR reports [5,6].

Figure 1. Example screenshot from a patient's dashboard within the RAPID platform. RAPID: Real-time Automated Platform for Integrated Data capture.



Orthopedic surgeons had access to identified individual patient responses via *RAPID* when the patient consented to share their responses (12,236/12,874 [95.04%] preoperatively and 4653/4780 [97.34%] postoperatively). In addition, surgeons were able to download patient responses in a Microsoft Excel format. Dashboards were provided to all surgeons and these graphically displayed their patient recruitment data and PROMs outcomes, as well as comparisons with national averages (Figure 2). Surgeons were able to filter their patient cohort based on age or sex and compare different hospitals in which they operate. Designated hospital staff could also obtain similar data for the hospital cohort, following the provision of appropriate consent. Specific reporting dashboards were also designed for project stakeholders who were provided with aggregated national-level data.

Figure 2. Example screenshot from a surgeon's dashboard within the RAPID platform. RAPID: Real-time Automated Platform for Integrated Data capture.



An additional software feature of *RAPID* was the ability to integrate PROMs data collected by third parties so that some hospitals and surgeons could continue to collect data in their systems. This was deemed necessary due to the length of time some of the previous data collection systems were in place. The AOANJRR developed a standardized template for use by hospitals to send PROMs data via *RAPID*. Integration of the data into *RAPID* was conducted by the data management and statistical teams following a manual review of the data file. Any data discrepancies were queried and addressed prior to upload. However, this feature proved to be a highly resource-intensive process and opportunities to streamline this will be considered for the national rollout.

Software Architecture and Security

The major components of the *RAPID* software architecture are a user interface built on the React web framework, with back end services using Spring Boot and a PostgreSQL database. These components were chosen due to their popularity within the software development community, breadth of documentation and community support, ease of development, and no licensing costs.

To securely log into *RAPID*, user access is role based for designated administrators, with access tailored depending on each role's scope of responsibility within the system. For other users (such as surgeons and hospital staff), access is tailored based on their roles within various hospitals and other projects in *RAPID*. Additional security measures in *RAPID* include session timeouts, password expiries, minimum password strength limits, restrictions on password reuse, lockouts when the number of successive incorrect password attempts reaches a threshold, and a secure password hashing algorithm (PBKDF2). Access to the raw data (ie, in the database) is limited to data managers, statisticians, and information technology staff through firewall and access control measures.

Results

Engagement: Participation, Recruitment, Data Collection, and Quality

Hospital Participation

The pilot program included a broad cross section of public and private hospitals from all Australian states, of all sizes (small [<100 beds], mid-range [100-499 beds], and large [>500 beds]) and from urban and nonurban areas. Hospital representatives either volunteered to participate in the pilot PROMs program, were recruited following surgeon recommendation, or were invited to participate based on previous collaborative projects. In total, 44 hospitals provided pilot data.

Patient Recruitment and Hospital Training

Patients scheduled for primary or revision hip, knee, and shoulder replacement procedures were eligible. Patients under the age of 16 and patients with a cognitive impairment that impacted their ability to provide informed consent were excluded. Initial patient recruitment involved registration into *RAPID* via the collection of limited data including patient name, date of birth, postcode, contact details (1 or more of the following: email, mobile phone, and home phone), joint, side, surgeon (optional, if known), and hospital. Patients registered themselves or were registered by an administrator, via the *RAPID* platform. Administrators were provided training in *RAPID* by the project team and had on-site visits (or when not possible on-site, online training). Once registered, patients were able to provide electronic consent and then PROMs could be completed, either immediately or at a later time. Once registered, patients were provided with an electronic patient information

sheet that detailed information about the Registry and the pilot program. A hard copy study information card was also provided to patients. If patients did not wish to participate, they were able to select "decline to participate" within *RAPID*, which deleted all identifying information recorded at registration from the system. However, only a small number of patients declined participation (944/14,890, 6.34%). SMS text messages and email reminders were effective in maintaining patient participation once patients were successfully registered in the electronic system [5]. Feedback provided by administrators and patients highlighted the efficiency of the patient registration and data collection system, indicating that it took 20-30 seconds to register a patient and 10-12 minutes for patients to complete their PROMs.

Data Collection

Automated email and SMS text message reminders were sent to patients via the *RAPID* platform as a reminder to complete their PROMs both preoperatively and 6 months postoperatively. The system allowed for a set number of reminders to be sent pre- and postoperatively, depending on the contact details provided at registration. Patients who had not completed their PROMs after 2 automated reminders appeared on a list for phone call follow-up. Phone call follow-up was trialed as part of the pilot and patients' responses were entered directly into *RAPID* by a member of the phone call follow-up team. Comparisons of demographic information determined no substantial difference between patients who required phone call follow-up and those that responded to electronic reminders. Given this finding and associated costs, phone call follow-up was later phased out.

Data Quality

Throughout the data collection phase, the project manager communicated with orthopedic surgeons and personnel assisting with patient registration to ensure hospitals were well supported. A data summary was distributed regularly (containing both patient registration and procedure registration at each hospital), and hospitals were also directed to their *RAPID* reporting dashboards. If a hospital was identified as having low registration of patients, it was contacted so that processes could be reviewed and refined. Through this process, the AOANJRR determined that hospital registration improved over the pilot period, where more than 60.2% (441/733) of procedures undertaken at pilot hospitals were registered within the *RAPID* platform after 12 months of data collection, compared with 44.85% (2366/5275) in the first 3 months of data collection [5]. By examining learnings from hospitals that improved registration rates, the AOANJRR was able to implement the same processes to improve the performance of less satisfactory hospitals.

Surgical procedure forms received from each hospital were entered into the AOANJRR database as part of routine Registry processes. The patient information from the procedure form was then matched with the patient information in *RAPID*. This process assisted with determining the proportion of joint procedures registered at each hospital as well as identifying any data entry errors. It was also required for electronically triggering postoperative data collection reminders based on the procedure date. Reports were produced on patient registration and procedure registration rates at each hospital.

Cost Analysis

Establishment Costs Associated With a PROMs Program

A multistakeholder approach to funding was established to foster a wide leadership base and to maximize engagement across the health care sector. Expenditure for the pilot PROMs program (n=14,890) was largely attributed to staffing costs as well as to the establishment of *RAPID*.

Staffing Costs

While the PROMs pilot was in the design and development phase, staffing costs were kept to a minimum by drawing on the expertise and experience of existing Registry staff. As the pilot developed and the scope increased, additional resources were required to establish PROMs collection within the pilot hospitals. This included the project manager (1.0 full-time equivalent [FTE]), software developers (2.5 FTE), data manager (0.8 FTE), and a statistician (0.6 FTE).

Information and Communications Technology Development Costs Associated With RAPID

A large portion of establishment costs was associated with the software development phase of *RAPID*. In addition to the information and communications technology (ICT) staffing costs, running costs included software licensing, servers (including nonproduction servers used for development and testing), and website certificates (Aus $27,000 [~US $20,000] over 2 years). Furthermore, to ensure secure storage of sensitive patient data, a security design review was conducted during the design phase and a follow-up software penetration test was conducted prior to launch (Aus $14,000 [~US $10,000] over 2 years). While these costs substantially contribute to the overall budget, the security of patient data is at the forefront of consideration in health care settings [7].

Trial of Tablets for Patient Registration Within Hospitals

A total of 70 tablet devices (specifically iPads) were purchased by the Registry and provided to 41 pilot hospitals to mitigate potential barriers relating to patients not having access to electronic devices and to encourage hospital participation. The total cost including providing cellular data for the devices was Aus $31,000 (~US $23,000). Data indicated that hospitals only intermittently provided patients with the tablets for patient self-registration and survey completion [5]. With this in mind, it has been decided that tablets will not be provided when the PROMs program rolls out nationally in Australia.

Cost of Telephone Follow-Up

During the pilot period, 1148/14,926 (7.7%) procedures registered in *RAPID* had a landline telephone only (predominantly patients aged ≥85 years) [5], precluding patient follow-up via SMS text messaging. Extrapolating the cost of Aus $65,000 (~US $48,000) for telephone follow-up in the pilot (involving about 15% [n=44] of available hospitals) to a broader national rollout produces an estimate exceeding Aus $450,000 (~US $336,000) annually. This was deemed to be financially unsustainable. Throughout the pilot and since its completion,

AOANJRR has encouraged hospitals to obtain the contact details of a proxy individual (eg, a family member or friend) to receive reminders on the patient's behalf and assist with the electronic completion of PROMs.

Discussion

Principal Findings

Owing to the success of establishing the PROMs pilot program within 44 Australian hospitals, a national rollout of the program is currently underway with ongoing government funding. A large portion of the funding attributed to the national rollout has been dedicated to staffing costs. The PROMs project manager, ICT software developer, data manager, and statistician have been retained. Two additional full-time project coordinators have subsequently been employed to facilitate expansion of the program from 44 hospitals to approximately 320 Australian hospitals, which requires significant engagement with each hospital site. The project coordinators are also responsible for continued engagement with the hospitals that participated in the pilot.

Prediction of Anticipated Ongoing Cost of a PROMs Program Nationally

On completion of the national rollout program, it is anticipated that PROMs staffing costs may decrease with the potential to reduce to 1 project coordinator and 1 software developer while retaining the project manager, data manager, and statistician. Conversely, ICT costs are likely to gradually increase as the size of the *RAPID* platform expands to accommodate for increased accessing, processing, and storage of patient data. Increased server storage and security enhancements as the *RAPID* platform increases capacity are expected. Assuming PROMs data are collected on 40%-80% of joint replacement procedures (a range of ~44,000 and ~88,000 procedures; based on 110,000 primary hip, knee, and shoulder procedures for osteoarthritis and revision procedures for the 3 joints per annum), we estimate a cost per patient of Aus $7-15 (approximately US $5-12). We recognize that cost and governance processes differ between countries and jurisdictions, which makes direct comparisons for implementation in other settings challenging.

Enablers and Barriers to Establishing a PROMs Program

Enabler: Successful Cost Minimization

Nesting the PROMs pilot project within the AOANJRR was key to successfully reducing costs as it allowed for shared staff resources throughout the lifecycle of the project, particularly in the planning and implementation phases of the project. This included utilizing the existing expertise, skills, and relationships of Registry staff to liaise with surgeons and clinicians directly at hospital sites. These relationships assisted with approval for hospitals to participate and reassuring surgeons regarding any process or security concerns. The well-established reputation of the AOANJRR allowed for confidence in data security by patients, surgeons, and stakeholders.

Enabler: Successful Online Electronic Data Collection

Electronic PROMs collection has proven to be a successful means of outcome data collection, as evidenced by other Registries, such as the Functional and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) Registry that has reported high levels of enrollment and data completion via electronic collection [8]. Our pilot has proven similar success in that of the patients who consented within *RAPID*, preoperative PROMs collection was obtained for 97.77% (12,871/13,164) of registered procedures, and 79.05% (4184/5293) of postoperative PROMs were completed [5]. Wilson et al [2] highlighted that paper-based questionnaires can be relatively easy for patients to complete, but issues persist with mail-out, having patients mail them back, following up on missing data, possible data entry errors, or duplications [2]. These issues were mitigated with the use of the *RAPID* platform. Another consideration is potential patient response differences when 1 question is viewed at a time (versus traditional paper-based collection) and the order in which the questions are answered. Some research has indicated that displaying 1 question at a time improves response rates; however, equivalence studies compared with paper-based collection would provide benefit to the orthopedic community [9]. In our pilot study, the small number of patients who were unable to access *RAPID* or could not be contacted via electronic means were encouraged to seek assistance from family or friends to complete their PROMs or to contact the Registry for assistance with online completion. In the pilot study, preoperatively, 10.34% (782/7562) of patients reported seeking assistance from a family member and 0.45% (34/7562) of patients reported seeking assistance from a friend. Technology is increasingly affordable and accessible with internet access in Australian private homes recorded at 86% [10]. Access and technological familiarity will likely continue to improve over time, including for older patients.

Enabler: Successful Customization of the RAPID Platform

The ability to adapt *RAPID* functionality following user feedback and respond quickly to address any identified issues was a critical enabler to improve engagement with hospital sites and optimize patient registration. Hospital staff feedback identified that patients in preadmission clinics are required to attend a variety of appointments during their preadmission review and this made it difficult to complete the survey on the supplied iPad in a single sitting. A system adjustment was then made to implement a "resume" function in *RAPID*. This allowed patients to exit *RAPID* part way through the survey and return to complete the survey within 14 days in their own time on any device.

Administrators identified during the pilot that the electronic consent format was proving onerous for patients as they had to click "I agree" to each consent statement (9 in total) before providing final consent. The system was updated so that the information sheet could be reviewed on a single page with patients consenting to participate in the study once the information was reviewed by pressing 1 button.

Registry staff identified that it would be helpful to generate additional PROMs completion reminders manually when patients requested. *RAPID* was updated to include a manual link that generated additional SMS text messages or email reminders on request.

Such enhancements proved important in facilitating data collection and reducing the burden on patients. This also underscores the importance of continuous software developer resourcing to support additional minor platform refinements, even after a project has launched.

Identified Barrier: Overburdening Hospital Staff and Patients

One of the main considerations for this program was to develop an electronic system that would not overburden hospital and administrative staff. Two pathways for patient registration were therefore developed; patient self-registration or registration of a patient by an administrative user. During the pilot, participant recruitment increased when the patient was registered by hospital staff. For the national implementation of this program, the Registry will continue to encourage the registration of patients by hospital staff.

Frequently reported barriers for patients to complete PROMs are the length of time to completion and difficulty using electronic devices [11]. Early reports from patients suggested that the time taken to complete the PROMs instruments was satisfactory (10-12 minutes for PROMs completion) [5]; however, further exploration of patient burden and preferences is necessary through seeking consumer representation [6].

Identified Barrier: Hospital Staff Turnover

Staff turnover at the hospitals was identified as an issue impacting patient recruitment. Registry staff were often unaware that a hospital staff member trained in using *RAPID* had left the hospital until a decrease in patient registration was identified. In these instances, it was identified that key project details were not communicated or understood when hospital staff handed over the task to new personnel. To alleviate this potential barrier, the Registry has implemented additional reporting strategies to monitor hospital recruitment as well as continuing to provide specific hospital training, education material, and induction documentation to meet the needs of new hospital staff.

Conclusions

Successful implementation of a national PROMs pilot program with planned scalability for a national rollout can be achieved but requires significant funding and resources. However, the expenditure can be considered worthwhile given the high level of patient participation and the potential for PROMs data to drive improvement processes, improve care for patients, and optimize health care efficiency. Importantly, strategies to improve stakeholder engagement with electronic reporting dashboards (particularly for patients and surgeons) need to be investigated further, as this will be critical for the ongoing success of a national PROMs program.

Conflicts of Interest

None declared.

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Abbreviations

AOA: Australian Orthopaedic Association
AOANJRR: Australian Orthopaedic Association National Joint Replacement Registry
FORCE-TJR: Functional and Outcomes Research for Comparative Effectiveness in Total Joint Replacement
FTE: full-time equivalent
HREC: Human Research Ethics Committee
ICT: information and communications technology
PROM: patient-reported outcome measures
RAPID: Real-time Automated Platform for Integrated Data capture

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Original Paper

Prioritizing Support Offered to Caregivers by Examining the Status Quo and Opportunities for Enhancement When Using Web-Based Self-reported Health Questionnaires: Descriptive Qualitative Study

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Abstract

Background: The Rosalynn Carter Institute for Caregivers (RCI) offers evidence-based interventions to promote caregivers' health and well-being. Trained coaches regularly meet with caregivers to offer education and instructions to improve caregiver health, build skill sets, and increase resilience. Two of these interventions, RCI Resources for Enhancing Alzheimer's Caregiver Health (REACH) and Operation Family Caregiver (OFC), use a set of caregiver-reported questionnaires to monitor caregivers' health status and needs.

Objective: This study aims to describe how web-based assessment questionnaires are used to identify and monitor caregiver status in the RCI REACH and OFC programs and outlines perceived enhancements to the web-based system that could support caregiver-coach encounters by directing priorities.

Methods: This was a descriptive, qualitative study. Data were collected via semistructured interviews with caregivers and coaches in the RCI REACH and OFC programs from July 2020 to October 2020. During the interviews, participants were asked to describe how the assessment questionnaires were used to inform caregiver-coach encounters, perceived usefulness of enhancements to web-based display, and preference for the structure of score results. The interviews were recorded, transcribed, and coded using structural and interpretive codes from a structured codebook. Qualitative content analysis was used to identify themes and summarize the results.

Results: A total of 25 caregivers (RCI REACH: 13/25, 52%; OFC: 12/25, 48%) and 11 coaches (RCI REACH: 5/11, 45%; OFC: 6/11, 55%) were interviewed. Most caregivers indicated that the assessment questions were relevant to their caregiving experience. Some caregivers and coaches indicated that they thought the assessment should be administered multiple times throughout the program to evaluate the caregiver progress. Overall, caregivers did not want their scores to be compared with those of other caregivers, and there was heterogeneity in how caregivers preferred to view their results at the question or topic level. Coaches were uncertain as to which and how much of the results from the self-reported questionnaires should be shared with caregivers. Overall, the results were very similar, regardless of program affiliation (RCI REACH vs OFC).

Conclusions: Web-based and procedural enhancements were identified to enrich caregiver-coach encounters. New and enhanced strategies for using web-based assessment questionnaires to direct priorities in the caregiver-coach encounters included integrating figures showing caregiver progress at the individual caregiver level, ability to toggle results through different figures focused on individual versus aggregate results, and support for interpreting scores. The results of this qualitative study will drive the next steps for RCI's web-based platform and expand on current standards for administering self-reported questionnaires in clinical practice settings.

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KEYWORDS

caregiver; web-based questionnaires; self-report questionnaires; caregiver outcomes; intervention technology; patient-reported outcome measures

Introduction

Background

One in five adults in the United States provides unpaid caregiving; these adults are also known as family caregivers [1]. Responsibilities for unpaid caregivers are wide-ranging and include interacting with clinicians on behalf of the care recipient, transportation, housework, shopping, paperwork, managing finances, helping with personal hygiene, and administering medical therapies [2]. Caregiving responsibilities often accumulate over time as the care recipients' health status worsens, and caregivers must manage the changing needs of their care recipients. For family caregivers, caregiving is associated with higher levels of depression and anxiety, worse self-reported physical health, and increased risk of early death [3].

The Rosalynn Carter Institute for Caregivers (RCI) offers evidence-based interventions to promote the health and well-being of caregivers and provides training on coping skills [4]. RCI coaches regularly meet with caregivers to offer education and training to improve their health, build skill sets, and increase resilience. During these one-on-one meetings, caregivers and coaches touched on a variety of topics, including the burden of caregiving, self-care techniques, problem solving, and community support. Two of these interventions, RCI Resources for Enhancing Alzheimer's Caregiver Health (REACH) and Operation Family Caregiver (OFC), use a set of caregiver-reported questionnaires to monitor caregivers' health status and needs.

RCI REACH is a coach-led one-on-one program for caregivers that focuses on building caregiver skills in stress and mood management, as well as problem solving. Caregivers in this program care for individuals with Alzheimer's disease and related dementia. The RCI REACH includes 12 in-person or web-based sessions with a coach. On average, it takes approximately 7.5 months for caregivers to complete the program depending on the spacing of the sessions. A preliminary single-group observational study showed that RCI REACH participants had a decrease in depression and caregiver burden, and caregivers reported being less troubled by care-recipient behavioral problems [5].

The OFC is a coach-led one-on-one program for caregivers of active-duty military personnel or veterans. Sessions were conducted in person or via a web-based video platform including FaceTime (Apple Inc) or Zoom (Zoom Video Communications) over the course of 8 sessions (average time to complete the sessions was 5.4 months). Coaches help caregivers recognize challenges, identify solutions, and develop problem-solving skills. Using a single-group, pre-post study design, Easom et al [6] showed that caregivers who participated in the OFC had decreased depression and feelings of caregiver burden, as well as increased life satisfaction and positive problem-solving skills.

Included in each of these RCI programs are a set of web-based questionnaires that are used to provide RCI with information on caregiver outcomes, otherwise known as *the assessment*, which consists of a variety of validated questionnaires, such as the Center for Epidemiologic Studies Depression Scale—Revised [7] to measure depression and the Zarit Burden Interview [8] to evaluate caregiver burden. Other questionnaires validated for caregivers were used to evaluate caregiver work performance [9], work-family conflict [10], self-efficacy for caregiving [11], problem-solving ability [12], life balance [13], caregiver perceived financial stress [14], and community support [15]. As the challenges and needs of caregivers in RCI REACH and OFC are different, the assessment also asks caregivers to report concepts specific to each program. For example, caregivers in the RCI REACH program are asked specific questions about caring for an individual with dementia, including care recipients' memory and behaviors [16], how bothered they are by their care recipient's memory status or behaviors, home preparedness and safety, and desire to place the care recipient in a nursing home or assisted living facility [17]. For the OFC, the assessment inquired about problem solving [12] and child anxiety for children living in the caregiver's household [18].

The web-based assessment is currently administered when caregivers enroll in the program (T1) and when they finish it (T2). Historically, this assessment was primarily used to evaluate the impact of the programs on caregiver outcomes at the aggregate level. However, the RCI was interested in learning what opportunities there might be to expand the usefulness of the assessments and results to coaches and caregivers.

Coach-caregiver encounters are similar to clinician-patient encounters in routine clinical care. Self-reported questionnaires, often referred to as patient-reported outcome (PRO) measures, are administered in clinical care to obtain information on patient status. Significant evidence supports the integration of PROs in clinical care with processes that report scores to patients and clinicians. PROs are associated with improved patient quality of life outcomes, patient-clinician communication, patient satisfaction, and facilitation of meaningful and focused conversations between patients and clinicians [19-30]. The rationale for this study is that, by exploring an analogous process in caregiver-coach encounters, RCI's web-based assessment could provide real-time feedback about progress on intervention targets and can serve as an intervention strategy to more directly tailor the intervention to improve caregiver-coach communication, support the coach in identifying and prioritizing caregiver needs, and achieve better intervention-related outcomes for caregivers.

Objectives

We conducted a qualitative study to describe caregiver and coach perspectives and proposed enhancements to the web-based assessment that could support caregiver-coach encounters. Specifically, we were interested in how the assessment would optimally integrate into the coach-caregiver encounter, including how often outcomes should be evaluated, which format of outcome presentation would be most helpful and to whom, how stakeholders would like to see outcomes presented (eg, figures and text), and what specific features of the assessment would support the encounter and shared decision-making about caregiver needs or successes. This project provides foundational knowledge for designing a web-based system that could support caregiver-coach encounters by providing timely feedback on caregiver needs.

Methods

We conducted a qualitative descriptive study including 1-hour one-on-one semistructured interviews with caregivers and coaches associated with RCI's REACH and OFC programs from July 2020 to October 2020.

Data Collection

Semistructured interview guides were developed to standardize the topics discussed during the interviews. The caregiver and coach interview guides were developed separately because of the different perspectives shared by each type of participant. Interview guides were iteratively developed before data collection began and included open-ended questions and scripted probes. During data collection, the team refined the interview guides by modifying the way questions were worded or adding probes to improve the flow of the interview and gain insight into specific sections.

During the interviews, participants were asked to describe how the T1 and T2 assessments were currently being used, how frequently they thought the assessment should be administered, perceived usefulness of enhancements to web-based displays, and preferences for the structure of self-reported score results. Caregivers and coaches were asked how they would prefer to see the results in figure format. To facilitate discussion about the format of the results, some caregivers and coaches were provided with example figures for discussion.

All interviews were conducted via Zoom with video being disabled. With participants' permission, the interviews were audio recorded and transcribed. The caregivers were given a US $25 gift card as compensation for their time. During and after the interviews, interviewers took notes describing patients' responses and impressions using semistructured debriefing forms.

Ethics Approval

This study was reviewed and exempted by the Duke University Institutional Review Board (protocol number Pro00105250).

Inclusion Criteria

Adults aged >18 years who completed at least 1 session with a coach in either the RCI REACH or OFC program were invited to participate. Eligible coaches included RCI REACH and OFC coaches who had coached at least 1 RCI-affiliated caregiver.

Recruitment, Consent, and Sampling

Recruitment was conducted in 2 ways. First, the Duke study team met with the RCI coaches on the web during a regularly scheduled coach meeting to introduce the study. At the meeting, coaches were provided with information about the study, which included an information sheet and a link to a secure web-based questionnaire (via REDCap [Research Electronic Data Capture; Vanderbilt University]), where coaches and caregivers could review written information about the study and answer screening questions. The coaches were asked to share the study information and REDCap link with caregivers. If an individual was eligible after completing the screening, the Duke study staff reached the coach or caregiver to provide more information and schedule the interview.

The participants were also recruited from the contact list provided by the RCI. Duke study team members reached out to potential participants via email and telephone to provide information about the study and subsequently enrolled the individual if they were eligible and expressed interest in participating in the study. Eligibility and screening responses were recorded via REDCap for both strategies.

During the recruitment process, the study team obtained information about the duration of caregiving, type of caregiving (child, spouse, or parent), time participated as a coach in the RCI REACH or OFC programs, and basic sociodemographic information. This information was used to ensure the diversity of experiences in the study sample. Purposive sampling was used to achieve a balanced representation of interviewees from each existing program (OFC and REACH), the duration of caregiving, caregiver type, and time enrolled in the program.

Analysis

Descriptive statistics were used to summarize the characteristics of the study participants. Qualitative content analysis was used to analyze the participant transcripts. The team used NVivo (version 12 for Windows; QSR International) qualitative data analysis software [31] to apply codes to transcripts, segmenting sections of the transcripts that were associated with particular concepts discussed in the interviews.

The analysts created a codebook (Multimedia Appendix 1) starting with deductive codes created from the interview guides and adding inductive codes identified during the initial review of the debriefing forms. To establish intercoder reliability, 3 analysts (NL, ED, and CS) independently coded 2 transcripts and then met to reconcile them. Discrepancies in coding were resolved through discussion and the codebook was refined. Next, the 3 analysts (NL, ED, and CS) divided the remaining number of transcripts and independently coded them. The analysts met once a week (including TC) throughout the process to check the coding process and refine the code definitions, as necessary. If significant changes to coding definitions or new codes were added, all transcripts were reviewed and recorded based on the latest definitions and codebooks. Once the coding was complete, the 3 analysts (NL, ED, and CS) reviewed the code reports and summarized the findings. The team compared

the results of the caregivers and coaches. Structural and qualitative content analyses were used to identify themes and summarize the results.

Results

Description of Study Participants

In all, 25 caregivers (RCI REACH: 13/25, 52%; OFC: 12/25, 48%) and 11 coaches (RCI REACH: 5/11, 45%; OFC: 6/11, 55%) were included in the study. Table 1 presents the sample characteristics. Most participants were women; 52% (13/25) of the caregivers and 45% (5/11) of the coaches had graduate degrees.

Table 1. Background characteristics of the study participants.

Demographic characteristics	Overall caregivers (n=25)	RCI[a] REACH[b] caregivers (n=13)	OFC[c] caregivers (n=12)	Overall coaches (n=11)
Age (years), mean; median (minimum-maximum)	55; 53.75 (34-74)	64.31; 65 (44-79)	45.6; 42.5 (24-69)	40.5; 40 (24-66)
Gender (female), n (%)	22 (88)	10 (77)	12 (100)	11 (100)
Ethnicity (Hispanic), n (%)	5 (20)	2 (15)	3 (25)	2 (18)
Race (check all that apply), n (%)				
White	19 (76)	11 (85)	8 (67)	8 (73)
Black, Indigenous, or people of color	5 (20)	2 (15)	3 (25)	2 (18)
Prefer not to answer	1 (4)	0 (0)	1 (8)	1 (9)
Highest education completed, n (%)				
Completed high school or some college or university	6 (24)	2 (15)	4 (33)	0 (0)
Associate degree, college, or university	6 (24)	3 (23)	3 (25)	6 (55)
Graduate school	13 (52)	8 (62)	5 (42)	5 (45)
Ability to pay for basics in the past month (food, housing, and heat), n (%)				
Very hard or hard	3 (12)	2 (15)	1 (8)	0 (0)
Somewhat hard	7 (28)	3 (23)	4 (33)	3 (27)
Not very hard	15 (60)	8 (62)	7 (58)	8 (73)
Length of enrollment in RCI program (caregiver), n (%)				N/A[d]
≤1 month	2 (8)	2 (15)	0 (0)	
1-3 months	13 (52)	8 (62)	5 (42)	
3-6 months	5 (20)	1 (8)	4 (33)	
≥6 months	5 (20)	2 (15)	3 (25)	
Length of time spent as an RCI coach, n (%)	N/A	N/A	N/A	
≤6 months				3 (27)
6 months-1 year				4 (36)
>1 year				4 (36)

[a]RCI: Rosalynn Carter Institute for Caregivers.

[b]REACH: Resources for Enhancing Alzheimer's Caregiver Health.

[c]OFC: Operation Family Caregiver.

[d]N/A: not applicable.

Most caregivers cared for their spouses or partners (20/25, 80%) or parents (4/25, 16%). The average length of time for caregiving was 4.1 years for RCI REACH (median 4.5; minimum-maximum 21-9) and 4.8 years for OFC (median 4.5; minimum-maximum 0.7-13). Most caregivers (24/25, 96%) lived with their care recipients. Approximately one-third of the coaches had experience coaching in other programs, either within or outside the RCI (4/11, 36%). The average number of caregivers' coaches who were coached simultaneously was 11 (median 10; minimum-maximum 3-22).

Mode of Survey Completion

Coaches often administered the assessments to caregivers verbally and entered caregiver responses into the web-based

system. The majority of coaches (8/11, 72% of the coaches) used Zoom to administer the assessment, and 27% (3/11; all OFC coaches) conducted the assessment over telephone. A few coaches indicated that before the COVID-19 pandemic, they administered the assessments in person, with the caregivers. Some coaches had the caregivers fill out the assessment in their presence to mitigate the burden of reading aloud every question while also being able to observe important nonverbal cues from the caregivers.

Overall, most caregivers appreciated taking the first assessment with their coach, whether it was via Zoom or telephone. Several caregivers mentioned that taking the assessment with their coach felt more personal, allowed them to share their caregiving story, and build rapport with their coach. There was agreement that the benefit of taking the first assessment with a coach lies in the caregiver's ability to share their stories. A coach described the first assessment (T1) as follows:

> *I think you can just garner a lot from what is being said and things that are not being said at T1, and I think that's where I focus. That's how I get to know them, and I don't know whether you're going session by session with the information, but I think a couple of things. I think the first session should be more of a get to know you session, and although I do tell them about the program in the first session, I focus more on letting them tell their story because I think that's how: 1) You build the relationship; but then 2) How you're able to assess the real need at hand.*

Two caregivers preferred to take the assessment on the web by themselves, and 3 coaches suggested that caregivers take the assessment on the web by themselves for at least the second assessment. Most caregivers appreciated taking the assessment with their coach to build rapport, so it is unclear if there is a significant value in having the caregiver fill out T2 with their coach because at that point, rapport would already have been formed.

Frequency of Survey Administration

The assessments were administered in the first (T1) and last (T2) sessions for the RCI REACH and OFC programs. The coaches and caregivers were asked if more frequent assessments would be useful. There was significant interest among caregivers and coaches of both programs in adding assessments midway through the program. Specifically, approximately 40% of the caregivers felt that it would be helpful to take the assessment again midway through the program, in addition to the current pre-post format. Participants generally agreed that the assessment could be used to evaluate the progress and assess the needs of caregivers. A RCI REACH coach said the following:

> *I think that it would be helpful to maybe even do it at the halfway point. That may help get some more scores then and to see if something needs to be reassessed or re-evaluated in how we continue the program for the caregiver. That way if there is something else that has come up or if we see a significant change in score, we can reflect that with the caregiver and decide how to proceed with the rest of the program.*

The importance of assessing caregivers' needs frequently was highlighted by 2 RCI REACH participants, who emphasized that their care recipients' needs would change frequently (weekly or monthly). One major detractor for not wanting to add a midway assessment was how long it would take (ie, coaches and caregivers believed it would add burden). Some caregivers and coaches suggested that the middle assessment should be condensed or completed on the web without the coach.

How the Assessment Scores Were Used

The caregivers were asked how they and their coaches used their assessment responses. The assessment did not include the functionality for caregivers to see their scores on their own. However, most caregivers remembered going over their assessment results to their coaches. Many caregivers remembered that their coaches provided them with resources after reviewing the assessment results. A caregiver said the following:

> *...We focused a lot on the ones that I was scoring the least on. And she tried to give me pointers and other resources if I wanted to take a look at them on my own.*

Of the few caregivers who did not recall the results of the assessment with their coach, there was agreement that this practice would be helpful. A caregiver said the following:

> *Yeah, but would I have appreciated it or gotten something out of it? Yeah! I answered questions for over an hour, so if somebody had sent me a printout or talked to me about it – ...It would have been helpful to get that feedback about that very first hour.*

At the time of data collection, the assessment tool provided score reports only to the coaches, and these score reports were available only at the topic level. Coaches said they use assessment responses to structure encounters, as well as identify where and what caregivers are struggling with so they can provide resources and support. Coaches also confirmed what caregivers speculated: that the baseline assessment was used to initiate dialogue between the coach and caregiver, build rapport, and gain a sense of how the caregiver is doing.

A few coaches expressed dissatisfaction with how they currently see results, namely that formatting is not helpful or user-friendly, and that the results do not provide much useful information about what to do next. A coach said the following:

> *I think most definitely having more information about what they responded and why it's a concern, and what would be the proper steps to take would be very beneficial because right now we have, we see that happy face and it gives us an explanation. The answers they gave us are concerning, but then that's all.*

Some coaches had trouble with the assessment tool or did not value it. For example, 2 coaches said that they had to take good notes during the assessment administration because they could not access the results. A RCI REACH coach said that they

administered the assessment because it was a requirement but did not use the assessment responses at all; they felt that they could gain the information they needed through conversations with the caregiver during the coaching sessions.

Facilitating Score Report Review in the Future: Caregivers

Caregivers and coaches were asked what score report features would be most useful in the future to inform coach-caregiver encounters. Caregivers were asked if they were interested in seeing individual questions or topic-level scores from the assessments. Table 2 shows caregiver preferences for viewing scores from the assessments (one REACH participant was not asked this question and another REACH participant indicated that they were not interested in seeing their results on the assessments at all).

Table 2. Caregiver preferences for viewing assessment results.

	Topic scores only, n (%)	Individual scores only, n (%)	Both scores, n (%)
RCI[a] REACH[b] (n=11)	3 (27)	3 (27)	5 (45)
OFC[c] (n=12)	4 (33)	2 (17)	6 (50)
Total (N=23)	7 (30)	5 (22)	11 (48)

[a]RCI: Rosalynn Carter Institute for Caregivers.

[b]REACH: Resources for Enhancing Alzheimer's Caregiver Health.

[c]OFC: Operation Family Caregiver.

Of the 7 participants who expressed wanting to see only topic-level scores, 5 (71%) mentioned that they felt that going through the individual item scores would be too burdensome because of the length of the assessment. One caregiver remarked, “I think it’s just a better quick snapshot of where you’re at in things, rather than an overwhelming individual number for every question.”

Of the caregivers who wanted to be able to see both the topic-and individual-level scores, more than half (6/11, 55%) wanted to see topic-level scores first so they could see overall progression, regression, or change over time; then, if certain areas did not change or scores regressed, they wanted to be able to view individual question scores for more details: “After seeing it by topic, if I have questions – then we can dive in for the question for that particular topic.”

Of the 23 caregivers, only 5 (22%) wanted to see individual item scores. One reason for this was that some caregivers wanted to see “all the details” and changes at the individual item level.

Most caregivers were interested in seeing the results and changes in their scores over time, but only a few caregivers were interested in seeing the scores that improved. Two caregivers were not interested in viewing the scores on the assessments that worsened (they only wanted to see scores for the topics or individual questions where they improved). These caregivers said that seeing worsening scores would not make them feel good about their progress. Some caregivers also mentioned that seeing the scores on the assessments would provide extra validation to help them see the program really helping them. When asked if reviewing the scores on the assessment would be helpful, a caregiver responded as follows:

> *[Yes], because I think it’s a little bit more concrete, a more visual way to understand where you’re at. Gosh, I scored really high or I scored really low or maybe things aren’t as bad as I thought they were...*

A few caregivers emphasized the importance of being able to interpret figures showing the results of their scores. For example, some caregivers mentioned that the figures needed to have clear legends to indicate which scores were good or bad or if they were moving in a positive or negative direction.

Facilitating Score Report Review in the Future: Coaches

Most coaches also wanted to see both topic level and individual item scores (7/11, 64%). In all, 3 coaches did not want to see individual item scores; 2 of them being OFC coaches who felt that going through individual item scores would be too burdensome because of the length of the assessment. Three coaches indicated that they would only want to look at individual item scores for specific high-risk topics such as safety or depression. Coaches were open to multiple formats and felt that sharing results with caregivers would be helpful in showing caregiver progress. A coach noted the following:

> *...I think it would be really cool for us to show them at the end of the program or even if another period of assessment’s introduced, checking in with them whenever that’s done, just to show them progress and how we’re doing.*

Overall, most coaches thought it would be beneficial to share all changes in assessment results with caregivers (scores that improved, worsened, or remained the same). A coach said the following:

> *And at the end, I just want to know if they’ve improved or if they’ve gone down then I can refer resources or do what I need to do at that point.*

However, 2 of the coaches were concerned that some caregivers may be discouraged or more stressed if they were told that their scores worsened or did not improve over the course of the program. One of these coaches said the following:

> *I think it would depend on the caregiver. I think some would find it stressful that they’re not meeting their goal, but others might find it motivating.*

However, overall, both caregivers and coaches felt that seeing and sharing the caregivers' improvement scores would make them caregiver and coach feel validated. A few coaches were not interested in sharing scores with caregivers; instead, they felt that the dialogue they would have with the caregiver would be more important in explaining how the caregiver has changed from T1 to T2. Two coaches suggested that the scoring be optional to the caregiver or used for goal setting.

Overall, both caregivers and coaches were extremely interested in reviewing scores on assessments throughout the RCI programs, with particular interest in how scores changed over time, and whether caregivers improved in certain areas or still needed support in others. Some wanted to see topic scores for a quick summary, whereas others wanted to delve into the details to see exactly where the changes were happening. Most of the coaches and caregivers were open to either option.

Comparing Caregivers

Caregivers were asked if they were interested in seeing how their scores on the assessments were compared with other caregivers in their respective programs. Across both programs, most caregivers (approximately two-thirds) said that they were not interested in seeing how they were compared with the other caregivers. One of the main reasons given by caregivers in both programs was that every caregiver is different and in a different situation, so comparing oneself to another was not useful. A caregiver said the following:

> *I don't think that [comparing caregivers] would be helpful because...in caregiving everybody's situation is different, everybody is caring for somebody different, and it's probably not relevant to you.*

The other main reason caregivers were not interested in seeing how they compared with the other caregivers was that they feared that it would cause them stress and anxiety and make them feel worse. A caregiver stated the following:

...If I had bad scores, then I'd be feeling like, "Okay, why are my scores not as good as theirs? Like, what am I doing wrong as a caregiver?" So, I wouldn't want to compare.

Of the caregivers who were interested in seeing how their scores compared with the other caregivers (8/24, 33%), the reasons for this were curiosity and getting a sense of where they stand compared with the other caregivers. Overall, coaches were less certain about whether they would like to compare caregiver scores on the assessments, and opinions varied according to the RCI program. Some OFC coaches noted that it would be helpful to compare caregivers because they could look at average scores and identify any trends or patterns. RCI REACH coaches were less enthusiastic about comparing caregiver scores on assessments. In general, they provided the same reasons as caregivers (ie, every caregiver's situation is different, and it is not useful to compare one to another). In addition, RCI REACH coaches were concerned that sharing score information with caregivers would cause more stress. A few OFC coaches (2/5, 40%) also shared the concern of adding additional stress, so they would keep this information to themselves and not share it with caregivers. The other 3 OFC coaches believed the opposite (ie, that it would actually be helpful for caregivers to see how they compare with others; it could be a learning experience and help validate their feelings).

Discussion

Principal Findings

This study aimed to describe how a web-based assessment is currently being used to identify and monitor caregiver well-being in 2 RCI programs and describe perceived enhancements to the web-based system that could support caregiver-coach encounters by directing priorities for the encounters.

Although the questionnaires included in the assessments were self-administered, RCI coaches used the questionnaires to elicit conversations and get to know the caregivers in their programs. Most assessments were administered verbally via Zoom or telephone, a practice that was likely initiated due to the COVID-19 pandemic but was also well accepted by caregivers and coaches. Coaches valued being able to observe the caregivers on Zoom while administering the questionnaires because they could pick up on nonverbal cues. At least 1 coach indicated that they preferred to share the questionnaire with their caregivers during the assessment.

Historically, the assessments were administered twice: once at the beginning and once at the end of each program. Coaches and caregivers generally agreed that more assessment administrations would be useful because they could receive feedback on caregivers' status and adjust the program as needed. The frequency of change in the care recipient should be considered when deciding the assessment frequency to pick up on new caregiver needs and have coaches able to address these needs in a timely manner. The primary concern regarding the addition of assessment administrations was the length of the assessment. One potential consideration for further refinement of the assessment is to prioritize topics that need to be specifically evaluated by individual caregivers and administer those topics only. Another way to reduce the time required to complete assessments is for caregivers to complete the follow-up assessments on their own because they have already built rapport with coaches; one risk of this approach is that caregivers may not complete a lengthy follow-up assessment on their own. Coaches could encourage caregivers to complete the assessment before the last meeting with their coaches.

Assessment scores were visible to the coaches but were not accessible to the caregivers. Most caregivers agreed that having access to scores would be useful for viewing their status and identifying areas where they needed the most help from their coaches. Caregivers who do not remember going over the assessment results with their coach may become frustrated with the assessment process if they do not think their coach is looking at the results. A formal portal for caregivers to review their own scores or review their scores in tandem with their coach would allow the process of reviewing scores with coaches to be more memorable and useful.

In general, coaches valued the assessments and indicated that they used the scores to identify areas where caregivers found them difficult. A number of coaches were unhappy with the

current functionality of the assessment score results format and emphasized the need for a clear interpretation of the assessment results. Coaches and caregivers provided a wide range of feedback on how they preferred to see assessment scores in the future and what would be most useful to them. Overall, most caregivers and coaches were interested in seeing the score results over time, indicating improvement or worsening. Most caregivers and coaches prefer access to topic- and question-level scores. There was considerable heterogeneity in how caregivers described why they preferred different levels of detail in their score reports. Coaches and caregivers were generally in support of viewing changes in scores in figure format. Some concerns about this practice were mentioned, such as caregivers feeling discouraged about a lack of progress or worsening. This opens an opportunity to reframe the assessment as a tool or intervention to identify needs rather than weaknesses. Most coaches and caregivers were not interested in comparing caregiver scores across other caregivers in the programs, although a few felt that it might be useful. Conflicting perspectives by both caregivers and coaches on whether they would like to compare caregivers to other caregivers demonstrate the importance of providing options for assessment result displays. The heterogeneity in preferences for the format of the results highlights the need for flexibility in the functionality of the assessment tool, with the ability to toggle higher- or more specific-level information, or whether improvement or worsening scores are displayed. One way to address this in the context of the program would be for coaches to ask caregivers about their preferences and adjust the score output for each caregiver's perspective.

The importance of being able to understand and interpret the assessment result figures was mentioned by a few participants. Building on the work that has been accomplished in the interpretation of figures in clinical care settings [32-35], additional research could evaluate the key features of figures that influence interpretation and understanding. Clear figure and score interpretation is critical for coaches and caregivers to determine which needs should be prioritized.

Building on This Study

Future steps for refining the assessment could include developing individualized functionality or features for caregivers and coaches. For example, it is possible that some caregiver characteristics, such as caregiver status (eg, caregiver is doing well or finding it difficult) could be associated with preferences for assessment functionality. Future research could investigate these characteristics and use them as predictors for the presentation of assessment functionality to individualize the assessment experience for caregivers. Another opportunity for individualizing assessment functionality is to set goals and track outcomes toward these goals. The goals of the programs were individualized for each caregiver based on the coach-caregiver encounters, and assessment scores were used to track these goals. Assessment score reports may need to be individualized to draw attention to the outcomes that are most important to the caregivers. Clear interpretation of guidelines for scores is also important. For example, the goal of the coaching intervention may be more protective in nature; therefore, caregivers should expect to see relatively consistent scores over time rather than an improvement.

Strengths

A key strength of this study was that the qualitative interviews included perspectives of the interventionists (coaches) and individuals receiving the interventions (caregivers). Stakeholder interviews are often conducted in clinical care contexts but focus on the individuals receiving interventions: patients. By including both stakeholders in the qualitative study design, we compared the results, resulting in a holistic set of insights and suggestions for the next steps. Another strength is that we had the opportunity to interview caregivers who were currently enrolled in RCI programs, as well as caregivers who had completed their RCI program. The results of this qualitative study will drive the next steps for RCI's web-based platform and expand on current standards for administering self-reported questionnaires in clinical practice settings. The results of this study could potentially be useful for health organizations when building or upgrading web-based portals for patients and clinicians.

Limitations

The results of this study should be considered in light of its limitations. First, the interview participants were only from RCI coaching programs; the generalizability of the functionality of the tool may be limited. Second, all coaches included in the interviews actively participated in the RCI programs; therefore, their interviews may reflect a more positive outlook than coaches who were no longer with RCI. Finally, the caregivers and coaches who dropped out of the program were not included in the study; consequently, the results may reflect a more positive view of the assessment.

Conclusions

We conducted qualitative interviews with the coaches and caregivers in the 2 RCI programs. Web-based and procedural enhancements were identified to enrich caregiver-coach encounters. New and enhanced strategies for using web-based assessments to direct priorities in the caregiver-coach encounters included (1) integrating figures showing caregiver progress at the individual caregiver level, (2) ability to toggle results through different figures focused on individual versus aggregate results, and (3) support for interpreting scores. The results of this qualitative study will drive the next steps for RCI's web-based platform and expand on current standards for administering self-reported questionnaires in clinical practice settings.

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Authors' Contributions

TC drafted the manuscript, interpreted the results, and was responsible for designing and conducting the study. NL contributed to the completion of the regulatory tasks (creating recruitment materials, reviewing or editing institutional review board application, managing staff effort on project, managing participant compensation, and managing audio files or transcripts) and participated in interview guide creation, conducted interviews, trained staff on interview techniques and qualitative data analysis, developed the codebook, managed the master NVivo file and ran the interrater reliability, coded and analyzed qualitative data, and participated in manuscript writing. ED contributed to the recruitment of caregivers and coaches and scheduling interviews, participated in interview guide and other study material creation, conducted interviews, coded and analyzed qualitative data, and participated in manuscript writing. CS contributed to the recruitment of caregivers and coaches (cold calling or emailing potential recruits, calling after completion of REDCap [Research Electronic Data Capture] eligibility, reviewing study information and materials, and scheduling interviews) and conducted interviews, completed the analysis for demographics (Table 1), coded and analyzed qualitative data, and participated in manuscript writing. KW contributed to the facilitated recruitment of caregivers and coaches and participated in the interview guide and codebook review and in manuscript writing. JO contributed to the facilitated recruitment of caregivers and coaches and participated in interview guide and codebook review and in manuscript writing. MSB provided feedback throughout the project and participated in manuscript writing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The final codebook used to code the qualitative transcripts.
[DOCX File , 17 KB - formative_v6i4e30877_app1.docx]

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Abbreviations

OFC: Operation Family Caregiver
PRO: patient-reported outcome
RCI: Rosalynn Carter Institute for Caregivers
REACH: Resources for Enhancing Alzheimer's Caregiver Health
REDCap: Research Electronic Data Capture

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Original Paper

Recruiting Black Men Who Have Sex With Men (MSM) Couples via Dating Apps: Pilot Study on Challenges and Successes

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Abstract

Background: HIV disproportionately impacts Black men who have sex with men (MSM), and targeting the primary relationship (ie, couples) using mobile technology for health holds promise for HIV prevention. Web-based recruitment of MSM is commonly employed in HIV prevention and intervention research. However, little known about recruiting Black MSM couples on the internet in the United States.

Objective: This study describes the process of recruiting Black MSM couples over social networking and dating apps frequented by MSM. We describe the activities for recruiting, screening, and enrolling participants as part of a randomized trial employing a multipronged recruitment approach.

Methods: Black MSM in couples were recruited via three apps (ie, *Jack'd*, *Adam4Adam*, and *Growlr*) between May 2020 and March 2021 during the COVID-19 pandemic in the United States. Black MSM couples were eligible if one or both partners are Black, MSM, and living with HIV, and if both partners were 18 years or older, and have been together for at least 2 months in what they both consider a primary relationship (ie, one in which both partners reported feeling most committed to over any other partner or relationship).

Results: A total of 10 Black MSM couples (n=20) were enrolled via social networking apps. App recruitment activities were a combination of passive (eg, in-app advertisements) and active (eg, direct messaging of users) engagement. Recruitment approaches varied by the social networking app owing to differences in app features. A full-time recruiter experienced challenges such as bugs (ie, technical errors in computer program or system), navigating technical requirements specific to each app, and web-based harassment.

Conclusions: Despite challenges, it was possible to recruit Black MSM couples virtually into research as part of a multipronged recruitment strategy. We identify tips for using web-based dating and other social networking apps as part of a recruitment strategy in future research with Black MSM couples.

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KEYWORDS

African American; sexual and gender minorities; homosexuality, male; HIV; mHealth intervention; mobile applications; apps; sexual partners; investigative techniques; community engagement; MSM; Black men; mobile app; LGBT; research methods; recruitment; online dating; social network

Introduction

HIV remains a global health issue requiring continued efforts in prevention and intervention in low-, middle-, and high-income countries [1,2]. Within the United States, HIV disproportionately affects men who have sex with men (MSM). This health disparity is even greater among Black or African American (hereafter "Black") men [3-6]. Half of all Black MSM are estimated to acquire HIV in their lifetimes compared to one in 11 for White MSM [7]. The primary romantic relationship is an intervention target given high rates of seroconversion among MSM in these relationships [8-11]. Among Black MSM, nationwide estimates indicate that one-third to a half of those with HIV are in a primary relationship [12-14]. Therefore, research on couples remains crucial in HIV/AIDS prevention and intervention.

Location-based dating and social networking apps have become an option for participant recruitment in HIV/AIDS and sexual health research [15-17]. The advantages of app-based recruitment in HIV research are recently highlighted by the COVID-19 pandemic whereby in-person recruitment was prohibited owing to physical distancing and other public health measures [18]. Recruiting couples on the internet requires special consideration for relationship verification and data validation [19-21]. Emergent studies have used apps and other social media (eg, Facebook and Instagram) to recruit MSM couples [22,23]. However, knowledge gaps exist for using dating and social networking apps to engage racial or ethnic minority MSM couples.

Recruiting Black MSM couples into research studies presents important considerations and is challenging for myriad reasons. Distrust of research and medical institutions and cultural stigma concerning race, sexual orientation, and HIV status are barriers to research participation for Black MSM [24,25]. MSM in couples may have a diverse range of agreements regarding sex with others outside of their relationship. Sexual agreements are the mutual understanding between primary partners regarding what sexual behaviors are allowed [26]. These agreements are prevalent among 58% to 99% of same-sex male couples [27], with 11% to 64% of these agreements including sex with outside partners [27]. Given that some MSM have agreements regarding outside partners, dating and social networking apps provide a way to reach partnered MSM that may use apps to socialize or find potential sexual partners.

Few studies have presented details on using dating and social networking apps to recruit Black MSM couples, highlighting a potential knowledge gap on methods for engaging couples into research. Thus, the goal of this study is to describe the process of using dating and social networking apps to recruit same-sex couples to inform future trial designs. This study is part of a multipronged recruitment approach of a pilot randomized controlled trial (RCT) with Black MSM couples with HIV.

Methods

Study Overview

The dating app recruitment process described herein was part of a multipronged recruitment approach of a pilot RCT to test the feasibility and acceptability of a mobile app intervention for improving HIV care and treatment among Black MSM couples living with HIV. We targeted recruitment efforts on dating and social networking apps frequented by Black MSM: *Jack'd*, *Adam4Adam* (*A4A*), and *Growlr* [19,28-31]. Qualitative data particular to each app are described below to highlight the unique success and challenges experienced using this underutilized recruitment approach. To maximize engagement with Black MSM, we hired a Black, cisgender, same-gender-loving–identified man as the study recruiter who performed all recruitment activities and documented the recruitment process. Recruitment occurred between May 2020 and March 2021. Black MSM couples were eligible if one or both partners are Black, MSM, and living with HIV, if both partners were 18 years or older, and have been together for at least 2 months in what they both consider a primary relationship (ie, one in which both partners reported feeling most committed to over any other partner or relationship).

Owing to differences in user engagement requirements by app, we used different engagement approaches by app. On *Jack'd*, recruitment was conducted through their in-app advertisements. Interested candidates who clicked on the advertisement were directed to a Qualtrics prescreener questionnaire that obtained basic qualifying information (eg, current place of resident, race, relationship and HIV status, and length of time on antiretroviral medications for HIV). Study staff then contacted eligible candidates via SMS text message using the telephone number provided.

Recruitment on *A4A* was carried out by sending private SMS text messages to potential participants using the in-app messaging feature. The recruiter identified potential participants using the app's search filters which allowed users to filter through other users' profiles on the basis of set criteria such as their race, HIV status, and relationship status. The study recruiter identified users whose race or ethnicity was set to Black, African American, or mixed. We included "mixed" race because many Black MSM may identify as mixed race given the diversity among Black communities. We also found that some users identify their race as mixed to avoid being filtered out by users who filter out Black-identified users within the app. The study recruiter identified users whose HIV status was set to HIV-positive, undetectable, or unanswered. Users who left their HIV status unanswered were considered for the study as it would encompass anyone who has never been tested or chose not to disclose their serostatus on the internet. Finally, the study recruiter identified users whose relationship status was set to dating, partnered, open relationship, polyamorous, or married.

Once potential participants were identified, the study recruiter privately messaged each individually. *A4A* has a message delivery report in its platform, which allowed recruiters to know if a message has been read or not. Users who read but did not respond within 48 hours of the first message being sent were

sent a follow-up message asking if they were still considering participation in the study or were no longer interested. The messages that remained unread would require no follow-up as those users were likely inactive. Users who communicated interest then were asked to complete a phone screener with a study staff to determine eligibility.

Recruitment on *Growlr* was carried out by sending private messages to potential participants using the in-app messaging feature and in-app advertisements contained the weblink to a Qualtrics prescreener. A *Growlr* paid service, the "SHOUT!" feature, allowed the recruiter to send the study information to multiple people in a specified vicinity.

A total of 10 couples (N=20) recruited via apps were enrolled in the trial, including 7 same-race Black couples and 3 interracial couples.

Ethical Considerations

This study received ethics approval from the institutional review board of University of California, San Francisco (IRB#15-18042). All participants provided informed consent to participate in the study.

Results

Results Overview

Individual- and couple-level characteristics of the couples recruited via apps are reported in Tables 1 and 2, respectively. The following outlines findings resulting from the process of recruiting participants via each app.

Table 1. Individual-level participant demographic characteristics of couples recruited from dating apps (N=20).

Characteristics	Values
Age (years), mean (SD), range	36 (13), 20-54
Length of relationship (months), mean (SD), range	5.7 (9.3), 2-336
Ethnicity, n (%)	
Hispanic or Latino	3 (15)
Not Hispanic or Latino	17 (85)
Race, n (%)	
African American or Black	15 (75)
White	3 (15)
More than one race	2 (10)
Serostatus, n (%)	
Living with HIV	15 (75)
Not living with HIV	5 (25)
Cohabitation, n (%)	
Living together	16 (80)
Not living together	4 (20)

Table 2. Couple-level characteristics by HIV serostatus and race (N=20).

Status	Same-race participants, n	Interracial participants, n	Couples, n (%)
Seroconcordant-positive (both members are HIV-positive)	4[a]	1	5 (50%)
Serodiscordant (one partner with an HIV-positive status and the other with an HIV-negative or unknown status)	3	2	5 (50%)
Total	7 (70%)	3 (30%)	10

[a]There was one serodiscordant-positive couple in which both partners are multiracial. They identify as African American or Black and another race (eg, Latinx and Native American).

Jack'd

Overall Findings

In-app advertisements on *Jack'd* were used for recruitment on the platform. Eligible candidates who completed the Qualtrics prescreener questionnaire through the study advertisement and were contacted by recruiters via SMS text message with the telephone number they had provided. If the candidate did not respond to the SMS text message within 24 hours, a recruiter would follow up with a telephone call and leave a voicemail message if there was no answer. Potential candidates had 1 week to respond before another attempt to make contact was made. This pattern of correspondence continued until either the candidate indicated that he/she was no longer interested or the telephone number was no longer in service. Interested and

eligible candidates who completed the Qualtrics prescreener would then complete a telephone screener. Participants were scheduled for an interview once they provide informed consent to participate.

A total of 35,912 unique impressions, or the number of times the study advertisement was displayed to a user for the first time, occurred on *Jack'd* in 4 major cities (Atlanta, Georgia; Los Angeles, California; Houston, Texas; and Washington, District of Columbia). Of these views, 924 users clicked on our advertisement at least once. Consequently, the click-through rate, or number of unique clicks divided by the number of unique impressions, ranged between 0.85% (Atlanta, Georgia) to 1.16% (Houston, Texas).

Character Limits for Advertisement Placement

Though recruitment on *Jack'd* was carried out through in-app advertisements, imposed character limits made it difficult to fully describe the target population and goals of the study. One solution was to include part of the study description into the image selected for our profile at an extra cost (Figures 1 and 2). *Jack'd* removed our advertisements and stated that adding more text to our recruitment advertisements would be an extra cost. Our team elected to pay the additional fee to include more description in our in-app advertisements so that interested applicants had more information prior to completing the prescreening measure.

Figure 1. Inclusion of part of the study description into the image selected for our profile at an extra cost in the app interface.

Figure 2. Screenshot of the image selected for our profile in the app.

Adam4Adam

Technical Bugs

The recruiter experienced functionality issues with the web-based browser and mobile app versions of *A4A*. The web-based version was designed to look like the app, but there were technical bugs with several functions. For example, the recruiter made edits to the profile on the web-based version; however, these edits were not always reflected in the app version. Moreover, blocks of text from the recruiter profile would often be removed without notification or explanation, which would leave out key details of the study and regular monitoring would be required to ensure that information published to the app profile was not deleted by the app. Unfortunately, when information was deleted from the profile no error messages or warnings had been communicated to the recruiter. As such, there may have been times when potential candidates missed vital information about the study.

Potential candidates were contacted on the basis of their eligibility potential, which was determined by using app search filters (eg, candidate identified race, relationship, and HIV status). Additionally, recruiters scanned through details on their candidates' profiles for information that may qualify or disqualify them for the study. A total of 292 potential candidates were contacted on *A4A* across 15 different states. Searches were conducted across all large geographical regions of the United States including the West (California, Nevada, Arizona, and Washington), Midwest (Ohio, Illinois, and Wisconsin), South (Mississippi, Texas, Georgia, Florida, North Carolina, and Tennessee), and Northeast (Massachusetts and New Jersey). Participants contacted in accordance with the state were as follows: Arizona (n=10), Georgia (n=17), Illinois (n=34), Massachusetts (n=7), Mississippi (n=14), Nevada (n=10), New Jersey (n=12), North Carolina (n=45), Ohio (n=19), Tennessee (n=18), Texas (n=25), Washington (n=9), and Wisconsin (n=3). Owing to an unexpected account suspension, we were unable to breakdown numbers between California and Florida (n=69).

Existence of Bots

Successful engagements with potential participants on *A4A* could be improved simply by the recruiter distinguishing

themselves from automated "bot" profiles that function to send spam and are often ignored by app users. The recruiter found positive changes in user responses when he developed rapport with other users. For example, one user had a profile photo with a dog, prompting the recruiter to comment, "Cute dog, it reminds me of my childhood pet," followed by a self-introduction. In another successful recruitment interaction, the recruiter started a conversation inquiring about the reference of a song in a user's profile name. The shared knowledge between the user and recruiter about the song lead to the user's interest in further discussion. After sharing the recruiter's role with the study, the user chose to enroll in the study.

Inability to Track Profiles and Messages

Tracking contacts on *A4A* were not straightforward and required additional steps. *A4A* offers a feature to "favorite" users, allowing their profile to be bookmarked through an in-app list. This list enabled the recruiter to stay connected to contacts even if they changed their username. However, the feature did not allow for more than one person to be added owing to technical bugs. Thus, the recruiter used the web-based version to save the URLs of users' profiles for tracking purposes. Additionally, the chat function only allows for a limited number of messages to be sent before older messages are lost. To save relevant information, the recruiter tracked and recorded usernames, dates of interaction, follow-up dates, user profile URLs, and other notes in Microsoft Excel.

Removal of Flyer Image From Recruiter Profile

During the recruitment process on *A4A*, the recruiter received an automated message indicating that the study's flyer image—which had been uploaded to the recruiter's profile—was removed because it violated the app's standards. The recruiter then changed the study's profile picture to a photo of himself. Thereafter, when potential participants expressed interest in the study through private SMS text messaging, the recruiter would send the flyer image directly to them.

Harassment

The recruiter experienced racially and politically charged verbal abuse during the height of the Black Lives Matter protests in 2020. Racial epithets (eg, "mountain caucus monkey") were used by an app-user without provocation. Romantic and sexual harassment were common.

Growlr

Similar to *A4A* and *Jack'd*, *Growlr* recruitment procedures involved both active and passive approaches. The study recruiter identified potential participants through the app's search filters and messaged eligible users privately; in-app advertisements with the study information also contained a weblink to the prescreener. A *Growlr* paid feature "SHOUT!" was used to send the study information to multiple users in a specified region. We paid for "SHOUT!" broadcasts in 4 separate cities (eg, Charlotte and Raleigh, North Carolina; Nashville, Tennessee; and Cleveland, Ohio). Users within a 25-30–mile radius were able to see these advertisements and resulted in 2955 total views.

Similar to *A4A*, the recruiter experienced verbal abuse and harassment. *Growlr* removed the study flyer from the recruiter's profile, with a message indicating that it violated company guidelines against in-platform solicitation. However, after a new flyer was posted that excluded any mention of the study participants being paid, it was nevertheless removed again, and *Growlr's* customer service did not respond to our inquiries about the second flyer removal. Owing to the technical bugs and low success rate (no eligible couples were found), the recruiter discontinued efforts on the platform after 2 weeks.

Discussion

Principal Findings

HIV incidence among Black MSM in the United States continues to be disproportionately high [3,4] with one-third to half of Black HIV-positive MSM to be in a primary relationship [13,14,32]. Nonetheless, societal stigma, distrust of research and medical institutions, and other systemic barriers negatively impact HIV prevention and treatment for this underserved community [24,25]. As such, novel approaches to recruiting Black MSM couples are needed.

There are relatively few dyadic HIV research studies with Black MSM couples (eg, time and staffing). Little information exists detailing the successful strategies for web-based recruitment of Black MSM couples into HIV research. While dating and social networking apps have been commonly used to recruit single MSM for research studies [19], no research has used dating apps to explicitly recruit couples of MSM. This study demonstrated the feasibility of dating and social networking apps for recruiting Black MSM couples as part of a pilot RCT of a couples-focused app for improving HIV care engagement. Recruiting MSM couples through dating and social networking apps is a necessary recruitment strategy given the prevalence of sexual agreements among MSM couples [27].

Consistent with previous research, this sample of couples contained predominately same-race Black partnerships [32]. The search and filter functions in the apps, such as filtering users on the basis of their reported relationship status, helped to identify potential participants per the eligibility criteria. *A4A* and *Growlr* offered the functionality to filter through user-identified race or ethnicity categories, which reduced the time needed to search for eligible users. Paid advertising campaigns through *Jack'd* and *Growlr* were an opportunity to recruit passively, instead of actively searching through users and initiating conversations to determine eligibility and interest.

Although the strategy of privately messaging potential participants on *A4A* was a successful recruitment strategy, it was not without challenges. Our Black, same-gender-loving–identified recruiter reported multiple episodes of harassment of various types (eg, sexual, racial, and political). Additionally, app-specific guidelines for study advertisements varied (eg, character limits and other rules). Regular check-ins between the principal investigator and recruiters and careful attention to the guidelines for each app are necessary.

Limitations

Our study recruited for a one-time interview, and we do not know how these findings generalize to other, longer-term

research requirements. Further, biases in the sample skew toward nonmonogamous couples owing to the generally sexual purposes of MSM using the apps. Finally, given the evolving nature of the software, some of the app features reported during the time of publication may or may not reflect what is currently available.

Comparison With Prior Work

Apps designed for MSM have become increasingly popular and users on those platforms may visit them frequently (eg, daily) [33]. Research has recruited single MSM [19,34-36] and Black MSM [37-39] via apps. Given high HIV transmission rates between MSM primary partners [8-11], recent studies have also recruited MSM couples through a combination of web-based engagement (eg, Facebook and gay websites) and apps [10,40-44], but not exclusively on apps. No research documents the utility of app-based recruitment for Black MSM couples [45,46]. Given the disproportionate rates of HIV [6,7,47] and the importance of coordinating HIV prevention, care, and treatment [45,48,49] within this community, there is urgency to finding novel approaches to recruiting Black MSM couples for HIV prevention studies.

Conclusions

Dyadic HIV research with Black MSM couples is important but knowledge gaps remain. Challenges to research with this population include participant recruitment, which can be resource intensive, underscoring the need for recruitment strategies that have been demonstrated to be feasible and acceptable. We discuss our strategies for engaging Black MSM couples via social networking apps, and associated technical challenges, including issues with harassment directed at our recruiter. We have identified a way forward with using social networking apps to engage Black sexual-minority couples to inform future research.

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Conflicts of Interest

None declared.

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Abbreviations

A4A: Adam4Adam
MSM: men who have sex with men
RCT: randomized controlled trial

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Original Paper

Using the Stay Strong App for the Well-being of Indigenous Australian Prisoners: Feasibility Study

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Abstract

Background: The gap between mental health needs and resources for Aboriginal and Torres Strait Islander people, the Indigenous people of Australia, is most marked in the prison population. Indigenous people are overrepresented in Australian prisons. In prison, this group experiences mental disorders to a greater degree than non-Indigenous prisoners. This group has also been found to experience mental disorder at a higher rate than Indigenous people in the community. In addition to pre-existing determinants of poor mental health, these high prevalence rates may reflect poor engagement in mainstream interventions or the efficacy of available interventions. In community populations, the use of digital mental health resources may help to increase access to well-being support. However, culturally appropriate digital tools have not been available to Indigenous people in prisons. The absence of feasibility and efficacy studies of these tools needs to be addressed.

Objective: The aim of this study is to determine the feasibility of the Stay Strong app as a digital well-being and mental health tool for use by Indigenous people in prison.

Methods: Dual government agency (health and corrective services) precondition requirements of implementation were identified and resolved. This was essential given that the Stay Strong app was to be delivered by an external health agency to Indigenous prisoners. Then, acceptability at a practice level was tested using postuse qualitative interviews with clients and practitioners of the Indigenous Mental Health Intervention Program. All Indigenous Mental Health Intervention Program practitioners (10/37, 27%) and client participants who had completed their second follow-up (review of the Stay Strong app; 27/37, 73%) during the study period were invited to participate.

Results: Owing to the innovative nature of this project, identifying and resolving the precondition requirements of implementation was challenging but provided support for the implementation of the app in practice. Acceptability of the app by clients and practitioners at a practice level was demonstrated, with nine themes emerging across the interviews: satisfaction with the current Stay Strong app, supported client goal setting, increased client self-insight, improved client empowerment, cultural appropriateness, enhanced engagement, ease of use, problems with using an Android emulator, and recommendations to improve personalization.

Conclusions: The Stay Strong Custody Project is a pioneering example of digital mental health tools being implemented within Australian prisons. Using the app within high-security prison settings was found to be feasible at both strategic and practice levels. Feedback from both clients and practitioners supported the use of the app as a culturally safe digital mental health and well-being tool for Aboriginal and Torres Strait Islander people in prison.

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KEYWORDS

First Nation; Indigenous; digital mental health; e-mental health; mental health; social and emotional well-being; SEWB; prisoner; prison; mobile phone

Introduction

Background

Mental disorders are a leading cause of the nonfatal global burden of disease. Commonly accepted estimates are that 21.2% of years lived with disability and 7.1% of disability-adjusted life years are experienced by people with mental disorders, but some researchers argue that these figures underestimate the true impact [1]. However, the picture is even more bleak for Indigenous people. Indigenous populations in western nations such as Canada, the United States, New Zealand, and Australia are particularly impacted as they have higher rates of mental disorder, substance misuse, and suicide than their non-Indigenous population [2-10]. The rates of incarceration are also higher for Indigenous people than for non-Indigenous populations, with this cohort shown to have a particularly high prevalence of mental disorders [11,12].

Aboriginal and Torres Strait Islander people, the Indigenous people of Australia, experience a burden of disease 2.3 times more than that experienced by the non-Indigenous Australian population, with mental disorders and substance use disorders accounting for 19% of this total disease burden [13]. Compared with non-Indigenous Australians, Indigenous Australians have higher rates of suicide (2 times) [13], higher rates of hospitalization for self-harm (2.7 times) [14], higher levels of psychological distress (2.6 times) [14], and higher rates of depression and anxiety [15] and are overrepresented in the mental health system (3 times) [16]. Differences in prevalence rates between Australia's Indigenous and non-Indigenous populations suggest an increased presence of determinants of poor mental health and well-being, a lower rate of engagement in interventions, and a reduced efficacy of the interventions available for Indigenous people in Australia. Indigenous Australians are 14 times more likely to be incarcerated than non-Indigenous Australians [17,18]. Although Indigenous people represent 3.3% of the Australian population, they constitute 29% of all prisoners [17,18]. As a breakdown of the overall prison population, Indigenous women constitute 36% of the female prisoner population and Indigenous men constitute 28.9% of the male prisoner population [17,18].

The gap between mental health and well-being needs and resources is at its most marked for Indigenous people in prison [19]. It is estimated that in Australia, the 12-month prevalence of mental disorders in Indigenous women in prison is 86% and in Indigenous men in prison is 73% (including substance use disorders). This is very high compared with the 12-month prevalence of mental disorders in the general Australian population, which is 22% for women and 18% for men [12,20]. This discrepancy is evident in other western colonized countries such as New Zealand, the United States, and Canada [19], where Indigenous people experience poor mental health [2,4,9], increased risk of substance misuse [2-4], higher rates of suicide [2,5,10], and overrepresentation in the prison population [21-23]. Although there is an improving commitment to the health and welfare of First Nations people, in these jurisdictions, there is limited Indigenous-specific well-being or mental health interventions for prisoners and limited published evaluations of these interventions [19].

The Correctional Investigator of Canada, Truth and Reconciliation Commission of Canada, and Canadian parliamentary commissions called on government to improve First Nations prisoners' access to culturally relevant intervention [24-26]. This aim is also reflected in New Zealand's Hōkai Rangi strategy to address the overrepresentation of First Nations people in prison [27]. Within this strategy, scaling up successful interventions, developing new Indigenous-specific interventions, and deciding how best to support their delivery have been identified as key challenges [27]. In Australia, the National Agreement on Closing the Gap aims to eliminate the gap between the health and welfare of Indigenous and non-Indigenous people [28-30]. Among the priority targets to be addressed through this agreement are reducing the rates of incarceration and improving Indigenous prisoners' social and emotional well-being (SEWB). This may be achieved in part through access to culturally safe, Indigenous developed and delivered, evidence-based interventions [28,30].

Although it is possible to develop and deliver culturally safe well-being interventions specifically for Indigenous people in prison, there is a lack of access for prisoners to evidence-based interventions [19]. There is a need for equity-oriented evidence-based interventions that engage a population with complex needs in a restrictive prison environment. The development of innovative, culturally safe, and effective interventions that make efficient use of the finite resources available to support prisoners would address the growing gap between need and service.

As a step toward achieving this vision, since September 2015, the Stay Strong Custody Project (SSCP) has been trialing culturally safe digital mental health resources with Aboriginal and Torres Strait Islander women and men in prison. This has been achieved through the use of these tools by the Indigenous Mental Health Intervention Program (IMHIP; Queensland Health's Forensic Mental Health Service). IMHIP is an SEWB service specifically for Indigenous people in prison, offering culturally safe early intervention and support for Indigenous people in custody and for up to 6 months after their release from prison. IMHIP's innovative service delivery model enabled the service to become an early adopter of digital mental health assessment and intervention tools within the high-security prison environment. The SSCP adapted a collection of 5 digital mental health tools to support the assessment of and intervention with IMHIP clients in prison. Internationally, digital tools or information and communication technology (ICT) are being used to support prisoners in completing day-to-day tasks,

enhancing education and vocation skills, accessing family and support, and videoconferencing as a platform for psychiatry and psychotherapy sessions. However, these ICT examples are the exception rather than the rule. Where these limited programs have been introduced in Europe, United Kingdom, Canada, and the United States, they have typically involved low-security prisons, which have fewer restrictions on internet access and ICT support [31].

Internet access is prohibited or extremely restricted within prisons in most countries to prevent breaches of security. These limits are extended to devices that have the potential for communication with contacts outside the prison, such as smartphones, tablet PCs, and laptops. Restrictions on devices and internet use place limitations on the availability of digital mental health and well-being tools to prisoners, both in Australia and in other countries.

Despite this challenge, the use of digital resources to support mental health and well-being in prison is likely to increase in the coming years, given the degree to which it is already influencing the delivery of mental health support in the general community [32-34]. As this occurs, access to digital mental health support within prisons may begin to more closely mirror the level of access available in the outside community. This extension of access will be enhanced by establishing a body of evidence supporting the feasibility and efficacy of digital mental health interventions in a prison context. A concerted effort in creating, evaluating, and raising the awareness of credible digital mental health apps, programs, and services is essential.

Capitalizing on the rapid advancement and widespread adoption of digital technologies, researchers and developers have written and tested digital interventions related to a range of mental health issues, resulting in a substantial evidence base supporting their efficacy. The most widely evaluated group of digital interventions include those that target depression and anxiety in the general population, with greater support for guided digital interventions than unguided [35-41]. However, the benefit of unguided interventions is their ease of accessibility for the general population. The evidence base for digital mental health tools and systems, guided or unguided, for Indigenous people is practically nonexistent, especially for Indigenous prisoners, which limits the generalizability of these results to this population [42].

An exception is the Stay Strong app, which is used as a guided or therapist-facilitated mental health and well-being intervention tool for Indigenous clients. The app was based on the original paper-based version of the Stay Strong Plan, which has been in use since 2007 and has demonstrated significant improvements in client well-being, life skills, and alcohol dependence [43]. An iOS (Apple) version of the Stay Strong app was developed in 2013, making it the first digital mental health app specifically for the First Nations people of Australia [44]. Both the Stay Strong Plan and the app combine motivational interviewing and problem-solving strategies within a brief, strengths-based assessment and intervention tool, developed specifically for Indigenous Australians and for promoting Indigenous cultural values and self-management. Studies have demonstrated the feasibility of the app for use with Aboriginal and Torres Strait Islander people in the community to address mental health and substance misuse issues [44,45]. The app provides a structured evidence-based process to improve engagement with clients and overcome the gap in service access for Aboriginal and Torres Strait Islander clients [44]. For this project, the app is adapted to an Android version, and only this version is used in this study.

Objective

This study assesses the feasibility of the Stay Strong app as a digital well-being and mental health tool for use with Indigenous people in prison. This study also describes the implementation of the Stay Strong app as a digital well-being and mental health tool for use with Indigenous people across 3 high-security prisons in Queensland, Australia.

Methods

Overview

In this section, we first explain the setting and preparatory work required to implement this project. Then, we describe the intervention itself, including the adaptations and recruitment of participants. Finally, we describe the procedure for implementing and evaluating the intervention.

Setting

IMHIP is an SEWB and mental health service provided in prisons by Queensland Health. The IMHIP team is led by an Indigenous project manager and has a staffing profile of 8 Indigenous health worker and practitioner positions, all filled by Aboriginal and Torres Strait Islander staff. The team includes social workers, psychologists, and other Indigenous health workers specializing in mental health and SEWB. Support is also provided to IMHIP clients, as needed, by a non-Indigenous forensic psychiatrist. The IMHIP service is provided within 3 high-security Queensland prisons (Brisbane Women's Correctional Centre, Southern Queensland Correctional Centre, and Woodford Correctional Centre)—2 women's prisons and 1 men's prison. Where possible, clients are matched with IMHIP staff of the same gender, in line with recommended cultural practice. The IMHIP service is offered to Indigenous prisoners on their point of entry into one of these correctional centers, with the level of service determined by the client's level of need.

The Brisbane Women's Correctional Centre is a high-security women's prison with a built capacity for 264 prisoners and current state of 276 prisoners (as of May 4, 2021). The Southern Queensland Correctional Centre is a high-security women's prison with a built capacity for 300 prisoners and current state of 302 prisoners (as of May 4, 2021). The Woodford Correctional Centre is a high-security men's prison with built capacity of 988 prisoners but is currently over capacity with 1426 prisoners (as of May 4, 2021), making it the largest prison in Queensland.

Differences in terminology can occur internationally when describing various security levels of prisons. In Queensland, there are three prison security levels: maximum, high, and low. High security is the most common classification provided to prisoners upon entry into the prison system, including those on

remand, with 94% (9176/9752; as of May 3, 2021) of prisoners being accommodated in a high-security prison. Prisoners on a high-security classification can only be accommodated in high-security prisons. In some jurisdictions, this security classification would be referred to as maximum security. In Queensland, maximum security refers to an uncommon classification applied to no more than 38 prisoners at any point of time, with all of them isolated in individual cells. A prisoner is placed under a maximum-security order only if his behavior is considered as a threat to the safety of other prisoners and staff or the security of the prison. Prisoners under a maximum-security order are placed in maximum-security units, which are separate from the main accommodation areas. Only Woodford Correctional Centre and Brisbane Correctional Centre have maximum-security units.

Contextual Preparation

Overview

To our knowledge, the SSCP is the first use of digital mental health tools in Australian prisons. The project's innovative mode of delivery required the research team to develop new pathways and protocols for delivery in prisons, from inception to implementation. IMHIP's ground-breaking model of service delivery presented numerous challenges that were overcome through the support, consultation, and involvement of community groups and key Indigenous stakeholders.

Implementation Process

Textbox 1 outlines the implementation process undertaken from conception to sustained adoption of the Stay Strong app within the IMHIP service.

Textbox 1. Steps in implementation of the Stay Strong app in a prison setting.

Step 1: Conception and initiation

- Identification of client base, app, and context.
- Scoping potential for project with stakeholders.

Step 2: Definition, planning, and approval

- Development of project plan and evaluation protocol.
- Gained support from the Indigenous Mental Health Intervention Program (IMHIP), Queensland Forensic Mental Health Service, leadership team of Brisbane Women's Correctional Centre, and Menzies School of Health Research.
- Gained approval from the health and correctional government agencies for implementation of Stay Strong app into service and for evaluation.
- Gained approval and adapted Stay Strong app to the Android custody version.
- Gained approval and adapted outcome measures from paper versions to Android apps.
- Development of feedback app (Android version).
- Development of the locked down tablet interface for project.
- Practitioners trained in Stay Strong app and in the use of the app in the context of IMHIP service.
- Tested functionality, user interface design, compatibility, performance, installation, and offsite and onsite security.

Step 3: Launch

- September 2015—first use of Stay Strong app by an IMHIP client (Brisbane Women's Correctional Centre)

Step 4: Performance and support

- Provision of technical support, clinical supervision, support in output production (practitioner reports, client cards, and management data), and continued training for practitioners.
- Introduction of Android emulator with change to Windows-based tablet PCs.

Step 5: Project transition into sustained adoption

- Evaluation of Stay Strong app's feasibility and efficacy with Indigenous prisoners.
- Management of transition of technical support from research team and tool developer to health agency.
- Continued use of the Stay Strong app as part of the formal IMHIP service delivery model.

Preparation for Expected Challenges

Attempting to bridge the digital divide in mental health interventions in prison involved a range of challenges: prisoners being denied access to internet, lack of access to technologies, and competing philosophies of the correctional environment (security and containment) with the external health service. For the SSCP, this required approvals and protocols for the use of digital mental health strategies and technology as part of IMHIP service delivery. This included acquiring ethics and security approvals across both correctional and health agencies, the leadership teams of the relevant prisons, the Queensland Forensic Mental Health Service, and the IMHIP team responsible for the delivery of the service. The approvals and

the training of IMHIP staff and those involved in the broad care of IMHIP clients ensured engagement and support for the project. From inception and acceptance-testing to implementation, this process took approximately 18 months, with the first use of the Stay Strong app and associated project apps by IMHIP clients occurring in September 2015.

In preparation for implementation, processes and safeguards were put in place to meet the security requirements of the prisons and ensure confidentiality of client data. These included the safe and secure storage of tablet PCs within health facilities and during transport from health facilities to prison facilities. It was agreed that upon entry into the prisons, practitioners would proceed through entry checks with devices being logged against practitioners' names in permanent entry logs for officer reference. Permanent entry logs are records of what items specific staff and visitors are permitted to bring into a prison. To obtain the approval for the study, we also had to agree that, once in the prison, practitioners would abide by the security restrictions placed upon the use of tablets, supported by the use of lockdown software on devices. This was to ensure that the digital environment met security requirements.

Given the research team's experience in working across both agencies and within a range of correctional environments, they were able to expediate many processes: pre-empting issues of security and communication; movement of digital devices through centers; concern over prisoners' access and use of devices; management of confidential prisoner or client information; use of audio recording apps on devices for client feedback; device charging, maintenance, and ICT support; staff and stakeholder training; stakeholder and leadership engagement and approval; client's willingness to consent to providing feedback and having their interviews audio recorded; and logistics of printing and sharing of the prisoners' Stay Strong app client cards with prisoners and their prisoner property for use upon release.

The software developer, principal researcher, and IMHIP team completed the key elements to support adaptation and implementation: functionality, user interface design (walk-through of general design heuristics), compatibility (operating system device, screen, and plan for no connectivity), performance (memory and battery), installation, and security testing (data flow with broad agency security requirements).

Apps were password-protected to ensure client confidentiality; practitioners had to re-enter passwords to wake devices from sleep mode or to reopen the app and when accessing existing data. Tablets were also controlled using lockdown software (SureLock software; 42Gears Kiosk lockdown software for Android devices) to meet the security and confidentiality requirements of the health and correctional agencies responsible for the care of IMHIP clients.

Project Support

Financial support for the purchase of technology, development of software, and ICT support was critical to the project's success (refer to the *Acknowledgments* section). Throughout this process, it was essential that partnerships across health, correctional, academic, and software development sectors were developed and maintained. Without these relationships, the project would not have developed and formed a precedent for digital mental health strategies in Australian prisons.

Intervention

The Stay Strong app and 4 other apps adapted or developed specifically for this project provide a collection of digital mental health tools to support IMHIP clients. The Kessler Psychological Distress Scale [46], the Warwick-Edinburgh Mental Well-being Scale [47], and the Growth and Empowerment Measure [48] were used as outcome measures along with the semistructured interview app to inform the intervention and support the subsequent efficacy evaluation of the Stay Strong app. All use of digital resources was through tablet PCs, facilitated by the practitioners and used as an extension of their assessment and intervention resources (Figure 1). All the outcome measures, semistructured interview app, and the Stay Strong app were completely stand-alone apps owing to the internet connectivity restrictions placed upon the project. Consequently, all the apps used in this project were able to work offline (ie, not requiring network connection to function), thereby meeting both the security requirements of the prisons and the client confidentiality requirements of the health service.

Figure 1. Home screen of the tablet PC showing the Stay Strong app and other related apps.

Approval was given by the original developers of the Stay Strong app to adapt the original iOS community version to an Android custody version. Subsequently, the community version has been superseded by a hybrid version (for use on both iOS and Android devices). Similar to the community version, the steps of the custodial adaptation are ordered to enhance engagement while using a holistic approach for assessing a client's well-being and mental health needs. This 11-step app aims to engage clients and provide a nonthreatening approach to the discussion of their well-being and mental health. A comparison between the stepped intervention process of the custodial version and the recently updated community hybrid version is presented in Multimedia Appendix 1. The stepped intervention process of both versions includes the following: (1) collecting demographics, (2) talking about family, (3) talking about a client's strengths, (4) identifying a client's worries, (5) setting first goal for change, (6) setting second goal for change, (7) tips to enhance emotional and physical well-being, and (8) tips to manage substance misuse (Multimedia Appendix 1).

Key differences in the custody version when compared with the community version of the Stay Strong app are the removal of the client photo option, research *collect information* tick box option on the demographics page, and email option on the completion page of the Stay Strong app. Removal of these options from the community version was needed to meet the client confidentiality requirements of both the health and correctional agencies for implementation of this project in 2015. Figures 2 and 3 show steps 2 to 9 of the custodial version, which is nearly identical to the community version, with the exception of the additional *my support* page.

Figure 2. Custodial version of the Stay Strong app—steps 2-5.

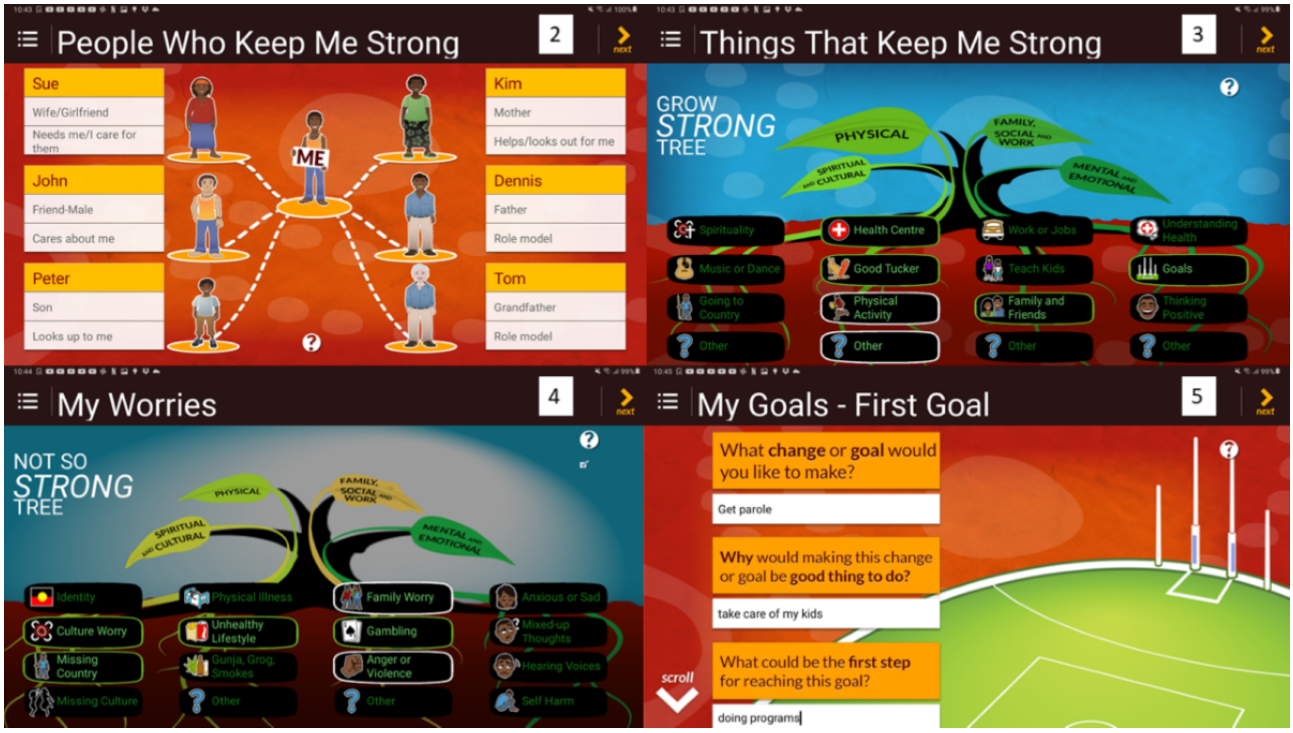
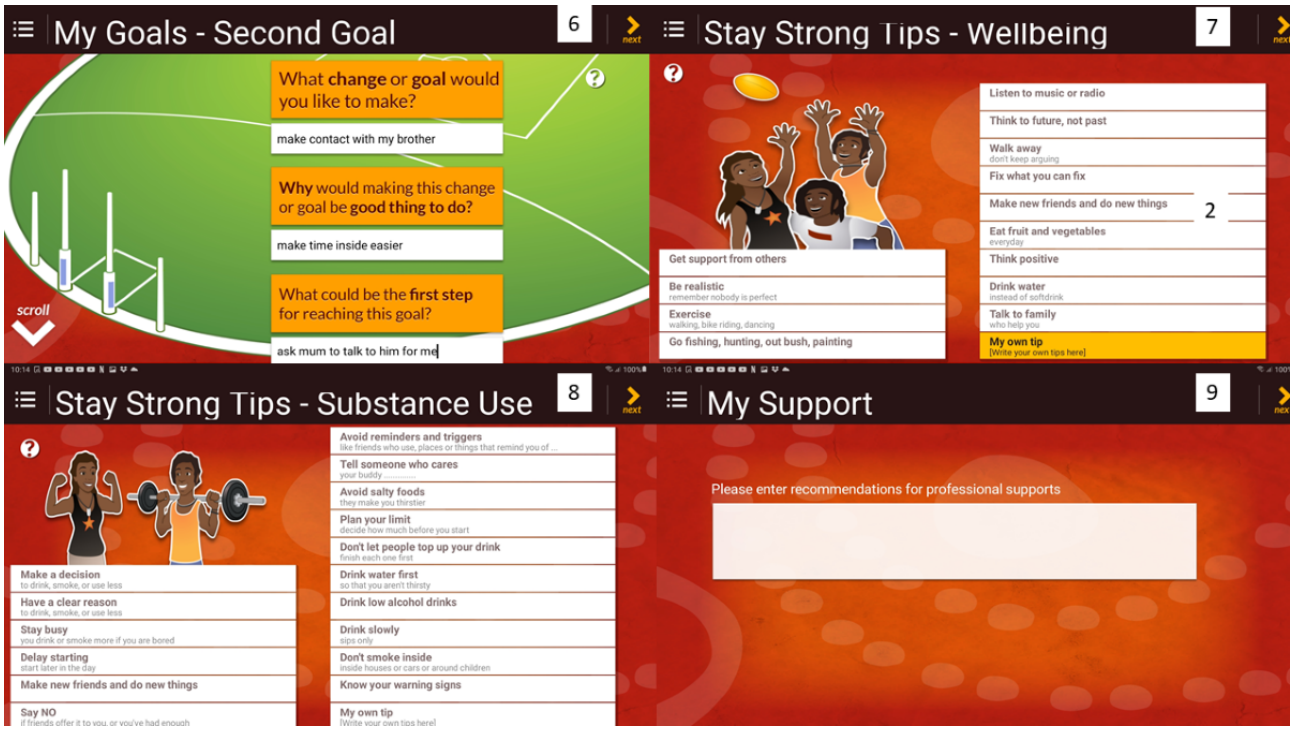


Figure 3. Custodial version of the Stay Strong app—steps 6-9.



In the custodial version of the Stay Strong app, step 9 is the *my support* page in which discussion with clients occurs regarding professional supports that may be of benefit during custody and upon release. This is important, given the risks and challenges experienced by people during their first 6 months after release from prison [49,50]. Contact details are listed in this section, which are then automatically copied to the client's summary (step 10) and client card (step 11).

The client summary is a pictorial summary of each step, which then can be made into the client card (Figure 4), which is a wallet-sized, folded, and laminated card version of the client summary. Clients were provided with 2 copies of their cards, one for use while in custody and another that was stored with other personal property for use upon release. The cards were also folded in a way that allowed prisoners to display the pictorial representation of their support network easily in their prison cells.

Figure 4. Custodial version of the Stay Strong app—Stay Strong client card (step 11).

Recruitment

Client Participants

Participants were recruited from the client base of IMHIP between January 2017 and September 2019 (19/27, 70% women and 8/27, 30% men). All IMHIP clients were from one of the 3 high-security adult Queensland prisons (2 women's prisons and 1 men's prison). The IMHIP staff recruited clients who had the capacity to consent to their involvement in the project and who were regarded as not presenting any safety concerns. An invitation to participate in the program involved both written and verbal explanations of the study and consent forms. Before their release from prison, only clients who completed the baseline and follow-up assessments were invited to participate in a semistructured feedback interview with an IMHIP practitioner. All IMHIP practitioners at the time of the study were involved in conducting the semistructured interviews with clients.

Practitioner Participants

During the same period, IMHIP practitioners were invited to participate in semistructured feedback interviews with the principal researcher (6/10, 60% women and 4/10, 40% men). Similar to that for the client participants, practitioners' invitations involved both written and verbal explanations of the interviews and written consent was obtained.

Initial training for all practitioner participants involved either a 2-day trainer or 1-day Stay Strong app workshop. The process also involved shadowing of colleagues as part of the staff induction processes and Stay Strong app supervision by the principal researcher for the period of the study. The accredited Stay Strong app training package was provided by recognized trainers, and workshop content was summarized, for ongoing reference, in the Aboriginal and Islander Mental Health Initiative Stay Strong Planning Brief Treatment Manual [51].

Ethics Approval

The study was approved by the Darling Downs Hospital and Health Service Human Ethics and Research Committee (clearance #HREC/14/QTDD/65), the Behavioural and Social Sciences Ethical Review Committee of the University of Queensland (clearance #2015000360), and the Queensland Corrective Services Research Committee (no clearance number provided) before the IMHIP clients and practitioners were invited to participate. Client participants did not receive any financial compensation for participation in the study. Payments were not allowed by the prisons in which the participants were accommodated.

Procedure for Implementation and Evaluation

The study synthesized feedback from client and practitioner semistructured interviews to determine the feasibility of integrating the Stay Strong app into an SEWB and mental health service for Indigenous prisoners.

Delivery of Intervention

Steps within the Stay Strong app were completed by clients with their trained IMHIP practitioners as part of the IMHIP service delivery model. This was facilitated and supported by practitioners in session. During the project, clients completed the Stay Strong and outcome measures apps (Kessler Psychological Distress Scale, Warwick-Edinburgh Mental Well-being Scale, and Growth and Empowerment Measure) at 3-month intervals (at intake, first follow-up, and second follow-up) if still in custody. All participants who were in custody for their second follow-up were offered semistructured feedback interviews with practitioners.

Semistructured Interviews

Following their use of the intervention, participating clients and IMHIP staff were invited to provide feedback on the effectiveness of the Stay Strong app, its mode of delivery, and the service context for its use. The purpose of the interviews was to evaluate the use of the Stay Strong app and identify benefits and areas for improvement. The questions for the client semistructured interviews about their experience with the Stay Strong app are reported in Textbox 2, and those for practitioner interviews are reported in Textbox 3. The Stay Strong app went through a name change during this project, dropping *plan* from its title; thus, users were asked about their use of the Stay Strong Plan in reference to what is now known as the Stay Strong app (Textboxes 2 and 3).

Textbox 2. Stay Strong app's client questions used during semistructured interview.

Questions

- What were the best things about working on a tablet?
- What were the best things about developing your own Stay Strong Plan?
- What were the worst things about working on a tablet?
- What were the worst things about developing your own Stay Strong Plan?

Textbox 3. Stay Strong app's practitioner questions used during semistructured interview.

Questions

- What has it been like working with the tablets?
- What has it been like using the Stay Strong Plan with women/men?
- What would you suggest we do differently?
- How would you explain the tablets and Stay Strong Plan to other practitioners?
- How do you explain the Stay Strong Plan to the women/men you work with?

Before the interviews, of the 27 client participants, 24 (89%) clients consented to have their interviews audio recorded and the remaining 3 (11%) clients entered their responses directly into the tablets in response to the interview questions. All the (10/10, 100%) practitioners consented to having their interviews audio recorded.

Analysis

Audio recordings of the feedback interviews were transcribed verbatim by the principal researcher (EP). Following transcription, researchers (EP and KH) used the constant comparison method [52] as a framework for conducting the thematic analysis, as used in previous qualitative analyses [53]. There were 2 iterations of the qualitative coding. Practitioner and client data were coded separately. On the first pass through the data, the 2 coders independently identified themes that arose from >1 respondent across the questions in >1 interview. Then, the themes were agreed upon by the research team and coded independently for each question and each respondent (yes=1; no=0). There was no limit on the number of themes that could be coded for each response. Data were entered directly into SPSS data sets, and direct quotes reflective of each of the themes were collated. At this stage, any theme that did not reach satisfactory interrater reliability were discussed until consensus between coders was attained. Following agreement on themes within practitioner and client data, EP compared the 2 sets of themes and identified commonalities between both practitioner and client themes; these were then checked by KH.

Results

This section outlines both themes emerging from feedback interviews and responses to unexpected challenges experienced during the project.

Stay Strong App Themes Emerging From Client and Practitioner Feedback Interviews

Overview

Interrater reliability across themes was moderate to strong (κ ranging from 0.71 to 1). The prominent themes identified across both client and practitioner interviews include the following: general satisfaction with the Stay Strong app in its current format; support of clients' goal setting, self-insight, empowerment, cultural development, and engagement in intervention; ease of use of the Stay Strong app; and initial problems with using an Android emulator. These themes are

discussed below and include example responses by both clients and practitioners.

Satisfaction With the Current Stay Strong App (General Positive Statements or No Recommended Changes)

There was clear support from both clients and practitioners who voiced their satisfaction with the Stay Strong app in its current format, providing general positive statements or specifically identifying that there was no need for any change in the app.

Responses from clients included the following:

> *Oh, I thought it was one of the best things ever.*
>
> *Gives me some bit of hope in myself that you know.*
>
> *Liked being able to tell my story and explain it.*

Responses from practitioners included the following:

> *I would say ninety nine percent of the clients that I worked with them on the tablet have really enjoyed it. It's been something that they haven't done before. You know, it's exciting because they're allowed to touch a computer. I think they've enjoyed it.*
>
> *It's amazing. It's very, it's, it's kind of fun. It's exciting. You feel like you've got this. You're like technologically advanced, it's something. You know, new and exciting, yeah, it's quite, it's user friendly, too, and I know it just kind of makes you, you look deadly and you, you know.*
>
> *Then they love [sic] piece of technology that they can use, but they probably don't get to use at all while they're incarcerated, something different to do.*

Supported Client Goal Setting

All participants welcomed the Stay Strong app's support for clients' in developing and learning the process of goal setting. Responses from clients included the following:

> *It got me thinking about goals, my goals.*
>
> *To know that you have got goals and that you can believe in making your goals; and just being yourself and believe.*
>
> *Working out a lot of my goals and things about myself that I didn't know.*

Responses from practitioners included the following:

> *I think it helps them gain an understanding of how to work through goals that probably never had that opportunity. Never had that experience so actually understanding the process and how to work through steps in a goal.*
>
> *That it is a very useful tool for building that rapport with the client and helping them identify their future goals and their strengths and weaknesses and their support systems.*
>
> *It's a cultural intervention tool used to establish, how do I say that? To establish, to help focus the kind of future goal settings and, and a, identify their support systems, strengths, weaknesses, future goals in a way that's not too invasive.*

Increased Client Self-insight

The Stay Strong app was recognized by both clients and practitioners as enhancing the development of client's self-insight and self-reflection. Responses from clients included the following:

> *So going through the app, it makes, it makes me realise that I've got a lot of good things about me and like I didn't even think of it, you know. And just going through it makes me realise that I do have some positive.*
>
> *I know how to think about things now before acting on it now, you know in positive ways.*
>
> *You can actually see my progress like on the tablet, which is pretty good. I spun out a bit.*
>
> *I think in the beginning, there's so much I didn't realise, how sad and how bad my mental health was...yeah. Very confronting.*

Responses from practitioners included the following:

> *It sort of draws their attention to thinking and reflecting on those aspects in their, in their lives.*
>
> *It is a very good reflective tool.*
>
> *It's helpful for people that are leaving prison to sort of revisit and understand what their risks are. So that hopefully when they are released and back in the community that they can continuously be aware of those.*

Improved Client Empowerment

There was agreement between clients and practitioners that the Stay Strong app represented a client-led and directed tool that enhanced clients' confidence, view of self, and empowerment. Responses from clients included the following:

> *You know, in the long run, with those little steps in between. That you get, you know, you feel like you're really proud of actually getting there.*
>
> *Knowing that I can actually do it. You know like because I always doubt myself.*
>
> *It helped me though, you know, it helped me through a couple of rough times.*

Responses from practitioners included the following:

> *It's definitely client focused, client based. It's their story. It's a chance for people to tell their story about, you know, the things that keep them strong, the things that take away their strength. It's a, it's a, it's an opportunity for people to start thinking about ways that they can, their path to recovery.*
>
> *It's client led, client driven.*
>
> *Really helpful for people who are needing to gain empowerment in their lives and get their lives back on track and understand more deeply what their strengths are, and what their worries are, and help them inform goals and form a plan.*

Cultural Appropriateness

Clients and practitioners alike identified the Stay Strong app as a culturally safe tool that supported clients. Responses from clients included the following:

> *Doing that Stay Strong Plan [referring to Stay Strong app] made me come out of my shell because I didn't think that I was a person, not just any person, but also identifying myself as Aboriginal.*
>
> *All of the support in bringing back the culture.*
>
> *Helped me identify doing something spiritual. So thinking of my spirituality. It's helping me try to connect even though it's not like outside connections in here [prison].*

Responses from practitioners included the following:

> *It's very culturally friendly. They, they are able to complete it fairly easily.*
>
> *This is an opportunity for the Aboriginal or Torres Strait Islander person, the First Nations person to identify their story, to identify and acknowledge the network that they have that does support them in their recovery and healing.*
>
> *So, this is really a document or a process that is, that gives an Aboriginal or Torres Strait Islander person an opportunity to use their own, their own ways and their own words in identifying what makes them strong. What takes away their strength and identifying their steps to recovery. What they need to do.*

Enhanced Engagement

Both clients and practitioners identified the Stay Strong app as engaging and supportive of rapport between clients and practitioners. Responses from clients included the following:

> *The visual, the visual thing, as opposed to, the before counselling things, like it's words, reports, it never, never got anywhere, it never hit home.*
>
> *It's more. You can relate to the pictures that to come up on it.*
>
> *It was fast, better than paper, you can talk.*

Responses from practitioners included the following:

> *When we spit out the cards and all that at the end of it and give it to the client, and they can see that, you know, that visual. We're very visual people.*
>
> *I think that the tool actually helps with rapport building and helps them focus on that stuff and breaks the ice a bit and actually helps you, you know, break down some of the walls.*
>
> *The focus of the app is to support that narrative approach, to support that talking space and that's really, really important or as we call it, the yarning space.*

Ease of Use

Both clients and practitioners voluntarily stated that the Stay Strong app was easy to use, with some saying that it was easier than the typical paper assessment and intervention processes. Responses from clients included the following:

> *It's a lot easier because again like up, working on paper would, I'll probably find it more difficult because not being able to read or write properly and probably get really frustrating, probably would have. I find it is a lot easier on the tablet.*
>
> *You don't have to fill out paperwork that I might not understand.*
>
> *Much easier to understand and to communicate my feelings.*

Responses from practitioners included the following:

> *Before the Androids, we were doing the paper-based, so which is not as cool as doing it on a touch screen, it's actually not. Yeah, some people, some of the clients didn't mind writing into the stay strong plans [referring to the paper-based version of the plan]. You know, they keep diaries and journals and things like that. But generally speaking, completing the Stay Strong Plan on an Android tablet is very user friendly.*
>
> *It's easy, you know, you know in a culturally appropriate way which is interactive.*
>
> *They like the design. It's really simple, easy, it's easy to use.*

Problems With Using Android Emulator

When the project moved from Android tablets to Windows-based tablets, it required the use of an Android emulator software program on the new devices. The emulator software allowed the app to run on a Windows-based device. A few problems were associated with the use of the emulator: interaction with the health agency computer system, lack of technical agency support for emulator use, and inclusion of additional steps to facilitate the download of client material. Feedback from both clients and practitioners supported the return to the earlier modes, with devices being matched to the app (Android app on Android tablet PC). Responses from clients included the following:

> *Losing all of the information.*
>
> *Saving and crashing.*

Responses from practitioners included the following:

> *The old ones we didn't have a problem with [referring to original Android tablets]. So simple. There was never an issue with them.*
>
> *Wouldn't need to log into that second tablet thing, emulator.*
>
> *It's written for an Android then maybe we could just get fast track it to using Androids. I think it will resolve a lot of issues with updates and things on that.*

Other Prominent Themes From Practitioner Interviews

Recommendations to Improve Personalization

Although no clients provided recommendations to improve personalization of avatars within the Stay Strong app,

practitioners recommended being able to alter the client's avatar, add pets to client's support network, and further change the clothing of all avatars. Only the custody version of the Stay Strong app uses an avatar to represent the client, as images of prisoners are not permitted owing to prison security requirements.

Responses from practitioners included the following:

> *Some of them, you know, they will have a giggle when they're clicking on the cartoon pictures to around, you know, their mum or sister. They like, you know, my brother here looks kind of like this. You know, it's, it's, it's, they enjoy that and it's quite...and it's personal. And they've chosen that themselves. But yeah, it would be cool to do the middle picture. And then they could choose their pet dog or cat or something like that. That would be kind of cool as well. Yeah. Yeah.*
>
> *I'd probably make it more interactive so they could actually, you know, pick the cap they put on the child's head or do the hairstyle, you know.*
>
> *I would love to see pets being added to, you know, the support, the support section. I think that would be really cool. Also, the ability to change the centre picture, but that might just be on my own.*

Responses to Unexpected Challenges

There were several challenges that were not apparent at the inception of the project. Limitations were placed on the type of devices the project could purchase through the health agency, which initially conflicted with the security requirements of the correctional system. There were costs associated with in-agency information technology support for devices and limitations placed upon initial devices' access to secure Wi-Fi, requiring practitioners to manually connect tablets to their workstation PCs to download outputs. Workplace health and safety requirements conflicted with secure storage requirements and charging of tablet PCs. There were issues with staff retention in the IMHIP service, which was seeking permanent funding at the time of the project.

As the project progressed, prison officials recognized the effectiveness of safeguards and protocols. Then, this allowed the IMHIP service to move from locked down Android tablets to Windows-based tablets that had access to the secure Queensland Health network within prison facilities. This change in device capability and access to secure networks via Wi-Fi allowed the new tablets to be used by practitioners as mobile workstations within and outside the prisons. Thus, although the restrictions for use remained the same for prisoners during appointments, practitioners' use of devices between sessions expanded, enhancing the administration efficiencies for staff. Although overall this was a positive outcome, there were issues in gaining ICT support for the app emulator software needed for continued use of the new Windows-based tablets.

Discussion

Principal Findings

To our knowledge, this paper describes the first project to successfully implement the use of digital mental health apps in prisons in Australia, with its use by the first client occurring in September 2015. The description and evaluation of this project through this paper provides an example to other jurisdictions that seek to implement digital mental health solutions within the prison environment; it also provides evidence of acceptance and engagement by First Nations prisoners with a culturally safe digital mental health app.

The Non-adoption, Abandonment, Scale-up, Spread, and Sustainability [54] domains provide a framework to understand and reflect on the implementation experience and participant feedback. Below, we use this framework to discuss challenges and successes and make recommendations for the long-term sustainability of the Stay Strong app in prison.

A long-identified consideration for successful implementation in the digital health domain is the relationship between users (clients, practitioners, and developers), technology (including design), and organizations or wider systems with their economic realities [54,55]. For this project, a shared vision was held by practitioners, management, research team, and agencies that focused on improving the mental health and well-being of Indigenous prisoners. Although the correctional agency and leadership within the forensic mental health service allowed for innovation in the adoption of the app at a service level, there was tension between this and the wider health agency support for technology change. The health district only supported iOS apps, and therefore, to overcome issues of software incompatibility, the Android emulator was used, which was itself problematic at times. Although the custody version of the app was developed without funding, further development in a hybrid format (for use on both iOS and Android devices) may offer a more stable and valued proposition for funders. With development of the new hybrid version of the app and precedents set in other health districts for use on Android devices, it is hoped that these issues are less likely to pose barriers to dissemination and upscaling, if the IMHIP service expanded. Thus, it is evident that development and implementation would have benefited from cross-disciplinary involvement being extended to ICT policy makers from the beginning of the project.

The new hybrid version of the app allows for greater flexibility in use. However, given the restrictions placed upon the use of technology within high-security prisons, there is still a need for a custody version. Therefore, without customization of the hybrid or iOS Stay Strong app, Android is the only operating system for which there is a custody version. Ultimately, the value of the app is defined by its clinical relevance to users—its health benefits and financial viability [56]. Although client and practitioner feedback confirmed that the Stay Strong app's design aims to promote client well-being, the financial investment needed to overcome the innovation-system conflict remains a hindrance to the sustained adoption in the Australian custodial environment.

Feedback through interviews revealed that the visual appeal, interactive interface, and ease of use supported clients' engagement. Although client engagement is the natural focus of app development, practitioner acceptance has been demonstrated to be the strongest determinant of health technology adoption [54]. Peer support for the appropriateness of the technology and credibility of the tool is key to practitioner acceptance [54,57]. This project has been an example of peer influence supporting sustained adoption of digital technologies through training (including the onboarding of new staff), acknowledgment of the tool's credibility by a national index of Australian evidence-based digital mental health resources [58]), support from the management and practitioners, and inclusion of the tool into the formal IMHIP service delivery model. Typical reasons for practitioners' resistance to new health technology include implementation requiring policy change, inefficiency of the technology, risk of compromised practice, and negative change to client relationships [54,59]. By ensuring that these key areas were addressed, the likelihood of sustained adoption of the app was increased.

To protect against the risk of compromised practice, the knowledge domain was another focus for sustained adoption. This domain extends beyond practitioners' and clients' direct knowledge of how to use the app. The broader knowledge required for its use involved understanding how best to facilitate its adoption. For the SSCP, and therefore IMHIP, this has required understanding of the app's use in clinical practice within a context involving both health and correctional agencies. This involved understanding the technical requirements of use and an ability to provide and receive clinical supervision. Deficits relating to an implementation facilitator's broader knowledge of the service, technical support, organizational readiness, and ability to provide ongoing supervision have been identified as reasons for poor adoption rates after training by other services [60,61]. In contrast, one of the most important driving factors for this project's sustained implementation has been the support and direction provided by its internal facilitators. The SSCP is an example of a project that involved continued training from developers, technical support from project software developers, supervision and project management by the principal researcher, and support in service delivery from the IMHIP service and forensic mental health service management. The benefit of implementing this digital mental health tool within a small developing service is the flexibility within the service delivery model to determine the most efficacious use and the support available from internal facilitators. The successful implementation and use of the app by IMHIP for >5 years at the time this paper was written demonstrates the feasibility of its use with Indigenous people in prison and, more broadly, the implementation of digital mental health tools within the prison environment. The app has evolved in use and content over this period. Both clients and practitioners value its functionality, engaging appeal, cultural appropriateness, and clinical value in goal setting, insight, and empowerment.

Limitations

The study used implementation and interview data only. To enhance sustained adoption by and value proposition for users and agencies, there is a need for additional research into the efficacy of the Stay Strong app with Indigenous people in prison. We hope to build toward this with the future publication of a pilot efficacy study.

The project was also limited to 3 sites covered by the IMHIP service; therefore, although the user population is representative of the broader Aboriginal and Torres Strait Islander population, the number of participants was limited. The fact that IMHIP itself was a temporary project at the time meant that the service periodically experienced high staff turnover and shortages. The periods of low staffing resulted in delays in intakes and follow-ups and in combination with the short periods of imprisonment for most IMHIP clients, reduced the overall number of participants who made it to their second follow-up before release. This ultimately limited the number of IMHIP clients who were able to be included in this evaluation. However, the sample size of clients who participated in this study is comparable with other qualitative studies assessing feasibility [62-64].

The other limitation to this sample was the relatively low proportion of men participating in the program and evaluation. The main reason for this was that the participants were recruited from 2 women's prisons and 1 men's prison. Therefore, our sample does not reflect the higher proportion of men than women in the prison population. Future research could examine barriers to and enablers for engagement in such a program from the perspective of gender.

Conclusions and Future Directions

The aim of this study is to determine the feasibility of the Stay Strong app as a digital well-being and mental health tool for use by Indigenous people in prison. The app was successfully implemented and it provided support, as expected, for client treatment and transition planning (transitioning from prison back into the community). It offered a culturally safe tool, delivering a match between the aims of the app and clients' needs.

Successful implementation of this digital mental health tool required the coordination of gatekeepers (management), users (practitioners and clients), and systems (agencies, environment, and technology). This innovative project demonstrated the meaningful, manageable, and sustainable adoption of digital mental health technologies into the high-security prison environment; it provides an example for other jurisdictions that are considering the implementation of digital mental health solutions for First Nations people in prison. The thematic synthesis of client and practitioner feedback on the Stay Strong app confirmed that it was culturally appropriate and helpful in developing clients' empowerment, self-insight, and goal setting. Users described the tool as easy to use, engaging, and supportive of client disclosure.

As discussed, previous community-based implementation studies of the Stay Strong app identified the complexity of digital mental health tools needing more than training, external follow-up, and external supervision [60]. Using the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability framework [54], this study identified additional factors, which supported

its implementation success. Key elements of the project's success were the match between the app and client needs, the benefits for users of app outputs, and having internal facilitators that drive the implementation and sustained adoption of the app.

Within the SSCP, the activity of supporting adoption of this app was a deliberate social process focusing on practice change through the support and training of practitioners, removal of barriers to implementation, provision of resources, monitoring of progress, and promotion of change [65]. Ultimately, the implementation steps that the project took to achieve this success provide a framework for other agencies and jurisdictions that want to implement either the app in prison or, more broadly, digital mental health tools within the prison environment. The project has demonstrated that the Stay Strong app and other digital mental health tools provide a novel and innovative opportunity for health and correctional agencies to bridge the divide in First Nations prisoners' mental health and well-being.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Comparison between community and custody versions of the Stay Strong app.
[DOCX File , 16 KB - formative_v6i4e32157_app1.docx]

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Abbreviations

ICT: information and communication technology
IMHIP: Indigenous Mental Health Intervention Program
SEWB: social and emotional well-being
SSCP: Stay Strong Custody Project

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Original Paper

A Veteran-Centric Web-Based Decision Aid for Lung Cancer Screening: Usability Analysis

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Abstract

Background: Web-based tools developed to facilitate a shared decision-making (SDM) process may facilitate the implementation of lung cancer screening (LCS), an evidence-based intervention to improve cancer outcomes. Veterans have specific risk factors and shared experiences that affect the benefits and potential harms of LCS and thus may value a veteran-centric LCS decision tool (LCSDecTool).

Objective: This study aims to conduct usability testing of an LCSDecTool designed for veterans receiving care at a Veteran Affairs medical center.

Methods: Usability testing of the LCSDecTool was conducted in a prototype version (phase 1) and a high-fidelity version (phase 2). A total of 18 veterans and 8 clinicians participated in phase 1, and 43 veterans participated in phase 2. Quantitative outcomes from the users included the System Usability Scale (SUS) and the End User Computing Satisfaction (EUCS) in phase 1 and the SUS, EUCS, and Patient Engagement scale in phase 2. Qualitative data were obtained from observations of user sessions and brief interviews. The results of phase 1 informed the modifications of the prototype for the high-fidelity version. Phase 2 usability testing took place in the context of a pilot hybrid type 1 effectiveness-implementation trial.

Results: In the phase 1 prototype usability testing, the mean SUS score (potential range: 0-100) was 81.90 (SD 9.80), corresponding to an excellent level of usability. The mean EUCS score (potential range: 1-5) was 4.30 (SD 0.71). In the phase 2 high-fidelity

usability testing, the mean SUS score was 65.76 (SD 15.23), corresponding to a good level of usability. The mean EUCS score was 3.91 (SD 0.95); and the mean Patient Engagement scale score (potential range 1 [low] to 5 [high]) was 4.62 (SD 0.67). The median time to completion in minutes was 13 (IQR 10-16). A thematic analysis of user statements documented during phase 2 high-fidelity usability testing identified the following themes: a low baseline level of awareness and knowledge about LCS increased after use of the LCSDecTool; users sought more detailed descriptions about the LCS process; the LCSDecTool was generally easy to use, but specific navigation challenges remained; some users noted difficulty understanding medical terms used in the LCSDecTool; and use of the tool evoked veterans' struggles with prior attempts at smoking cessation.

Conclusions: Our findings support the development and use of this eHealth technology in the primary care clinical setting as a way to engage veterans, inform them about a new cancer control screening test, and prepare them to participate in an SDM discussion with their provider.

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KEYWORDS

lung cancer screening; decision aid; usability; implementation; cancer screening; shared decision-making; veterans; patient engagement; mobile phone

Introduction

Background

Shared decision-making (SDM) is a valuable and, in some settings, mandated approach to helping patients make informed and value-aligned decisions in medical care. SDM is especially useful in decisions of equipoise when the benefits of intervention do not clearly outweigh the harms and when the value patients assign to these attributes vary [1,2]. Lung cancer screening (LCS) is an evidence-based intervention that meets these criteria [3,4]. However, despite expert guidelines dating from 2014 that recommend LCS for eligible persons [5], LCS uptake and adherence to follow-up protocols have remained low [6]. A number of SDM tools for LCS have been developed [7-10]; however, the implementation of SDM in practice has been limited [11], and the uptake of LCS remains low [12]. A participatory design approach, including patient end users such as US veterans, may increase the uptake of SDM tools and support value-aligned decisions regarding LCS. A user-centered design of SDM interventions guided by usability metrics is required to advance the integration of web-based SDM tools into clinical practice [13].

LCS with low-dose computed tomography has proven effective in decreasing lung cancer mortality in two large randomized controlled trials: the National Lung Screening Trial in the United States [4] and, more recently, the Dutch–Belgian LCS trial [3]. The trials reported a decrease of 20% and 25% in lung cancer mortality among those screened compared with control populations for the United States and Belgian studies, respectively. However, clinical trials also reported harms, including false positive tests, significant incidental findings, and an excess incidence of lung cancer cases indicative of overdiagnosis. False positive tests require follow-up imaging and, in some cases, invasive diagnostic procedures that can cause harm. False positive rates vary across trials and decrease in the later years of screening. The National Lung Screening Trial reported false positive rates of 26.3 %, 27.2 %, and 15.9% at baseline, year 1, and year 2, respectively. The Dutch–Belgian trial reported false positive rates of 19.8 %, 7.1 %, and 9.0% at baseline, year 1, and year 3, respectively [14].

Decision aids (DAs) are structured tools that include a description of decision options, evidence-based benefits and harms associated with each option, a value clarification exercise, and support for a SDM conversation with one's health care provider [15]. In systematic reviews, DAs have been found to improve the quality of decision-making with respect to the outcomes of knowledge, preparation for decision-making, and value-aligned decisions [16]. However, the implementation of DAs has been limited. A primary barrier has been their integration into the flow of clinical practice [17-19].

Objectives

Veterans of the United States military are at a higher risk of developing lung cancer than the general population because of older age, higher rates of smoking, and environmental exposures [20]. Veterans are also at higher risk for mental health conditions, including anxiety and posttraumatic stress disorder (PTSD), which increase the burden of LCS, thus affecting the balance of benefits and potential harm from LCS [20]. To address these challenges, we used a user-centered design to develop a veteran-centric LCS decision tool (LCSDecTool) for use in a primary care setting. This tool was designed to be used independently by the patient before the clinic visit (either at home or in the waiting room) with the option of sharing some components with the clinician during the clinic visit. In this study, we report an iterative process of usability testing of a prototype tool and a revised high-fidelity version, with the latter conducted as part of a hybrid type 1 effectiveness-implementation trial. Usability assessment is a key component in the development of web-based decision support tools. Common methods used in usability testing include observation, cognitive interviews, and self-reported feasibility and usability with validated scales [21]. We seek to determine whether veterans find the tool useful to use in the context of a clinical visit and elucidate key aspects of the user experience that had an impact on usability.

Methods

Description of the LCSDecTool

We developed the LCSDecTool using the Promoting Action on Research Implementation in Health Services (PARiHS)

implementation framework. The PARiHS framework includes the domains of evidence (scientific evidence supporting intervention efficacy), context (the setting in which the intervention is delivered), and facilitation (training and support needed to deliver the intervention) [22,23]. Systematic reviews have established the efficacy of decision aids in improving the process of medical decision-making, as indicated by an increase in knowledge, perceptions of being informed, accuracy of risk perceptions, and clarity about values [24]. We were guided by criteria from the PARiHS framework in the tool design and usability testing for the prototype and high-fidelity LCSDecTool, both of which were evaluated among eligible veterans receiving primary care in Veteran Affairs (VA) Medical Centers and later in the context of a clinical visit. Both focused on the support needed by veterans to access and navigate the tool. The development and usability assessment were also informed by the Technology Acceptance Model (TAM) [25,26]. The TAM posits that people need to perceive the technology as useful and easy to use to continue using it. This model supported our choice of the quantitative outcome measures of the System Usability Scale (SUS) and the End User Computing Satisfaction (EUCS) measure, which include questions in these domains [27-29].

Stakeholder focus groups (clinicians) and structured interviews (veterans) further informed the content and features of the prototype LCSDecTool [30]. The LCSDecTool was designed to (1) use in advance of or during a primary care clinical visit where LCS may be initiated, (2) ensure that veterans understand the key benefits and potential harms of LCS, (3) help veterans weigh the benefits and potential harms of LCS, (4) provide resources for smoking cessation and mental health treatment, (5) support communication with their provider regarding this decision, and (6) include a clinician portal to streamline the use of the tool with a clinician in the clinical setting. The tool was designed for the primary platform of a tablet but has compatibility with a computer or mobile phone. The stakeholder inputs that informed these goals are summarized in Table 1. The data collection form with illustrations from the prototype version of the LCSDecTool is available in the supplemental materials (Multimedia Appendix 1).

Table 1. Feedback from veteran and clinician stakeholders to support the design of the lung cancer screening shared decision-making tool.

Features and content and description	Supportive data from stakeholder interviews	
	Veterans (n=32)	Clinicians (n=9)
Computer based		
Accessed by a URL link on devices: tablet, desktop, laptop, and smartphone	• 12 (38%) recommended the lung cancer screening shared decision-making tool be computer based; some wanted paper instead of digital	• 6 (67%) supported a web-based module • 5 (56%) supported a phone app • 4 (44%) supported an app for a tablet
Overview of LCS[a]: simulated discussion between patient and provider		
Simulated dialog with questions and answers about LCS	• 8 (25%) recommend a web-based tool that is engaging and interactive to hold attention; one suggested that they could ask a question, and it would be answered back	• Only 2 (22%) indicated they thought patients were knowledgeable about LCS
Overview of LCS: clickable knowledge boxes		
6 knowledge boxes, each covering a key LCS content area; must click on all boxes before advancing to the tool	• 17 (53%) recommended a simple user-friendly website, suggested simple words, examples, and graphs; break knowledge down into topic categories, and have limited words on each page	• Only 2 (22%) indicated they thought patients were knowledgeable about LCS
Evidence-based outcomes: pictograph		
Main outcomes from the National Lung Screening Trial displayed in pictograph: lung cancer deaths and deaths averted, false positives, biopsies, and complications	• 17 (53%) commented they wanted understandable graphics • 10 (31%) commented they wanted updates in research	• 4 (44%) wanted graphical representation of risks and benefits
Value elicitation—rating scale 1 and rating scale 2 and Cancer Screening Attitudes Rating Scale		
Ratings to indicate value attributed to LDCT[b] attributes; high-fidelity version used rating scale 2	• Qualitative analysis of 23 (72%) veteran interviews indicates wide variation in how LCS attributes are valued and that attitude and beliefs about LCS may affect value ratings [30]	• 4 (44%) noted that LCS is not a priority for veterans compared with their other concerns
Veteran-centric content—smoking cessation and mental health		
VA[c] resources highlighted with an option to request consultation	• 12 (38%) wanted to include smoking cessation options in the tool • 19 (59%) indicated that LCS might increase their anxiety or worry	• 6 (67%) wanted to use LCS discussions to promote smoking cessation • 4 (44%) noted that LCS might increase patient anxiety and worry about having cancer
Enter questions for the provider		
Free text option; questions inserted on the summary sheet	• 8 (25%) stated that they wanted the tool to be engaging and interactive	—[d]
Summary page		
Includes ratings of values and attitudes; ability to print, save, or email page	• 10 (31%) veterans stated the tool should prepare them for a discussion about LCS with their provider	—
Clinician portal		
Link from entry page to features for use at the point of care: pictograph, value and attitude assessment, and summary page	—	• 5 (56%) noted they did not have time to participate in shared decision-making about LCS. • Clinicians indicated that the tool must be short and easy to use in the clinical setting.

[a]LCS: lung cancer screening.

[b]LDCT: low-dose computed tomography.

[c]VA: Veteran Affairs.

[d]Data not available.

Approach to Usability Testing

We used both quantitative and qualitative methods for usability testing. The SUS and the EUCS scales have been widely used and well-validated to assess interventions in the domains of ease of use and usefulness [28,29,31-36]. The SUS is a 10-item scale developed for the assessment of a broad range of products; scores (ranging from 0=low usability to 100=high usability) correspond to the following adjective descriptors: worst imaginable, awful, poor, okay, good, excellent, and best imaginable [27,37]. The EUCS scale is a 12-item scale that captures the domains of content, accuracy, format, ease of use, and timeliness relevant to a computer application. Scores range from 1=low satisfaction to 5=high satisfaction [28,29]. The Patient Engagement (PE) scale has been used to assess engagement in web-based programs in the medical setting [38,39]. The PE scale assesses engagement in the domains of caring for one's health, concerns addressed about LCS, understanding LCS guidelines, and understanding information about LCS. Scores on the PE scale range from 1=low engagement to 5=high engagement.

To better interpret the results of the quantitative measures, we used qualitative approaches, including observations of the testing sessions and brief interviews at the completion of the testing sessions. These qualitative approaches have been applied in usability testing to identify barriers to the effective navigation of tools and processing of information [40,41]. The research assistants (RAs) who obtained the qualitative data underwent formal training in qualitative interviewing before the study. This process included 8 hours of training in qualitative methods in the Mixed Methods Research Lab at the University of Pennsylvania for our senior RAs (JP: Bachelors of Science with Major in Biology; JI: Bachelor of Science with a major in Neuroscience). Our junior RA was trained by the senior RAs on the observation of interviews and feedback (JM: Bachelor of Arts with a major in Psychology).

Phase 1 Prototype Usability Testing

Phase 1 Study Participants and Recruitment

Veterans were eligible if they were aged 55 to 80 years, had a 30 pack-year history of cigarette smoking, and continued smoking sometime within the past 15 years. The exclusion criteria were cognitive impairment; a life expectancy of <2 years, as determined by their primary care provider; and having received LCS within the past 18 months. The participating sites were the Michael J Crescenz VA Medical Center in Philadelphia, Pennsylvania, and the West Haven VA Medical Center in West Haven, Connecticut.

We used the Corporate Data Warehouse to identify eligible veterans based on age, an algorithm of indication of tobacco use based on primary care visits and dental visit structured fields in the computer record, and pharmacy records of the use of smoking cessation medications, as well as having an upcoming primary care appointment. We sent recruitment letters with follow-up phone calls to confirm eligibility. Veterans who were interested were then scheduled for a study visit. Recruitment for the phase 1 protocol study occurred between August 2018 and January 2019. A voucher for US $50 was offered to compensate the participants for their time. The recruitment goal for veterans was 16 from each site (total of 32)—a sample size that has been validated in the literature for usability testing [42,43].

Phase 1 Prototype Usability Testing Procedures

Following informed consent and the completion of a baseline survey to assess demographic information, participants were individually seated in a room with an RA. Participants were provided with a tablet device to use the LCSDecTool. The session was audio recorded and transcribed. Following the use of each section of the tool (Table 2), the RA asked the participants to describe their user experience. The RA documented field notes during the session to highlight responses to specific sections. At the completion of the tool, the participants completed the SUS and EUCS scales [27,29].

Table 2. Qualitative feedback in phase 1 prototype usability testing.

Features and content of the LCSDecTool[a]	Feedback from phase 1 prototype testing	
	Veterans	Clinicians
Computer based		
Accessed by a URL link on devices: tablet, desktop, laptop, and smartphone	• Users varied in preferred device: tablet, laptop, phone	—[b]
Overview of LCS[c]: simulated discussion between patient and provider		
Simulated dialog with questions and answers about LCS	• Users found this engaging • Most recognized that it was a physician and patient discussion and found this engaging • The scrolling function was intuitive to most • Recognized the format as similar to texting • Easy to navigate • One did not realize it was a physician–patient discussion	• Consider adding audio • Clarify who is speaking • Dialog seems natural • Shorten • Define CT[d] scan • Change *Nodule* to *Spot* • Liked clarification that a false positive is not a mistake • Change *Doctor* to *Provider* • Indicate most nodules are small
Overview of LCS: clickable knowledge boxes		
6 knowledge boxes, each covering a key LCS content area; one must click on all boxes before advancing to the tool	• Most found this to be more informative and easier to navigate than simulated dialog • Some noted that the repetition of some content in this format reinforced the information that was being conveyed • The pictures on each box were engaging	• Add a box for *what is a CT scan?* • Navigation may be confusing • Symbols would be better than pictures • Be careful about using relative risk reduction for mortality benefit • Consider the pictorial representation of statistics • Add a box for *what happens if my scan is abnormal?* • Agree with bringing up annual screening; include that interval cancers may occur
Pictograph		
Main outcomes from the National Lung Screening Trial displayed in pictograph: lung cancer deaths and deaths averted, false positives, biopsies, and complications	• Users (except for 1) understood that the 2 side-by-side pictographs were comparing outcomes between screened and not screened populations • Understood dots to represent people and colored dots to represent outcomes • Some needed to be guided through the pictograph to understand	• Good color contrast • Would use with patients • Helpful visual aid • Describe a major complication • Clarify screened and unscreened groups
Value elicitation—rating scale 1 and rating scale 2		
Rating scale 1 response scale: much less likely to much more likely to want screening; rating scale 2 response scale: not at all concerned to extremely concerned	• For most users, rating scale 2 was easier to use and demonstrated greater variation in ratings among benefits and potential harms of screening. • One user found rating scale 1 to be more relevant and helpful in evaluating these attributes	• Less user friendly than the attitudes section • Shorten • Explain that answers go to the summary page • Lacks assessment of cost • Prefers scale 2 • Carry over stem to each question
Cancer screening attitudes—rating scale		
An assessment of general cancer screening attitudes and beliefs	• Questions were intuitive and easy to answer	• Reads well • Clarify what *repeat testing* means • Clarify why these questions were asked
Veteran-centric content—smoking cessation and mental health		

Features and content of the LCSDecTool[a]	Feedback from phase 1 prototype testing	
	Veterans	Clinicians
VA[e] resources highlighted with the option to request a consultation	• Most acknowledged that these were important, and some clicked boxes to request consultations. • One user cautioned that raising the issue of anxiety may discourage a veteran from LCS	• Provide phone numbers in a handout • Note that the risk of lung cancer decreases after smoking cessation • Change the description to *mental health or behavioral health provider* • It is important to include smoking cessation to emphasize benefit, even with LCS • State that smoking cessation is more effective than LCS in preventing lung cancer deaths • Loved mental health access • Include information specific to veterans • Integrates well with the tool
Enter questions for the provider		
Free text option; questions inserted on the summary sheet	• Users all supported this feature	—[b]
Summary page		
Includes ratings of values or attitudes; able to print, save, or email page	• Users all supported this feature	• Clarify where the email goes • Simplify and shorten • Title value responses with “Why I want screening” • Clarify that it goes to the provider • Improve that format of presenting scale results; use color coding • Give suggestions to providers about how to address concerns; goal to distinguish beliefs from misunderstandings • Like how it looks; will be helpful to providers
Clinician portal		
Link from entry page to features for use at the point of care: pictograph and value and attitude assessment	—	• Name *Clinician* or *Provider* rather than *Physician* portal • Add picture with active link to the portal • Make more accessible to the clinician • Use term save *document* versus *PDF* • Like that the provider has quick access to patient summary

[a]LCSDecTool: lung cancer screening decision tool.

[b]No information emerged for this feature.

[c]LCS: lung cancer screening.

[d]CT: computed tomography.

[e]VA: Veteran Affairs.

Phase 1 Prototype Analytic Plan

Quantitative Analysis

Descriptive statistics were used to summarize the following outcomes: (1) time in minutes for completion of the tool, (2) participant characteristics, and (3) scores on the SUS and EUCS scales. Participant characteristics included sex, race, ethnicity, age, and education level.

Qualitative Analysis

Members of the research team (MS, JP, and JM) reviewed the transcripts of the user sessions with veterans and the field notes documented by the RAs from provider interviews. Comments were summarized for each section of the LCSDecTool to indicate feedback from veteran users and clinicians regarding the features and content of the LCSDecTool (Table 2).

Phase 2 High-Fidelity Usability Testing

Phase 2 Study Participants and Recruitment

Usability testing of the high-fidelity version was conducted as part of a pilot type 1 hybrid effectiveness-implementation trial that compared the LCSDecTool with a control web-based intervention providing general education about cancer screening. The participating sites were the Michael J Crescenz VA Medical Center in Philadelphia, Pennsylvania, and the West Haven VA Medical Center in West Haven, Connecticut. Eligibility criteria

for veteran participants were identical to the phase 1 prototype usability testing protocol with the following exceptions: (1) the additional exclusion criteria of a prior diagnosis of cancer (except for stable prostate cancer or nonmelanomatous skin cancer) and (2) the additional inclusion criteria that the veterans' primary care provider consent to participate in the study. Recruitment for the phase 2 high-fidelity usability study occurred between March 2019 and February 2020. Participants received a US $50 voucher for the baseline visit, which included usability testing.

Phase 2 High-Fidelity Usability Testing Procedures

Following informed consent and the completion of a baseline survey, participants were given a tablet that was open to the first page of the LCSDecTool. Participants were instructed to navigate the tool on their own. The RA observed the session, took field notes to document observed difficulties in navigation, and answered the participants' questions during the usability session. The time from when the participant started to interact with the tool until the summary page was reached (ending the session) was documented by the RA.

Upon completion of the use of the tool, the RA conducted a brief interview with the participant, which included the following questions:

1. What were your general impressions of the LCSDecTool?
2. Did you have any trouble using the tool, and if so, describe (if the RA had noticed any issues in navigating the tool that were not mentioned, they would prompt by adding "I noticed you had trouble with...")?
3. Do you have suggestions for improvements?
4. On the page that has boxes with knowledge content, do you think that it should be required to click on every box to move forward?
5. Did you find the tool repetitive in any way?

When the user responded affirmatively, follow-up questions were asked so that the patient could further elucidate.

Upon the completion of the usability testing session, participants proceeded to their scheduled primary care appointments. A postclinic survey was completed directly after the primary care appointment. The postclinic visit survey included the SUS, EUCS, and PE scales. The study was approved by the institutional review boards of the participating sites.

Phase 2 High-Fidelity Analytic Plan

Phase 2 Quantitative Analysis

Descriptive statistics were used to summarize participant characteristics, including sex, race, ethnicity, age, annual household income, and comorbidity. Descriptive statistics were used to summarize the responses to the SUS, EUCS, and PE scales.

Phase 2 Qualitative Analysis

We used a thematic analysis to analyze the qualitative data from the following sources: (1) notes taken by the RA while observing usability testing and (2) documented responses to the brief interview that followed the user session. Thematic analysis is an approach for identifying, analyzing, and reporting themes or patterns within a set of data using standard methods for qualitative research [44]. We used an inductive approach to identify themes pertaining to the user experience with the tool. A total of 2 members of the study team (JP and JM) initially reviewed the data and created an initial coding scheme. The data and codes were reviewed and finalized with input from additional members of the study team (MS and DK). Final coding was conducted by 2 independent coders, with differences resolved by consensus.

Ethics Approval and Informed Consent

The study was approved by the institutional review board of the participating sites. Participants provided informed consent to complete the baseline survey in phase 1, and the clinicians of participating veterans signed informed consent forms in phase 2 at the time of enrollment in the study. IRB approval obtained from the Michael J Crescenz VA Medical Center, Philadelphia VA (IRB# 01635, IRB #01721, IRB#01780) and the VA Connecticut Healthcare System (MIRB# 02071, MIRB#02240).

Results

Phase 1 Prototype Usability Testing

Phase 1 Study Participants

A total of 70 recruitment letters were mailed to the Philadelphia VA Medical Center. Of the 70 veterans, 12 (17%) had confirmed eligibility by phone interviews and were enrolled in the study. A total of 101 letters were mailed to the West Haven VA Medical Center. Of these 101 veterans, 6 (5.9%) were confirmed to be eligible and were enrolled in the study. Of the 18 participants, 15 (83%) were male, 8 (44%) were African American, and 15 (83%) had up to a high school–level education. Additional participant characteristics are presented in Table 3.

Table 3. Description of study populations.

Participant characteristic	Prototype cohort[a] (n=18)	High-fidelity cohort (n=43)
Sex, n (%)		
Male	15 (83)	39 (91)
Female	3 (17)	4 (9)
Race, n (%)		
African American or Black	8 (44)	27 (63)
Asian	—[b]	—
Hawaiian native or Pacific Islander	—	—
Native American or Alaska Native	—	—
White	8 (44)	15 (35)
Other	1 (6)[c]	—
Unknown	2 (11)	1 (2)
Ethnicity, n (%)		
Hispanic	2 (11)	1 (2)
Non-Hispanic	16 (89)	42 (98)
Age (years), mean (SD)	64.7 (5.0)	64.5 (4.7)
Education, n (%)		
Grade school	1 (6)	3 (7)
Up to grade school	6 (33)	17 (40)
High school or GED[d]	8 (44)	21 (49)
Some college or university	3 (17)	1 (2)
≥4 years of college	—[e]	1 (2)
Annual household income (US $), n (%)		
0 to 25,000	—[a]	21 (49)
>25,000 to 50,000	—[a]	12 (28)
>50,000 to 75,000	—[a]	5 (12)
>75,000 to 100,000	—[a]	1 (2)
>100,000	—[a]	2 (5)
Prefer not to answer	—[a]	2 (5)
Comorbidity, n (%)		
Posttraumatic stress disorder	—[a]	20 (47)
Depression	—[a]	17 (40)
Arthritis	—[a]	17 (40)
Asthma	—[a]	17 (40)
Hypertension	—[a]	15 (35)
Anxiety	—[a]	12 (28)
Diabetes	—[a]	11 (26)
Emphysema	—[a]	8 (19)
Heart disease	—[a]	4 (9)

Participant characteristic	Prototype cohort[a] (n=18)	High-fidelity cohort (n=43)
Other	—[a]	4 (9)

[a]The prototype cohort did not have an assessment of income or comorbidity.

[b]There were no self-reports of race in these categories.

[c]One participant selected *Other* and *White*.

[d]GED: General Educational Development.

[e]No self-reports of education in this category.

Phase 1 Prototype Quantitative Results

In the phase 1 prototype usability testing, the mean of the SUS score (potential range: 0-100) was 81.90 (SD 9.80), corresponding to an excellent level of usability. The mean of the EUCS score (potential range 1-5) was 4.30 (SD 0.71; Table 4).

Table 4. Quantitative outcomes for phase 1 prototype and phase 2 high-fidelity usability.

Categorization	Prototype cohort (n=18), mean (SD)	High-fidelity cohort (n=43), mean (SD)
SUS[a,b]: total (0-100); individual items (0-10)		
Total	81.90 (9.80)	65.76 (15.23)
I think I would like to use this tool frequently.	7.64 (2.18)	7.09 (2.11)
I found the tool unnecessarily complex.	8.75 (2.46)	7.09 (2.11)
I thought the tool was easy to use.	8.47 (152)	6.40 (2.45)
I think that I would need the support of a technical person to be able to use this tool.	8.06 (2.79)	7.03 (2.33)
I found the various functions in this tool were well integrated.	8.75 (1.29)	6.91 (2.17)
I thought there was too much inconsistency in this tool.	8.75 (1.96)	6.57 (2.25)
I would imagine that most people would learn to use this tool very quickly.	7.92 (2.46)	7.26 (1.79)
I found this tool very cumbersome to use.	7.92 (3.12)	6.22 (2.52)
I felt very confident using the tool.	8.47 (1.94)	7.44 (1.87)
I needed to learn a lot of things before I could get going with this tool.	7.22 (3.31)	5.11 (2.67)
EUCS[c,d] measure (score 1-5)		
Total	4.30 (0.71)	3.91 (0.95)
EUCS content subscale	4.25 (0.90)	3.81 (0.93)
Does the web tool provide the precise information you need?	4.17 (0.99)	3.81 (1.11)
Does the web tool information content meet your needs?	4.28 (0.89)	3.74 (1.03)
Does the web tool provide help that seemed to be just about exactly what you need?	4.22 (01.17)	3.67 (1.06)
Did the web tool provide sufficient information?	4.33 (0.84)	4.02 (1.01)
EUCS accuracy subscale	4.25 (0.83)	3.87 (1.10)
Was the web tool accurate?	4.22 (0.88)	3.86 (1.10)
Were you satisfied with the accuracy of the web tool?	4.28 (0.89)	4.05 (0.95)
EUCS format subscale	4.28 (0.69)	3.97 (1.00)
Did you think the web tool information is presented in a useful manner?	4.28 (1.02)	4.05 (0.95)
Was the web tool information clear?	4.28 (0.83)	4.05 (1.05)
EUCS ease of use subscale	4.53 (0.70)	4.0 (1.02)
Was the web tool user friendly?	4.5 (0.86)	4.05 (0.10)
Was the web tool easy to use?	4.56 (0.62)	3.95 (1.13)
EUCS timeliness subscale	4.25 (0.83)	3.88 (1.06)
Did you get the web tool information you needed quickly?	4.28 (0.96)	3.86 (1.08)
Did the web tool provide up-to-date information?	4.22 (0.88)	3.91 (1.11)
PE[e,f] tool (score 1-5)		
Total score	—[g]	4.12 (0.67)
How well did the tool support you in caring for your health?	—	4.00 (0.70)
How well were your concerns about lung cancer screening addressed?	—	4.27 (0.77)
How well did you understand the guidelines for lung cancer screening?	—	4.12 (0.76)
How well did you understand the information provided about lung cancer screening?	—	4.14 (0.83)

[a]SUS: System Usability Scale.

[b]The SUS is a 10-item Likert scale with individual item scores ranging from 0 (low usability) to 10 (high usability) and a total score ranging from 0 to 100.

[c]EUCS: End User Computing Satisfaction.

[d]The EUCS is a 12-item scale measuring domains of content, accuracy, format, ease of use, and timeliness.

[e]PE: Patient Engagement.

[f]The PE scale includes four items assessing whether the tool (1) supports users in caring for their health, (2) addresses health concerns, (3) informs users about lung cancer screening guidelines, and (4) informs users about lung cancer screening. Scores on the PE scale range from 1 (low engagement) to 5 (high engagement).

[g]Patient Engagement was not assessed on the prototype cohort.

Phase 1 Prototype Qualitative Results

The veterans' and clinicians' qualitative feedback for the prototype testing are summarized in Table 2. Key feedback received from veterans included the following: (1) the dialog feature was engaging; (2) the knowledge boxes were an effective way of presenting information and reinforcing content introduced in the dialog feature; (3) the pictograph effectively conveyed a comparison of outcomes among screened versus nonscreened groups; (4) the value elicitation questions using a response scale measuring level of concern regarding potential harms were more intuitive to most than the response scale assessing if the attribute made it more or less likely for the veteran to have LCS; and (5) there was enthusiasm among users about the interactive features, including a text box and summary sheet to ask questions and share questions, values, and preferences with their provider. Clinician feedback included recommendations for simplifying the terminology used and enthusiasm for the pictograph as a visual aid to support provider–patient communication about LCS.

Modifications Made in the High-Fidelity Version

Results of the phase 1 testing informed changes made to the prototype in the development of the high-fidelity version, including the following: (1) use of a color scheme aligned with the US Department of Veterans Affairs branding, (2) replacement of stock graphics with icons and symbols, (3) use of directions and well-placed buttons to improve self-navigation, (4) a more prominent link from the entry page to the clinician portal, (5) simplified text and definitions, (6) single value clarification exercise, and (7) improved graphics and format of summary page to increase the visual impact and clarity. A link to the LCSDecTool is found in Multimedia Appendix 2. The dialog, knowledge box, pictograph, and value elicitation features are illustrated in Figures 1-4.

Figure 1. Illustration of the dialog feature in the lung cancer screening decision tool (LCSDecTool).

Figure 2. Illustration of the pictograph feature in the lung cancer screening decision tool (LCSDecTool). CT: computed tomography.

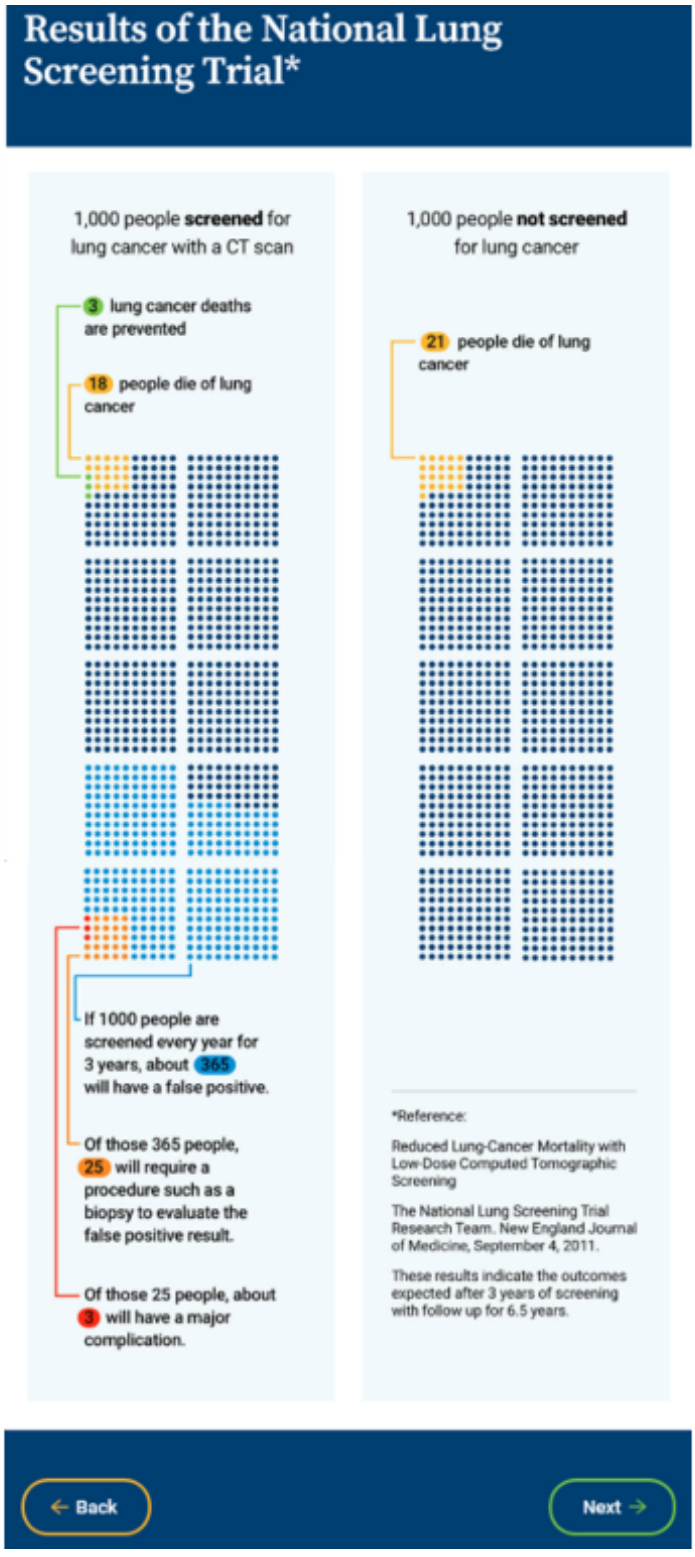
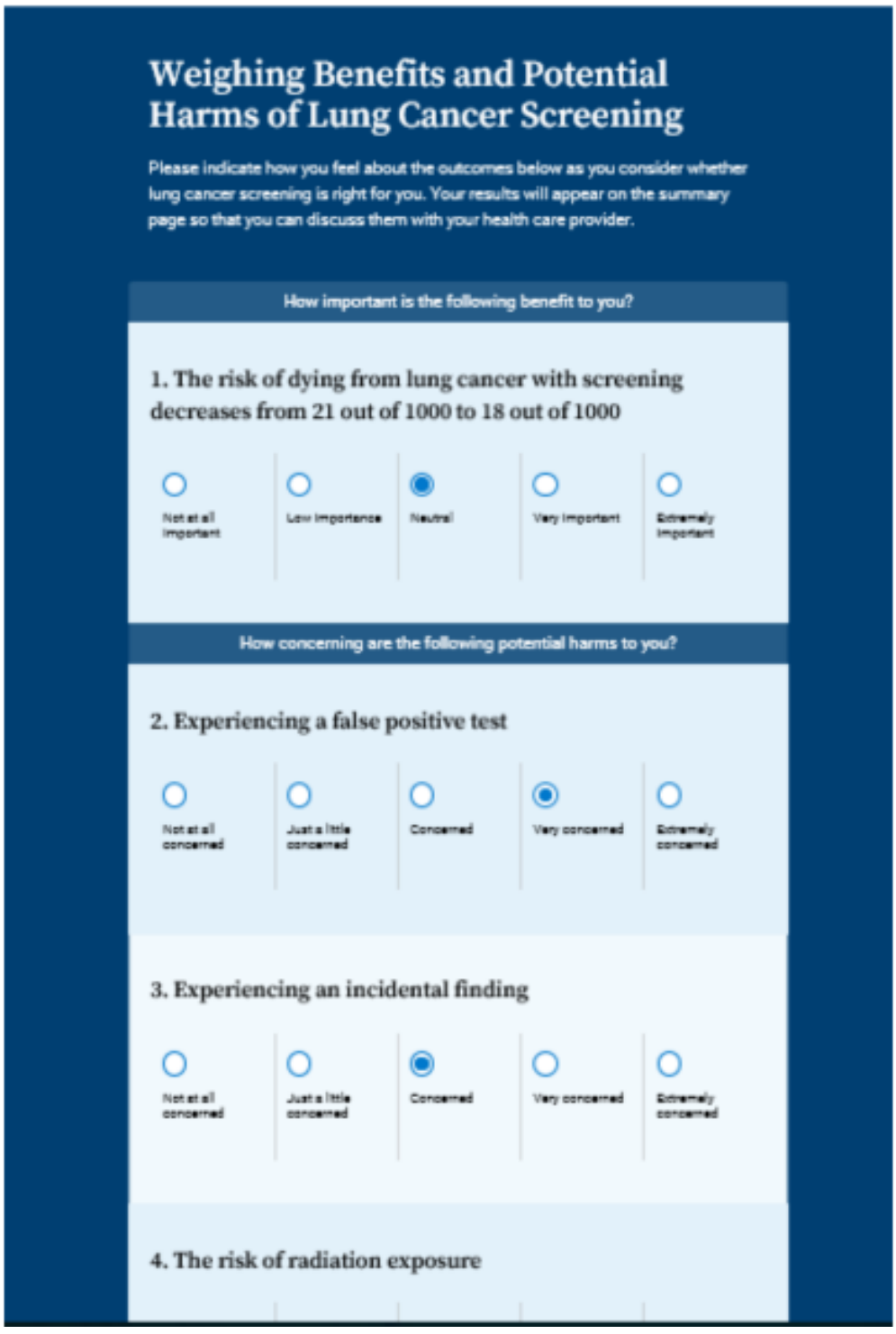


Figure 3. Illustration of the knowledge box feature in the lung cancer screening decision tool (LCSDecTool).

Figure 4. Illustration of the value elicitation feature of the lung cancer screening decision tool (LCSDecTool).



Phase 2 High-Fidelity Testing

Phase 2 Study Participants

At the Philadelphia VA Medical Center, 465 recruitment letters were sent. Of these 465 persons, 376 (80.9%) were reached by phone, and 281 (60.4%) were confirmed to be eligible for the study. Of the 281 eligible persons, 80 (28.5%) were enrolled in the study, with 42 (53%) in the experimental arm and participating in the usability analysis. At the West Haven VA Medical Center, 136 letters were sent. Of these 136 individuals, 96 (70.6%) were reached by phone and found to be eligible for the study. Of the 96 eligible persons, 5 (5%) were enrolled in the study, with 1 (20%) in the experimental arm and participating in the usability analysis. Of the 43 participants, 27 (63%) were African American or Black, 39 (91%) were male, and 41 (95%) had up to a high school–level education. Additional demographic details are presented in Table 2.

Phase 2 High-Fidelity Quantitative Results

In the phase 2 high-fidelity usability testing, the mean SUS score was 65.76 (SD 15.23), corresponding to a good level of usability. The mean of the EUCS score (potential range 1-5) was 3.91 (SD 0.95). The mean PE score (potential range 1-5) was 4.12 (SD 0.67; Table 3). The median time to completion in minutes was 13 (IQR 7-30; Table 4).

Phase 2 High-Fidelity Qualitative Results

A total of five themes related to usability emerged from the qualitative analysis of the field note–documented observations and responses to the short interview. These themes were as follows: (1) a low baseline level of awareness and knowledge about LCS increased after using the LCSDecTool; (2) users sought more detailed descriptions about the LCS process; (3) the LCSDecTool was generally easy to use, but specific navigation challenges remained; (4) some noted difficulty understanding medical terms used in the LCSDecTool; and (5) the LCSDecTool evoked veteran struggles with prior attempts at smoking cessation (Textbox 1).

Textbox 1. Qualitative feedback from phase 2: high-fidelity usability testing.

Qualitative feedback from phase 2

Thematic analysis

- Theme 1: low baseline awareness and knowledge about lung cancer screening (LCS) that increased after use of the LCS decision support tool (LCSDecTool)
- Theme 2: users sought more detailed descriptions about the LCS process
- Theme 3: the LCSDecTool was generally easy to use; however, specific navigation challenges remained
- Theme 4: some noted difficulty understanding medical terms used in the LCSDecTool
- Theme 5: the LCSDecTool evoked veteran struggles with prior efforts at smoking cessation

Navigation challenges

- Scrolling for physician–patient dialog (n=15)
- Advancing through knowledge boxes (n=10)

Negative affective responses of using the tool

- Worry about cancer risk
- Reading about the harms are scary
- Difficulty of smoking cessation

Genuineness of tool

- Dialog seemed scripted (n=1)

Ease of understanding

- Needed help to understand pictograph (n=1)

Veteran-specific features

- Resources for smoking cessation: some veterans were already familiar with the resources
- Mental health consultation: comment that a mention of anxiety related to LCS would discourage veterans from ever having LCS (n=1)

Theme 1 indicates a need for more information about LCS among this population. A participant stated that they “learned a lot and didn’t know much about LCS and lung cancer before using the tool.” Another stated that they “didn’t know that the VA even had a screening test.” This feedback supports our finding of high PE scores in the quantitative testing. Theme 2 reflects the desire for more information about the LCS process, with one of the participants asking, “What actually is a CT scan?” and another questioning, “if it is painful?” This theme indicates what information could be added to the tool to increase the content domain of the EUCS measure. Theme 3 indicates that the tool was generally easy to use; however, navigation was challenging for some of the features. For example, a participant described the tool as “helpful, with a lot of information, easy to use.” However, specific navigation problems were identified. A participant indicated that they “did not know how to scroll through the Dialogue,” and an RA observed and commented that another user was “stuck on Box page until I told him he had to click on the boxes.” Some participants had difficulty using the radio buttons on the value elicitation feature. Theme 4 indicates that some users struggled to understand the medical terminology. A participant stated that “some wording can get you twisted up” and provided feedback to “keep it simple and use plain language.” For example, the meaning of the words “nodule,” “CT Scan,” and

"Overdiagnosis" were not understood by some users. This theme is relevant for interpreting the SUS scores in the format domain.

Theme 5 indicates that the tool evokes veterans' struggles with prior attempts at smoking cessation. One of the specific veteran-centric features included in the tool highlighted the importance of smoking cessation and mental health. Users could click a radio button to request to speak with a primary care provider about smoking cessation or a mental health provider about either smoking cessation or LCS. Some users stated that they were already familiar with these resources or had successfully quit smoking. Others commented on the difficulty of smoking cessation, recalling multiple efforts to do so. A participant commented that he quit smoking for 1 year but recently restarted, stating, "don't ask me why I started again, I don't have a reason, I just did it," and another commented, "I have tried the smoking cessation classes here at the VA but they don't work." Other users clicked the boxes conveying an interest in speaking about these topics to a provider.

Discussion

Principal Findings

The LCSDecTool was designed to create an engaging experience, inform veterans about LCS, support a value-aligned decision, and facilitate communication with their provider about LCS. We found that usability among veterans was good when administered in the context of a primary care clinical visit. These results provide evidence that an older group of US veterans can navigate tablet-based DAs. Our study was noteworthy for engaging veterans in the design of a decision support intervention in a meaningful way. In creating a veteran-centric tool, we involved veterans at every step of development and incorporated their feedback in an iterative process of tool development. Veterans were able to help determine the components of the SDM process and provide reactions and comments that could help other veterans. The motivation to provide feedback to help other veterans reflects a military culture of caring for and deriving satisfaction from helping other veterans [45].

Given that veterans in this age group may not have been familiar with technology, usability testing was particularly important to ensure that they could interact with and understand the information in the tool. Our usability findings were strengthened by conducting the assessment in the setting of a primary care visit where the LCSDecTool was designed to be used. Through this evaluation, we identified areas of strength and areas that require further refinement and modification.

The qualitative feedback obtained from our findings revealed 5 underlying themes. Two of these themes (low baseline awareness and knowledge about LCS that increased after use of the tool and the desire for more detailed descriptions of the LCS process) indicate that usability testing increased awareness of LCS. This is a key step in the process of adopting this evidence-based and provides preliminary evidence that the tool will increase awareness of LCS. Two additional themes (the tool was generally easier to use, but navigation challenges remain and difficulties in understanding some medical terminology remained) indicate the importance of veteran feedback in creating a tool that veterans are able to understand and use. These themes will guide further refinements of the tool. A final theme indicates that the tool may enhance discussions with providers about smoking cessation and mental health. This theme reinforces that veterans perceive a relationship between mental health, smoking cessation, and LCS and further supports the decision to address this relationship in the LCSDecTool.

Our study sample was a particularly vulnerable population in terms of sociodemographic factors (low level of education and income) and health status. Among those in the phase 2 high-fidelity cohort, 47% (20 out of 43) reported a diagnosis of PTSD. Rates of PTSD are known to be higher in veterans than in the general US population. Furthermore, among veterans, the rates of PTSD are higher in those receiving VA care than those who do not [46]. Veterans who receive care in the VA are also known to have lower education and income than veterans receiving care outside of the VA. Given these differences in socioeconomic status and health status, usability testing among a sample of veterans receiving VA medical care focuses our study on a more vulnerable population of veterans.

We observed a decrease in the usability measures from the prototype testing cohort to the high-fidelity testing cohort. There are several potential reasons for these differences. First, in the prototype cohort assessment, quantitative usability measures were collected immediately after completing the tool. In contrast, in the high-fidelity cohort, the user experience and quantitative usability assessment were separated by a clinic visit. The goal of this study was to assess the usefulness of the tool when used in the clinic setting. However, the intervening clinic visit may have decreased the salience of user experience. Of note, the purpose of the primary care visit was not limited to the topic of LCS, although addressing age and risk factors for appropriate cancer screening is an expected component of a primary care visit. Second, the study directed RAs to be more engaged with participants in the earlier prototype testing than in the high-fidelity testing. For example, in the prototype testing, the RAs discussed the participants' experience with each section of the tool before progressing to the next section. The increased level of RA engagement during the prototype user session may have positively affected user experience.

According to the TAM, users need to perceive the technology as useful and easy to use to continue using it. Our qualitative data provide additional insights on participant perceptions of the tool regarding usability and usefulness. The design of our value assessment measures was based on qualitative studies conducted with veterans regarding how they perceived and valued the potential benefits and harms of LCS [30]. In usability testing, the value assessments were completed without difficulty, with some participants commenting that they enjoyed responding to these scales and found them helpful. Our PE survey indicates that users of the LCSDecTool felt engaged in the decision-making process, a primary goal of any SDM intervention, as in the development of other eHealth applications [35,36]. Our results suggest that users perceived that the tool supported them in caring for their health, addressed their concerns, and informed them about LCS.

Comparison With Other Work

In our study, we observed that 100% of the participants completed the use of the LCSDecTool. Completing the tool included moving through all sections, responding to the value assessment questions, and submitting the summary page. In a recent Cochrane review, which was a subgroup analysis of 105 studies involving >31,000 participants, the median effect of a DA on the length of a medical consultation was to lengthen the consultation by 2.6 minutes in comparison with usual care [24]. Although the length of the LCSDecTool did not emerge as a concern among users in our qualitative feedback, the time required to complete the tool could have contributed to lower scores on the SUS and EUCS scales. Our qualitative data suggest that improving navigation and allowing users to choose which sections to review would decrease the time to completion of the LCSDecTool without compromising usability and effectiveness.

Prior studies on cancer screening DAs provide a comparison of the usability scores for the LCSDecTool. Carter-Harris et al [8] developed an LCS DA that included audio and video features and scripts tailored to the user's smoking status. The tool, named *Lung Talk*, reported mean SUS scores of 75.7 (SD 7.9), indicating a good level of usability [8]. Coe et al [47] developed a breast cancer screening DA for use among multi-ethnic women. This tool, named *Real Risks*, reported mean SUS scores of 80.0 (range 50.0-95.0) and 66.3 (range 55.0-75.0) for the English and Spanish versions, respectively [47]. Our study design is unique in reporting usability scores prospectively as the tool moved from the evaluation of a prototype to the evaluation of a high-fidelity version within a clinical setting. In our study, the SUS scores decreased when the tool was integrated into the clinical setting but remained at an acceptable level of usability.

Our LCSDecTool differs from existing LCS DAs in several respects. It was developed using the principles of user-centered design to increase engagement with the tool among a veteran population. This includes the look and feel of the tool, such as using the Department of Veterans Affairs branding, content that acknowledges the mental health conditions that may affect LCS, and smoking cessation referrals specific for veterans receiving care in VA medical centers.

Limitations

Our study has some limitations. First, data for the phase 2 high-fidelity version were obtained in the context of a pilot hybrid type 1 effectiveness-implementation trial. In this research setting, participants were able to ask an RA for help with the tool if needed. This may not be feasible in routine care outside the context of a research study. Second, the LCSDecTool was tested on a limited number of veterans and clinical sites. Our population reports high rates of mental health conditions and other comorbidities and has particularly low levels of education and income. The findings may not be generalizable to a broader population of veterans or the general US population. Despite these limitations, the strengths of our study include the evaluation of the usability of the LCSDecTool among veterans who are diverse in race, meet eligibility criteria for LCS, and are receiving care in a VA primary care setting.

Conclusions

In conclusion, our study found that a web-based LCS decision support tool developed for and tested among US veterans receiving care in a VA medical center demonstrates an acceptable level of usability. We designed the LCSDecTool for use before and during a clinical visit, incorporating content, formats, and functions that can be used across these settings. The decision regarding LCS requires patients and their providers to consider scientific evidence of benefits and harms, as well as patient values, priorities, and beliefs. Given these complexities, it is important to conduct usability testing of this patient-centered LCSDecTool in its target population. Our findings support the use of this eHealth technology in the primary care clinical setting as a way of engaging veterans, informing them about a new cancer control screening test, and preparing them to participate in an SDM discussion with their provider. Our study further indicates that involving veterans in all phases of the development of the tool extends veteran involvement to the design of SDM processes. Future work is needed to fully address the information and decision support tools that will help veterans understand and apply the principles of SDM for LCS in the context of a comprehensive health care program.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Prototype Lung Cancer Screening Tool Usability Assessment field notes form.
[DOCX File , 2474 KB - formative_v6i4e29039_app1.docx]

Multimedia Appendix 2
Link to the Lung Cancer Screening Decision Tool.
[DOCX File , 12 KB - formative_v6i4e29039_app2.docx]

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Abbreviations

DA: decision aid
EUCS: End User Computing Satisfaction
LCS: lung cancer screening
LCSDecTool: LCS decision tool
NLST: National Lung Screening Trial
PARiHS: Promoting Action on Research Implementation in Health
PE: Patient Engagement
PTSD: posttraumatic stress disorder
RA: research assistant
SDM: shared decision-making
SUS: System Usability Scale
TAM: Technology Acceptance Model
VA: Veteran Affairs

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Original Paper

Helping Children to Participate in Human Papillomavirus–Related Discussions: Mixed Methods Study of Multimedia Messages

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Abstract

Background: Human papillomavirus (HPV) can cause several types of cancers and genital warts. A vaccine is available to prevent HPV infections, and several efforts have been made to increase HPV education and, eventually, vaccination. Although previous studies have focused on the development of messages to educate children about HPV and the existence of the HPV vaccine, limited research is available on how to help children better communicate with their parents and health care professionals about the HPV vaccination. In addition, limited research is available on the target audience of this study (Italian children).

Objective: This manuscript describes a study assessing the feasibility of using an evidence-based animated video and a web-based game to help children (aged 11-12 years) participate in discussions about their health—in particular when such conversations center around the HPV vaccination—and improve several HPV-related outcomes. The study also compares the effects of these 2 educational multimedia materials on children's knowledge and perceptions of HPV prevention.

Methods: A mixed methods approach consisting of focus group discussions and an experiment with children (N=35) was used to understand children's experiences with, and perceptions of, the animated video and the game and to measure possible improvements resulting from their interaction with these materials.

Results: Both the animated video and a web-based game increased children's knowledge and positive perceptions about HPV and HPV vaccination. Any single message was not more effective than the others. The children discussed aspects of the features and characters they liked and those that need improvements.

Conclusions: This study shows that both materials were effective for improving children's education about the HPV vaccine and for helping them to feel more comfortable and willing to communicate with their parents and health care professionals about their health. Several elements emerged that will allow further improvements in the design and development of the messages used in this study as well as the creation of future campaigns.

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KEYWORDS

animation; game; HPV; child-parent communication; child-physician communication; pilot study; children; health communication; communication technologies; vaccination; health education

Introduction

Background

Engaging children and preteens in conversations about their health is important for their well-being and future health behaviors [1,2]. However, children and preteens are often not included in such conversations, even when they express a specific interest in being involved, because both parents and health care professionals consider such conversations particularly challenging [3]. Furthermore, research aimed at understanding and improving children's engagement in health discussions is limited [4-6]. As a consequence, children's

information needs are often unmet, despite evidence showing that children can actively participate in health discussions and decision-making processes [4], as well as benefit from being included in them [1,2,6]. Some health-related conversations are perceived as more challenging by both parents and their children; for example, conversations about sexual health or cancer [7,8]. A conversation concerning HPV vaccinations is one such because it shares barriers faced by both sexual health–and cancer-related discussions. Human papillomavirus (HPV) can negatively affect the human body by causing several types of cancers and genital warts [9]. Today, HPV is known to be the most frequently diagnosed sexually transmitted disease [10]; yet, vaccination hesitancy remains a problem. To limit the risk of contracting an HPV infection, children should receive the HPV vaccine at age 11-12 years [11,12].

Given children's need to receive health information and the communication challenges they may face, recently researchers developed and assessed several educational strategies targeting in particular preteens and adolescents in the United States [13-15]. In addition to improving attitudes and knowledge, these educational materials seem to support an increased rate of HPV vaccinations over methods that target parents only [14,16]. These promising results and the barriers that children and preteens face to communicate about their health indicate the importance of developing evidence-based interventions and message strategies to educate children about specific health topics such as HPV and support them in discussing these health topics with their parents and health care professionals [17]. These interventions need to take into consideration the cultural background of the children and the perceived social norms because these can influence the way children and adolescents talk about health with their family and the way they conceptualize health [18,19].

Interventions using communication technologies have shown the potential to improve HPV vaccination behaviors [20]. These interventions can allow for customization of information to individuals' needs [20] and culture [21]. However, only limited research exists on how communication technology can support children's learning about health [14,22,23]. Even less research is available on the role that communication technology–based interventions can have in empowering children and preteens to discuss their health or the HPV vaccine [7].

Communication Technologies for HPV Education and Vaccination

Research and interventions about HPV vaccinations have adopted several communication technologies such as videos, Facebook pages, SMS text messages, and emails [20], as well as mobile apps [24,25]. However, when communicating with children, preteens, or adolescents specifically, researchers have tested mainly videos and SMS text messages focused on HPV [14,20], despite the fact that several other strategies have been shown to be promising for educating children about health [23,26,27]. For example, serious games and educational animations can encourage adolescents' engagement in health decision-making [26,28-33]. Thompson et al [28] developed and assessed a serious videogame about the HPV vaccine for adolescents. The game increased adolescents' likelihood of receiving the vaccine and aided the participants in personal health decision-making. Similarly structured videogames have also been used for other health-related behavior changes in terms of, for example, diet and exercise [13,29,33]. In addition, there is evidence that supports the use of educational animations to communicate about several health-related topics [30,32,34].

A systematic review of adolescent-targeted HPV educational animations found that the animations significantly increased motivation toward receiving the HPV vaccination [30]. However, the analysis also showed that the interventions were not effective with regard to attitudes or behavior in the long term [30]. These findings indicate that more research needs to be conducted to determine how to design such messages and the effects these messages may have on individuals' outcomes and health conversations [30,32]. In addition, more research is necessary to understand the effects these interventions can have on diverse audiences [20].

Rationale for This Study

This study describes the development and assessment of two theory-based multimedia messages (an animated video and a game) to communicate with children about HPV and the HPV vaccine. The format and content of these messages were created based on the insights of children collected through previous formative research [35,36]. The study's aims are as follows:

1. Understand children's acceptability of the messages.
2. Measure the effects of the messages on children's HPV-related outcomes.
3. Verify whether children's confidence and willingness to communicate with their parents and health care professionals about the HPV vaccine increased after message exposure.

This study was conducted in Italy. In this country, HPV vaccination rates for middle school children are worryingly dropping. The most recent data indicate that the HPV vaccine coverage rates for females in 2015 were 66.64% and 56.26% for the first and second dose, respectively, but in 2018, the rates dropped to 61.68% and 40.36%, respectively. For males, the situation is even more severe. In 2018, the vaccination rate was very low: 44.05% for the first dose and 20.82% for the second one. Official data from 2015 are not available for males [37].

Methods

A multidisciplinary team composed of experts in health communication, social science, and interaction design used (1) a human-centered–design approach to develop the game and the animated video and (2) a mixed methods design consisting of focus group discussions and an experiment with Italian middle school children to evaluate the effects of 2 multimedia messages (animated video and game).

Ethics Approval

Ethics approval was received by the University of Kentucky IRB (institutional review board application number 54851).

Participants and Recruitment

Once ethics approval was received, Italian middle school children from a large public school in north Italy were invited to join the study. Teachers distributed a leaflet and the informed consent documents to all the parents of children (aged 11-12 years) enrolled in the second year of middle school. Children whose parents signed the informed consent document were considered to have given child assent. In total, 35 middle school students participated in the project. Most of the participants were female (20/35, 57%). All the students recruited were attending the second year of middle school at the time of the study. This sampling decision was made because in Italy the HPV vaccine is provided for free to all children in their 12th year of life (aged approximately 11-12 years).

Procedures

Overview

Focus groups were conducted in January 2020. All focus groups were conducted in Italian by the same moderator (AO) for purposes of consistency. Considering the number of children recruited, 9 focus groups were scheduled and randomly assigned to either the animated video or game conditions. Children recruited for this study were then randomly assigned to 1 of the 9 focus groups. After an initial ice-breaking exercise, the children were asked to complete a preintervention questionnaire. Next, they watched the animated video (20/35, 57%) or played the game (15/35, 43%). After watching the animated video or playing the game, the children were asked to complete a postintervention questionnaire. The measures used in the preintervention and postintervention questionnaires were the same. This choice allowed us to evaluate differences in responses due to being exposed to either of the 2 messages. Once all the children completed the postintervention questionnaire, the focus group discussion on the animated video or game began. The children were asked a few questions about the message they interacted with. The questions concerned (1) the purpose of the animated video and game, (2) what they thought children would like about the animated video and game, (3) what they thought children would not like about the animated video and game, (4) their opinions of the characters in the animated video and game, and (5) how (and if) they would use the animated video and game to talk with other people about health and the HPV vaccine. After this discussion, the children were invited to interact with the experimental message that they had not been randomized to (either the animated video or the game). They were then invited to discuss the same questions for the second message as well. The procedures used to analyze the focus group discussions and the experimental data are described in the following sections.

Questionnaire Measures

Knowledge

Knowledge of HPV was measured with an 8-item scale adapted from Forster et al [38]. Examples of the items included *Males cannot get HPV* (False) or *HPV can cause cancer* (True). Participants could answer on a scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Attitudes

Attitudes were measured using a 5-point semantic differential scale with 3 pairs of opposite adjectives regarding vaccinating against HPV: bad and good, harmful and healthy, and cannot protect me from some cancers and can protect me from getting cancers. The scale showed good reliability (Cronbach α=.76).

Intention to Talk

Intention to participate in the conversations about the HPV vaccine was measured by 1 item: *I feel I will be invested in deciding whether to have the HPV vaccine.* The children could answer this item on a scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Self-efficacy

Self-efficacy was measured using a 5-item scale from Forster et al [38]. Examples of the items included *I feel comfortable talking to my parents about whether to have the HPV vaccine* and *I feel comfortable asking my physician any questions I may have before receiving my HPV vaccination*. The scale showed medium reliability (Cronbach α=.50).

Subjective Norms

Subjective norms were measured using the 4-item scale from Forster et al [38], with each item measured on a scale ranging from 1 (strongly disagree) to 5 (strongly agree). Examples of the items included *My parents think that getting the HPV vaccine is important* and *My friends think that getting the HPV vaccine is important.* The scale showed good reliability (Cronbach α=.70).

Fear

Fear was measured using the 6-item scale from Forster et al [38]. Examples of the items included *I expect that the HPV vaccination will be very painful* and *I am worried about the side effects of the HPV vaccine.* The scale showed medium reliability (Cronbach α=.56).

Enjoyment

Enjoyment was measured with 2 items: *I had fun watching the animation* or *I had fun playing the quiz game* and *I found the animation pleasant to watch* or *I found the quiz game pleasant to play*. The children could answer each item on a scale from 1 (strongly disagree) to 5 (strongly agree). This measure was used in the postintervention questionnaire only.

Involvement With the Message

This construct was measured with 2 items that the children could rate on a scale from 1 to 5: *The animation I watched was important to me* or *The quiz game I played was important to me* and *The animation I watched was interesting to me* or *The quiz game I played was interesting to me*. This measure was used in the postintervention questionnaire only.

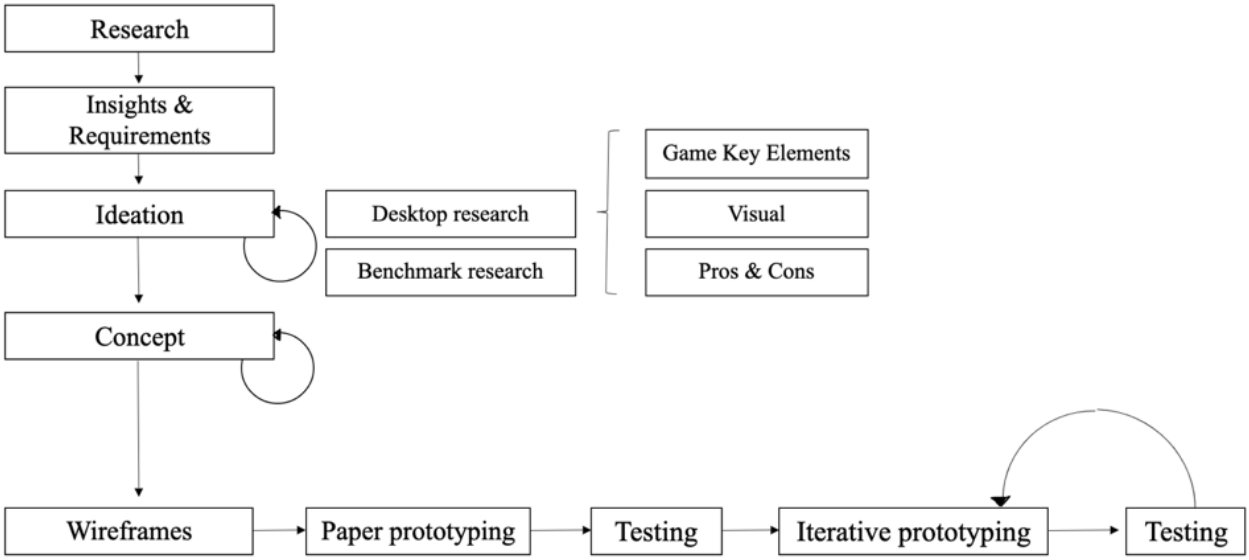
Development of the Game and the Animated Video

Overview

The content and format of the messages were informed by previous formative research that (1) explored Italian children's understanding of, and concerns about, HPV and the HPV vaccine; and (2) investigated channels, sources, strategies, and

characters that may be acceptable and useful to learn and talk about HPV and the HPV vaccine with their parents and health care professionals [35,36]. This formative research indicated that a promising approach to work with Italian children would be to develop multimedia materials that children could access both at school and at home. Such materials needed to focus on a few key questions the children had about HPV and the HPV vaccine to help them find an answer to key questions they identified as important [35,36]. The findings from the formative research and key constructs from the theory of planned behavior (TPB) [39], social cognitive theory (SCT) [40], and the gamification approach [41] were used to create the text and characters of the animated video and to design the logic of the game. The development of the game logic followed a human-centered–design approach, indicated in Figure 1.

Figure 1. The human-centered–design approach followed in this project.



The TPB [39] identifies intentions to perform a behavior as the main predictor of the behavior. To positively influence intentions, it is necessary to work on individuals' attitudes toward the behavior, their perceived social norms, and perceived control over the behavior [39]. The SCT argues that we learn to perform a behavior by observing other people doing it and by looking at the outcomes of such behavior [40]. The gamification approach identifies several affordances that support and promote the value that an individual will assign to a game [41].

The TPB helped us to identify the key constructs to include in our game and animated video to help children engage in conversations about the HPV vaccine. We considered the insights from the SCT in designing the scenes of the animated video and game. Specifically, we showed children in the act of discussing the HPV vaccine with a health care professional, showing the positive outcomes of such a discussion and the strategies to address the challenges of engaging in such conversations.

Animated Video

The animated video *Salute e HPV* (Health and HPV) aims to guide 2 middle school children (characters in the animated video) to discover the guidelines to be healthy. The video introduces the HPV vaccine to the children as a standard activity (such as practicing physical activity or eating a healthy diet) that they should pursue at their age to remain healthy. The video shows several scenarios in which the children practice physical activity, eat a healthy diet, and brush their teeth, along with their parents. The video also mentions the importance of sleeping at least 8 hours per night. At the end of these scenarios, the narrator (a health care professional) highlights that children also need to take the HPV vaccine to remain healthy. The choice of including this activity among several that children in Italy are typically comfortable with was made to reduce the fear and stigma associated with the HPV vaccine [37] and to stress the importance of getting vaccinated during the middle school years, as per the recommendation of the Italian ministry of health [35]. At this point in the video, the health care professional appears on screen and starts answering questions from the children about the HPV vaccine. First, the health care professional describes HPV and the diseases that it can cause. Second, the health care professional focuses on the safety of the vaccine, showing scientists in a laboratory studying and evaluating the vaccine. Third, the health care professional describes how the procedure for getting vaccinated works. The health care professional is shown talking with the 2 children, one of whom raises some concerns and explains that they are scared. The health care professional reassures them, telling them that it is common to "be scared" and to "talk about" these feelings. The health care professional also identifies some strategies the children can follow to reduce their fears. After this interaction, the children feel encouraged and receive the vaccine. Fourth, the health care professional explains that the vaccine is available for free and recommends that the children talk with their parents and physician to obtain more information. The health care professional and the children together indicate some sources that children and their parents can use to obtain more information. The video is available on YouTube [42]. Figure 2 shows a screenshot from the animated video.

Figure 2. Screenshot from the animated video.

Game

The game *Salute e HPV* (Health and HPV) was designed following the human-centered–design approach indicated in Figure 1. This approach, successfully adopted in several health-related interventions [43], helps to design interfaces and web-based platforms able to meet the needs of the audience (in this study, Italian middle school children). The approach includes several iterative phases. In the ideation phase, several insights on children's needs and preferences were gained. We collected these insights through a series of focus groups conducted in the year before the development of the game [36,37]. After developing a greater understanding of children's perspectives, concepts were identified by the designers in collaboration with the researchers who conducted the preliminary focus groups. The proposed solutions were then developed and improved through the refinement and testing of several prototypes [43,44]. The research team tested the prototypes multiple times before using the final prototype adopted in this study.

The game is a web-based quiz available on the web that can be played by children alone at home or in a group if at school. In this study, children played in groups of 2 because of the limited number of computers available. The game gives children the opportunity to choose a character to play with (the options are a boy or a girl, the same used in the animated video). The characters' names were Francesco and Giulia, the most common names given to newborns the year the children in this study were born. This choice was made to help the children better identify with the characters. For the health care professional, the same character as in the animated video was used. The role of the health care professional was to provide children with correct information. Children could not choose to play with the health care professional character.

The content of the game was consistent with the content of the video. The game included the same key questions and information as in the animated video. For each of the 5 questions, the children were shown 4 pairs of statements related to the question. Each pair included 1 correct and 1 incorrect statement for the children to choose from. Once the children read the objective of the game and instructions for playing it, they could start the game. The game was designed to include several motivational affordances (Textbox 1).

These motivational affordances were selected because they can influence gamers in several ways. In particular, *points and achievements* and *feedback* were included in the design of the game to support children's autonomy and competence [45]. A *clear goal* and the *progress bar* were included to provide children with a means to measure their performance [46]. Ultimately, previous research indicates that these motivational affordances can influence the enjoyment of, and engagement with, the game experienced by gamers [46]. Figure 3 shows a screenshot of the game.

Textbox 1. Motivational affordances included in the game.

Points and achievements

• Numbers and medals were used to reward children for successfully progressing in the game

Progress bar

• Stars were used to show children at which point of the game they had reached

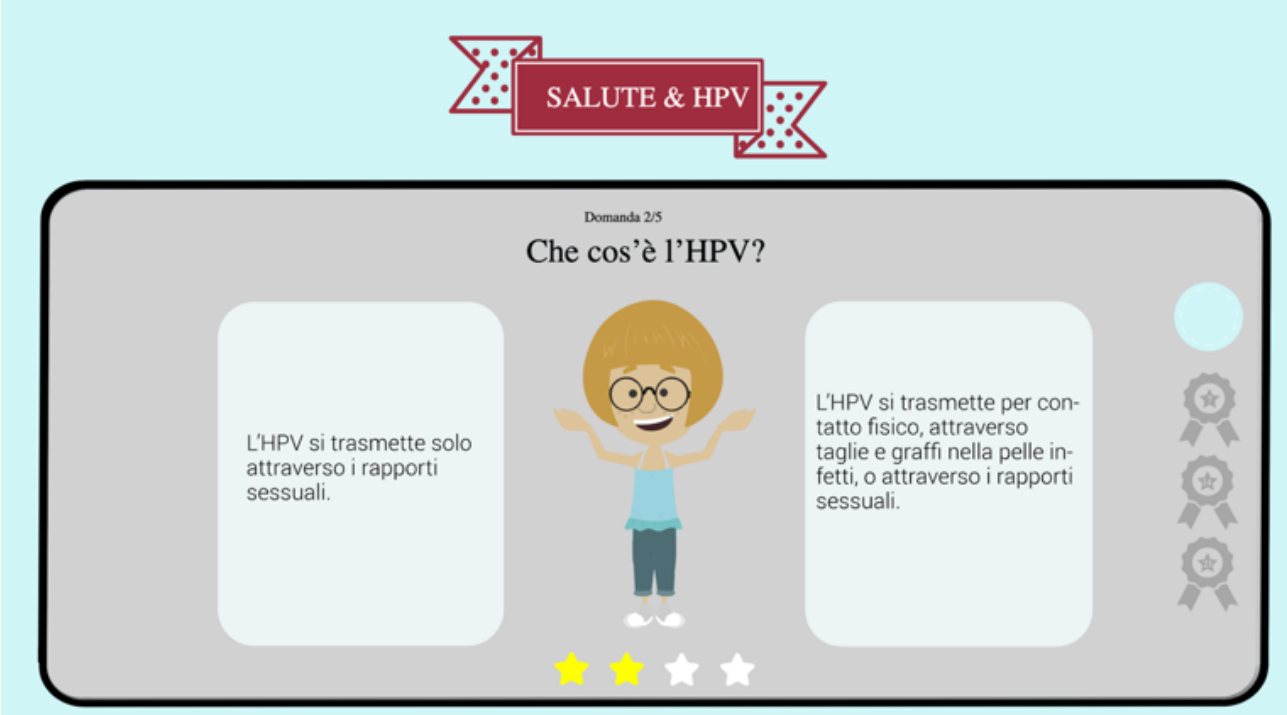
Clear goal

• The goal of the game was described at the beginning of the game, along with the instructions for playing the game

Feedback

• Children received feedback through the use of colors (green for correct answers and red for incorrect ones) and the physicians' statement, provided at the end of each level (after each of the board's 5 questions)

Figure 3. Screenshot from the web-based game. HPV: human papillomavirus.



Data Analysis

Focus Group Discussions

The focus group discussions were audio recorded and transcribed verbatim in their original language. The real names of the children were deleted and substituted to protect their identity. The transcripts were uploaded in NVivo (version 12), a qualitative data analysis software (QSR International). The analysis of the discussions proceeded through several steps. First, the researcher (AO) familiarized herself with the transcripts. This process included reading the transcripts several times and considering the notes taken for each of the focus groups. Second, the transcripts were coded line by line [47], following a constant comparative method [48]. Third, recurring themes were identified and further refined. Fourth, the transcripts were recoded to include the changes made for each specific category. Finally, data were compiled in brief summaries. The brief summaries are reported in the *Results* section.

Experiment

A series of analyses of covariance were run to verify whether the animated video and the game were effective in improving the children's attitudes, knowledge, subjective norms, self-efficacy, intentions, and emotions regarding the HPV vaccine. Preintervention scores were inserted as covariates. Analyses of variance were run to measure the children's enjoyment and involvement with the animated video and the game.

Results

Focus Group Discussions

Overview

Several themes emerged from the focus groups. First, the children discussed the knowledge they acquired or retained from watching the animated video or playing the game. Second, the children explained what they liked and what should be improved upon in the animated video and the game. Third, the children reflected on the characters in the animated video and the game.

Finally, the children commented on how they would use the information from the animated video and the game in their lives.

Knowledge Acquired

After watching the animated video or playing the game, the children tried to summarize the information they remembered the most. In particular, they mentioned the association between the virus and some types of cancers, as well as the fact that the vaccine is an effective strategy to prevent cancer:

> *I'd heard about this vaccine, but I didn't really know much. I knew it was transmitted through sexual intercourse and that's all, but I didn't know it could cause cancer.* [Mia]

Next, the children remembered that the vaccine is available in many countries around the world, and that in Italy, it is given for free to every child aged 12 years. According to the children, this was a very important insight that could also help parents:

> *This vaccination in Italy is also free of charge, so parents may be less worried about possible costs.* [Luke]

Features Children Liked

The children indicated several features of the video and the game that they liked. For both the animated video and the game, they mentioned the colors, which they described as "bright" and "attractive":

> *The designs are very clear but are not exaggerated, they are stylized, beautifully colored.* [Marzia]

The children also commented on the strategies used to present the information. In particular, for the animated video, the children appreciated the use of the *whiteboard* to illustrate the concepts presented by the health care professional. They specifically liked the fact that both the health care professional and the images of what she was describing were shown at the same time, and this aided their comprehension:

> *It's nice that there's the tarp [whiteboard] with the projector.* [Lia]
>
> *It's very detailed.* [Peter]
>
> *You see the images at the same time as the doctor explaining, there's not just the voice.* [Lia]

Regarding the game, they appreciated the summary of the information provided at the end of each question. They felt that they could still learn from the game even if they did not know much about HPV or the HPV vaccine before playing it:

> *It's pretty clearly explained. It's nice that every time it asks you a question, you get the summary afterward. Even if you haven't seen the video, maybe you can get most of the answers wrong, but then with the summary, you understand.* [Thomas]

In the end, when asked which of the 2 materials they preferred, the children said that they liked the animated video and the game equally. They said that children should use both these educational materials because, although they included the same information, they felt that the 2 materials complemented each other:

> *They are two things that talk about the same subject, but they are different because in the game you had to think about what you understood, whereas the video serves to confirm your hypothesis.* [Azzurra]

Features That Need Improvement

The children recommended that a few elements could be improved in both the game and the animated video. In particular, the children felt that there was some missing information:

> *The length [of the video] is right, but maybe you could add a part explaining what the consequences are if you don't get this vaccine.* [Tia]

More specifically, the children indicated that they wished they had been able to learn more about the possible side effects of the vaccine as well as the symptoms of an HPV infection, besides the risk of getting cancer:

> *Always add, as in the video, always add what can happen if you don't get the vaccine.* [Marzia]
>
> *And what are the side effects.* [Tia]
>
> *Also because we could convince more people that this infection isn't a small thing, so it's much better to prevent it with the vaccine.* [Marzia]

Characters

Overall, the children liked the characters in both the animated video and the game for several reasons. The most liked character was the health care professional, appreciated for both her caring attitude and for the type of information she provided:

> *I [liked] the doctor because even [though] the children are afraid of the needle, she advises them to close their eyes, she's thoughtful.* [Lia]
>
> *She also gives them advice on how to feel less pain, have less anxiety.* [Peter]

The children also liked the 2 young characters, both their design as well as their personality. Regarding the overall design, some children also mentioned the presence of diversity as a positive characteristic that they valued and helped them to better identify with the characters:

> *I liked that the children were of different ethnicities.* [Tobias]
>
> *She [the doctor] looks like me!* [Mara]

Regarding the personalities of the characters, one of the moments the children appreciated the characters the most in the animated video was when the children visit the physician's office to receive the vaccine, and 2 different emotional reactions were displayed:

> *Then the characters are nice, they make the idea. The boy was worried about the vaccination while the girl wasn't, it indicates that there are different kinds of people.* [Luke]

A negative comment about the characters concerned the size of the children. For some of the children, this contributed to making the characters look as though they were younger than the children:

Maybe looking at them like that, the characters being too short may look like children. They don't look like children my age to me. [Philip]

Use of the Animated Video and Game

The children mentioned that one of the most interesting elements they liked about the video and the game was that they could use these tools to learn more about HPV and the HPV vaccine:

This game is instructive. It can be the litmus test [literally prova del nove (test of 9) in Italian] to see if you understand. [Duccio]

It's like some kind of test, and it makes you realize what you've figured out but it doesn't make you feel anxious at least. [Agata]

The children expressed the desire to talk more about these topics with adults as well as with their friends. This concept emerged consistently in each of the focus groups, either explicitly or in the form of the questions asked by the children. For example, the children asked whether they could show the video to their parents or have a say in the decision to receive the HPV vaccine:

But is it something that parents choose, or can I choose too [to get the vaccine]? [Elia]

What do you think? [Moderator]

I'd like to make the decision too, because it's about me, and if I want to do it, I can do it. [Elia]

The children consistently mentioned that the video could be a means to facilitate the discussion with the parents. It could be something that parents could use to talk to their children about HPV:

It could be good for the parents, too. You say there's this disease, it can also cause tumors, my daughter has to be cured, I have to give her vaccinations. So, it might help the conversation a little bit. [Azzurra]

The children also wished that the video and the game were available on the web on several social media platforms so that both they and their parents could access them easily:

Can we find it online? To show it to our parents? [Sarah]

I would go to see the video on YouTube, as a platform that would be great, but also Instagram and Facebook, where there are many adults who could make the decision to have their children vaccinated. [Maria]

Experiment

Several analyses of covariance were run to understand the effects of the messages assessed in this study. The dependent variables used were, in turn, postintervention knowledge, attitude, intention, self-efficacy, subjective norms, and fear scores. The independent variable was the modality used (animated video vs game). Participants' preintervention scores were used as covariates. Both the animated video and the game were effective in changing some of the key variables explored to improve children's knowledge and perceptions of the HPV vaccine, but any single message was not statistically more effective than the others. For the animated video, significant changes from pre- to postintervention scores were observed for most of the variables assessed, with the exclusion of attitude and subjective norms. For the game, the only statistically significant change from pre- to postmessage exposure was observed for knowledge and intention. The results for each of the variables for both the animated video and the game are shown in Table 1.

These results reinforce what emerged from the focus groups data: the children retained the information from both educational strategies (animated video and game) and enjoyed watching, and interacting with, them.

Table 1. Results and descriptive statistics for study variables by experimental condition (N=35).

Condition	Time point				*t* test (*df*)	*P* value	Mean difference
	Before the intervention		After the intervention				
	Mean (SD)	n (%)	Mean (SD)	n (%)			
Animated video, n=20							
Knowledge	3.34 (0.36)	18 (90)	3.90 (0.37)	18 (90)	6.06 (17)	<.001[a]	0.55
Attitude	3.97 (0.94)	20 (100)	4.12 (1.23)	20 (100)	0.81 (19)	.42	0.15
Intention	3.20 (1.19)	20 (100)	3.80 (0.83)	20 (100)	3.94 (19)	<.001[a]	0.60
Self-efficacy	3.63 (0.51)	19 (95)	3.88 (0.37)	19 (95)	3.13 (18)	<.001[a]	0.25
Subjective norms	3.86 (0.63)	20 (100)	4.01 (0.52)	20 (100)	1.35 (19)	.19	0.15
Fears	2.94 (0.49)	20 (100)	2.69 (0.50)	20 (100)	–3.96 (19)	<.001[a]	–0.25
Enjoyment	N/A[b]	N/A	4.45 (0.39)	20 (100)	N/A (19)	.29[c]	N/A
Message involvement	N/A	N/A	4.37 (0.48)	20 (100)	N/A (19)	.72[c]	N/A
Game, n=15							
Knowledge	3.34 (0.51)	13 (87)	3.79 (0.35)	13 (87)	3.13 (12)	<.001[a]	0.45
Attitude	4.38 (0.66)	15 (100)	4.47 (0.53)	15 (100)	1.00 (14)	.33	0.08
Intention	2.93 (1.10)	15 (100)	3.73 (0.70)	15 (100)	2.86 (14)	.01[a]	0.80
Self-efficacy	3.72 (0.54)	15 (100)	3.75 (0.56)	15 (100)	0.24 (14)	.81	0.03
Subjective norms	3.40 (0.51)	15 (100)	3.62 (0.67)	15 (100)	1.94 (14)	.07	0.22
Fears	2.76 (0.55)	15 (100)	2.71 (0.53)	15 (100)	–0.69 (14)	.49	–0.05
Enjoyment	N/A	N/A	4.60 (0.43)	15 (100)	N/A (14)	.29[c]	N/A
Message involvement	N/A	N/A	4.43 (0.45)	15 (100)	N/A (14)	.72[c]	N/A

[a]*P*<.05.

[b]N/A: not applicable.

[c]Information pertaining to the comparison of animated video and game.

Discussion

Principal Findings

This study adopted a mixed methods approach consisting of focus group discussions and an embedded experiment to assess the feasibility of 2 educational multimedia materials on HPV and the HPV vaccination. The purpose of these educational materials was to educate children and provide them with the skills to discuss these topics with their parents and health care professionals. Both the qualitative findings and the results from the experiment indicated that the 2 educational materials were well received and improved children's intention to discuss the HPV vaccine from pre- to postmessage exposure. Children liked the characters presented in the animated video and the game and provided several suggestions on how to improve these materials. By educating children on the HPV vaccine, researchers and practitioners have the potential to aid in the promotion of personal health decision-making, strengthening communication about personal health, and enhancing personal health behaviors, including developing more favorable attitudes toward receiving the HPV vaccine [7].

This study took place in Italy, a country where the field of health communication is still underdeveloped, and it represents a pioneering effort to engage and represent a relatively understudied audience: Italian children. The study provides evidence in support of the use of multimedia interventions such as animated videos and web-based games to improve child-parent communication and HPV-related discussions. It indicates how communication and behavior change theories can be integrated into the human-centered–design approach. It also describes the working process used by the interdisciplinary team of communication scholars and interaction designers who created and evaluated the educational multimedia materials.

This study suggests that animated videos and web-based games can be effective multimedia strategies to improve children's knowledge about the HPV vaccination and their intention to discuss their health, in particular the HPV vaccine, with their parents and health care professionals. During the focus group discussions, the children indicated the features they appreciated in both the animated video and the game, which included in particular the personality and caring attitude of the characters. This finding suggests that showing positive examples of

communication exchanges may be important to help children feel comfortable when discussing the HPV vaccine and looking for health-related information. The children also expressed the desire to show the 2 messages to their parents and friends, indicating that multimedia messages should be easily retrievable and shareable in possible future campaigns to support children's discussion and information needs.

The experiment allowed observation not only of the improvements in knowledge of HPV and the HPV vaccine but also of the different changes in the outcome variables, depending on the message the children interacted with. When considering the emotional reaction to the vaccine, the animated video seemed to have an advantage over the web-based game. It is possible that, by showing enacted behaviors, animations may reduce children's fear while improving their self-efficacy with regard to health discussions. These findings are significant, considering that children encounter several challenges to engaging in conversations about their health, particularly when such discussions include a sexual-education component [49,50]. It is important to note that the children participating in this study felt that the video and game complemented each other, and that by using both, they were able to learn and test their knowledge. The children also suggested that the animated video and the web-based game would also be helpful to parents in providing an explanation of HPV to their children.

Limitations and Future Directions

There are some limitations to this study that should be mentioned. First, data were collected at only 1 school in the northern part of Italy. It is possible that children from different areas of Italy would have different perceptions and previous experiences that may affect how they receive the animated video and game. Second, parents' and physicians' comments about the game and animated video were not collected, limiting our ability to contextualize the children's experiences. Third, the scales used in this study were translated from English to Italian, but the translated questionnaire had not been previously validated with an Italian audience.

Future research is necessary to further extend this preliminary investigation to control for the effects of the specific features of the game by increasing the number of children exposed to these educational multimedia materials. A greater sample of children would allow researchers to evaluate the possible role of mediators and moderators to explain the effects of the animated video and the game to improve children's self-efficacy and attitudes. Future studies should also aim to measure improvements in the conversations between parents and their children resulting from the exposure to the game and the animated video through observations of dyadic conversations. Furthermore, it would be beneficial to understand whether the animated video and game are useful tools to help parents begin a discussion with their child about HPV. Future studies should also better explore the effects that educational multimedia messages have on children's conversations with their teachers and peers to inform the design of school-based interventions. Future studies should also control for the HPV vaccination status of the children and consider targeting the messages to it. Ultimately, future studies should integrate and evaluate these materials and educational modules in comprehensive health education packages that include information on several health issues relevant to children aged 11-12 years.

Conclusions

Engaging children in discussions about their health in general and HPV and the HPV vaccine in particular is important for empowering children and meeting their information needs. The animated video and web-based game evaluated in this study were well received by the children and were shown to be promising messages to improve several outcomes. We hope that the findings of, and procedures used in, this study will inspire other researchers to continue this line of research and further identify and develop strategies and campaigns to engage children in their health care.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

HPV: human papillomavirus
SCT: social cognitive theory
TPB: theory of planned behavior

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Original Paper

Health Care Professionals' Clinical Skills to Address Vaping and e-Cigarette Use by Patients: Needs and Interest Questionnaire Study

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Abstract

Background: Widespread vaping and e-cigarette use is a relatively new phenomenon. Youth vaping peaked in 2019, with over 25% of high school students currently vaping. e-Cigarettes are used where smoking is not permitted or as an alternative smoking cessation treatment instead of Food and Drug Administration–approved options. Vaping and e-cigarette use has the potential to harm health, including causing adverse respiratory effects and nicotine addiction. Health care professionals need skills training to help their patients with this relatively new and evolving health problem.

Objective: The aim of this study is to understand health care professionals' training needs in this subject area to determine the focus for web-based continuing education training.

Methods: We reviewed the literature on clinical aspects of vaping and e-cigarette use. Using the results and our experience in substance use continuing education, we created a list of key clinical skills and surveyed health care professionals about their training needs. We also asked about their interest in a list of related topics. We recruited individuals who completed our web-based courses on substance use, members of health care professional–related groups, and experts who had published an article on the subject. Half of the 31 health care professionals who completed the survey were physicians and the remainder were primarily nurses, social workers, and counselors. Participants self-identified as nonexperts (n=25) and experts (n=6) on vaping.

Results: Participants who were nonexperts on average agreed or strongly agreed that they needed training in each of 8 clinical skills (n=25; range 3.7-4.4 agreement out of 5). The top two skills were recommending treatments for patients (4.4 out of 5, SD 0.49) and evaluating and treating the health effects of vaping and e-cigarette use (4.4 out of 5, SD 0.50). Experts agreed on the importance of training for health care professionals in all skills but rated the need for training higher than nonexperts for each topic. Over half of the participating health care professionals (44%-80%) were interested in nearly all (9/10, 90%) vaping-related topics on a checklist. The topics participants were most interested in were the pros and cons of vaping versus smoking and the health effects of second- and third-hand vaping. Primary care physicians showed more interest in vaping-related topics than nonprimary care physicians (t_{13}=2.17; P=.02).

Conclusions: This study confirmed gaps in health care professionals' vaping-related clinical skills identified in the literature by identifying a perceived need for training in related skills and health care professionals' interest in key topics related to vaping prevention and cessation. This study provides specific guidance on which clinical skills training is most needed and which topics are most interesting to health care professionals.

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KEYWORDS

clinical skills; vaping; e-cigarettes; nicotine; brief interventions; addiction treatment; health care professionals; continuing education

Introduction

Background

The growth of e-cigarette devices, after their initial promotion as safer alternatives to traditional cigarettes, brought about a disturbing trend of youth vaping, fueled in part by marketing directed to this age group [1] that minimized potential harm [2]. Whereas current cigarette use by high school students steadily decreased in the past 20 years to only 9.4% by 2019 [3], vaping, especially nicotine vaping, was on the rise. By 2019, when we conducted this study, 27.5% of high school students were vaping [4-6]. Vaping by youth later continued at a significant rate of 11% in early 2021 despite less time spent inside schools owing to the pandemic [7]. Many adults who use e-cigarettes as smoking cessation treatment alternatives to Food and Drug Administration (FDA)–approved options end up using both forms of nicotine [8].

Nicotine's harmful health effects were already known to medical science when nicotine vaping became popular, including nicotine's addictive properties [9,10] and harmful cardiovascular effects [11-13]. Other harmful health effects became evident over time, including a greater potential for nicotine overdose with vaping than with cigarette smoking, as well as harm to the lungs related to the inhalation of toxic chemicals in vaping liquids [10,11,14,15]. The serious lung disease, e-cigarette or vaping product use–associated lung injury, primarily associated with a vaping liquid additive, underscored the potential for respiratory damage, affecting over 2000 individuals and causing 68 deaths, mainly in the latter half of 2019 [16]. The long-term effects of inhaling various harmful ingredients are not yet fully understood.

With the addictive potential and health effects of vaping and e-cigarette use and increased use by their patients, health care professionals need to know how to prevent and address the use of these products. In the absence of large-scale studies on the best approach to preventing and treating vaping and e-cigarette use, many health care professional societies and addiction specialists recommended following existing evidence-based guidelines for tobacco cessation [17-21]. For example, the questions of the 5 As approach often recommended for tobacco cessation can be modified to pertain to the differences between vaping and e-cigarette use and other tobacco use, such as the nicotine delivery method and typical patterns of use [22]. Professionals also need sufficient knowledge to provide patient and parent education. Tobacco interventions by primary care providers are effective, including for adolescents [23,24]. Educational programs on best practices in this area need to be fluid, as further research gathers data on the best clinical approach to preventing and treating vaping and e-cigarette use by patients. Similarly, the use of e-cigarettes by many people to help with tobacco cessation requires further research [25]. Health care professionals need to understand that the FDA has not approved e-cigarettes as an aid to quit smoking and respond to patients who are using them for this purpose [26].

As a group, the authors brought significant experience in developing nicotine and cigarette addiction cessation training programs [27] and substance abuse cessation training for health care professionals [28-35]. With this experience, we were familiar with the evidence that health care professional screening and interventions effectively improve patient outcomes for substance use problems [36,37], including for tobacco cessation in children and adolescents [38,39]. This experience formed a solid basis to begin developing a curriculum and content.

To address the challenge of determining health care professionals' greatest needs and interests, we conducted a literature review to identify evidence-based protocols and current thinking on clinical skills thought to be effective for addressing patient vaping and e-cigarette use. We refined the list of skills that we identified with input from expert consultants in vaping and e-cigarette use and using our experience with addiction treatment education. We followed this with a needs analysis using a web-based survey asking health care professionals about the clinical skills training they most needed and topics of most interest to them.

Objectives

This study aims to determine the need and interest health care professionals have in training on clinical skills to address vaping and e-cigarette use by their patients. We also aim to prioritize the needs and determine differences by groups of clinicians or level of expertise.

Methods

Literature Review

The newness of widespread vaping and e-cigarette use and the emerging recognition of the associated adverse health impacts and limits as a tobacco cessation tool created a challenge in developing an evidence-based continuing education program for health care professionals on the topic. To address this challenge, we completed an extensive literature review from 2014 to 2019. Using PubMed, Google Scholar, and PsycINFO, we searched for research-based articles on vaping and e-cigarette use, covering the topics of brief interventions, epidemiology, motivations, prevention, risk factors, health effects, psychosocial impact, addiction, knowledge and practice gaps, clinical guidelines, vaping products and ingredients, and regulations. We used standard internet searches to identify available training for health care professionals on the topic, Centers for Disease Control and Prevention updates, clinical guidelines, and news. Additional keywords used in the internet and web-based searches included *gateway drugs*, *e-cigarettes*, *vaping*, *e-liquid*, *vaporizers*, and variants of these terms. We also searched for previous studies examining health care professional' perspectives and knowledge on e-cigarette use and vaping and current, evidence-based recommendations for a prevention and treatment clinical protocol. We created survey questions from the clinical skills and related topics most recommended in the literature.

Ethical Considerations

This research was considered exempt from institutional research board review because it involved survey procedures, and the information obtained could not be linked to the participants and did not place them at risk (approval number: 2019/007).

Recruitment

Owing to the formative, exploratory nature of this study and a condensed time frame required by the funding mechanism, we used a convenience sample. We recruited and enrolled participants from October 21, 2019, to November 14, 2019, via direct email. Recruitment efforts included contacting the first 100 health care professionals who had taken a Clinical Tools addiction-related continuing education activity a year previously and inviting participants to share the invitation with colleagues. We also contacted approximately 100 health care professionals using social media and email lists. We modified recruitment to achieve participant diversity similar to the distribution in health care professionals. To obtain input from experts in the field, we also emailed 50 authors of research articles on the clinical aspects of vaping and e-cigarettes. We linked to the human participants' or institutional review board exemption information in the emails. Completing the survey after reviewing that information signified enrollment. Identifying information and study data were stored separately. Participants completing the web-based survey received a US $20 gift card. We checked IP addresses for any duplicate submissions from the same computer.

Data Collection and Analysis

We developed survey questions on potential clinical training needs and key topics by gathering recommendations from the existing literature on how to address patient vaping [17,18,40] and substance use interventions [41-45], as well as our experience of providing training on addiction for health care professionals for over 20 years. Questions were based on evidence-based clinical skills and topics recommended most frequently; gaps in knowledge, skills, and practice; and general principles of addiction assessment and treatment, particularly for tobacco cessation. Question types included Likert-style questions (5-point agreement) about the perceived need for training in key clinical skills, a checklist of topics related to patient vaping, an open-ended question asking whether they had other related needs and interests, and multiple-choice knowledge questions about common vaping myths. Survey questions included a not applicable or do not know option; all survey questions were required. We administered the needs analysis web-based survey from October 21, 2019, to November 16, 2019.

We asked about the need for clinical skills training, interest in vaping topics, and knowledge of several common myths about vaping. We also asked participants to identify their level of expertise in the field of vaping and e-cigarettes (expert or nonexpert) and whether or not they worked in primary care. We asked both experts and nonexperts about the training needs of nonexperts by changing the question stem for each group.

We calculated average Likert rating scores and their SDs for the skills and knowledge data, plus the percentage of participants rating each item with *agree* or *strongly agree*. For the topic interest data, we calculated the percentage of participants who endorsed each topic. We calculated *t* scores and *P* values to compare the overall results in the groups (expert vs nonexpert and primary care physicians vs not primary care physicians). Descriptive statistics were used to analyze and compare the results for the individual questions across groups. A single response to the optional open-ended question is reported without analysis.

Results

Literature Review

The literature review identified several gaps in health care professionals' medical knowledge, clinical skills, and practice related to vaping and e-cigarettes [46-50]. The gaps in health care professionals' knowledge were of health effects [48,49], vaping methods, products, and patterns of use; recommended interventions; and the effectiveness and safety of e-cigarettes to aid smoking cessation. Gaps in clinical skills or practice were evident in health care professionals' infrequent practice of screening [51], following up on screening results [52], and providing interventions [48,49]. Health care professionals screen patients for the use of noncigarette products and advise quitting them less frequently than they do for cigarettes [46]. Health care professionals also need to be prepared to provide patient education and recommend resources, such as social media or SMS text messaging support for vaping or e-cigarette cessation [53].

The clinical guidance from national professional organizations available at the time of this search in September 2019 was limited and included guidelines by the American Academy of Pediatrics recommending tobacco cessation counseling and FDA-approved tobacco dependence pharmacotherapies [20] and clinical tips sheets by the American Academy of Family Physicians [54]. Another resource was the Surgeon General's report on e-cigarettes and young people [10]. Several journal articles drew conclusions about effective prevention interventions, identified youths and young adults at greater risk, and recommended counseling interventions based on the available evidence [40,50,55-57]. The search also revealed only a few, often expired, web-based trainings for health care professionals on the topic [40,58-62]. Boston Medical Center and Montreal University subsequently published a guideline based on tobacco cessation interventions and expert opinion [18]. As of this study, there were no nationally recognized clinical guidelines for vaping cessation treatment (2020). However, a curriculum was developed subsequently for pediatricians by the American Academy of Pediatrics in 2021 [63].

We consolidated the literature review results to produce a list of skills and topics generally considered by experts in the field as important for clinicians to understand. This list is reflected in the survey questions.

Participants

A total of 31 health care professionals participated in the needs analysis surveys and self-identified as nonexperts (25/31, 81%) or experts (6/31, 19%) in vaping. Nonexperts included physicians (15/25, 60%), nurses (4/25, 16%), social workers or counselors (3/25, 12%), and other health care professionals (3/25, 12%). Self-identified experts on vaping were physicians (3/6, 50%), a psychologist (1/6, 17%), an epidemiologist (1/6, 17%), and a social worker (1/6, 17%). Physicians were divided

nearly evenly between primary care (8/15, 53%) and nonprimary care (7/15, 47%).

The diversity of the sample reflected ethnic and racial percentages of the professions in US physicians and nurses [64,65], except for low representation by Black participants. The demographics, voluntarily described by participants, were Asian 19% (6/31), Black 0% (0/31), White 68% (21/31), >1 race 10% (3/31); other 3% (1/31), and Hispanic or Latino 3% (1/31; prefer not to answer 3/31, 9%). More participants were women (22/31, 71%) than were men (9/31, 29%).

Survey Results and Analysis

Clinical Skills Training Needs

For clinical skills training, we asked participants to rate their perceived need for training in 8 clinical skills, listed in Table 1, using a Likert-type survey with a 5-point agreement scale.

Table 1. Health care professionals' perceived need for clinical skills training on vaping (N=31).

"I or Healthcare Professionals NEED MORE TRAINING in how to"	Nonexpert (n=25)		Expert (n=6)	
	Rating[a], average (SD)	Agree or strongly agree, n (%)	Rating[a], average (SD)	Agree or strongly agree, n (%)
Recommend treatments for patients who vape or use electronic cigarettes (e-cigarettes)	4.4 (0.49)	25 (100)	4.8 (0.41)	6 (100)
Evaluate and treat health effects in patients who vape or use e-cigarettes	4.4 (0.50)	25 (100)	4.7 (0.52)	6 (100)
Provide brief interventions for patients who vape tetrahydro-cannabinol	4.3 (0.69)	22 (88)	4.8 (0.41)	6 (100)
Helping patients who are using e-cigarettes to quit smoking	4.1 (0.78)	21 (84)	4.5 (0.82)	5 (83)
Talk with parents about vaping prevention or helping their adolescent child quit	4.1 (0.85)	20 (80)	5.0 (0)	6 (100)
Counsel patients about how to quit vaping or e-cigarette use	4.0 (0.75)	21 (84)	4.8 (0.52)	6 (100)
Motivate patients to quit vaping or e-cigarette use	4.0 (0.79)	20 (80)	4.8 (0.52)	6 (100)
Assess vaping and e-cigarette use in patients	3.7 (0.95)	20 (80)	4.3 (0.82)	6 (100)

[a]Likert rating: 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree.

Participants generally agreed that they need training in clinical skills to address their patients' vaping or e-cigarette use. The ratings by all participants are presented first, followed by comparisons of expert opinion versus nonexpert opinion and primary care physicians versus nonprimary care physicians.

A majority of participants agreed that clinicians need more training for all 8 clinical skills listed (Table 1). The skills that health care professionals who were not experts on vaping (n=25) most often agreed that they required training were as follows: (1) recommend treatments for patients who vape or use e-cigarettes (average 4.4, SD 0.49; 25/25, 100% agree or strongly agree) and (2) evaluate and treat health effects in patients who vape or use e-cigarettes (average 4.4, SD 0.5; 25/25, 100% agree or strongly agree).

Nonexperts (n=25) and experts (n=6) generally agreed about the need for training in the same clinical skills. However, nonexperts' average ratings ranged lower than experts' ratings (3.7 to 4.4 out of 5 vs 4.3 to 4.8 out of 5).

Experts agreed that all skills listed were needed, rating none of the skills below 4 (agreement). According to experts, the skills needed the most were as follows: (1) talk with parents about vaping prevention or helping their adolescent child quit (average 5.0, SD 0; 25/25, 100% agree or strongly agree) and (2) four other skills were rated nearly as highly (average rating 4.8, SDs 0.41-0.52; 25/25, 100% agree or strongly agree). These pertained to patient counseling, motivating patients to quit, recommending treatment, and providing brief interventions for patients who vape tetrahydrocannabinol (THC).

The clinical skills with the largest rating differences between the expert and nonexpert groups (0.8-0.9 points) were talking with parents about vaping prevention or helping their adolescent child quit, counseling patients about how to quit vaping or e-cigarette use, and motivating patients to quit vaping or e-cigarette use.

The clinical skills that primary care physicians (n=8) on average agreed most strongly that they need training in were as follows: (1) evaluate and treat health effects in patients who vape or use e-cigarettes (average rating 4.8 out of 5, SD 0.46; 8/8, 100% agree or strongly agree), (2) recommend treatments for patients who vape or use e-cigarettes (average rating 4.6 out of 5, SD 0.51; 8/8, 100% agree or strongly agree), (3) provide brief interventions for patients who vape THC (average rating 4.6 out of 5, SD 0.52; 7/8, 88% agree or strongly agree), and (4) counsel patients about how to quit vaping or e-cigarette use (average rating 4.4 out of 5, SD 0.74; 7/8, 88% agree or strongly agree).

Primary care physicians on average agreed more strongly that they needed training in the 8 clinical skills listed than did nonprimary care physicians, averaging 4.3 out of 5 (SD 0.34) versus 3.9 out of 5 (SD 0.37; t_{13}=2.56; 95% CI for the difference 0.0734-0.8266; *P*=.01).

Topics of Interest

We asked nonexperts in vaping (n=25) to indicate which topics relevant to vaping interested them on a checklist of 10 topics, listed in Table 2. Most of the nonexpert participants indicated an interest in most (9/10, 90%) of the topics listed, with the percentage of participants interested in each topic ranging from 52% to 80% (Table 2). Topics endorsed most often were *Pros and cons of vaping versus smoking*, selected by 80% (20/25) and *Health effects from second- and third-hand vaping*, selected by 76% (19/25).

Table 2. Number of health care professionals who are not experts on vaping who indicated an interest in vaping-related topics (n=25).

Topics related to vaping and e-cigarettes (in order from most often selected to least)	Health care professionals endorsing interest in topic, n (%)
Pros and cons of vaping vs smoking	20 (80)
Health effects from second- and third-hand vaping	19 (76)
Risks of vaping specifically	18 (72)
Vaping and e-cigarette devices, liquids, and their ingredients	17 (68)
Vaping prevention	16 (64)
Biology of endocannabinoids and pharmacology of tetrahydrocannabinol	16 (64)
Special needs regarding vaping because of cultural, racial, ethnic, or socioeconomic differences	14 (44)
Pathology and radiology of e-cigarette and vaping-associated lung illness	13 (52)
Patient and parent resources on these topics	13 (52)
Biology of the nicotine system and pharmacology of nicotine	13 (52)
None of the above	1 (4)

Physicians (n=15), all of whom were not experts in vaping, were most often interested in *Health effects from second- and third-hand vaping* (n=13, 87%) and *Pros and cons of vaping versus smoking* (n=12, 80%). The fewest physicians were interested in the topics *Special needs regarding vaping due to cultural, racial, ethnic, or socioeconomic differences* (5/15, 33%) and *Biology of the nicotine system and pharmacology of nicotine* (5/15, 33%).

Primary care physicians (n=8) on average showed interest in significantly more topics than nonprimary care physicians (n=7): 5.5 topics (55%, SD 1.51%) versus 3.6 topics (36%, SD 1.4%; t_{13}=2.168; *P*=.02).

We also offered participants the opportunity to add skills or interests that were not included via an open-ended question. In response to this optional, open-ended question, a hospital staff participant identified “negative consequences of vaping.” No other participants responded to this question.

Vaping Knowledge

We asked participants to indicate their level of agreement with 3 myths about vaping, described in Table 3, using the same Likert-type survey style.

Table 3. Health professionals’ agreement with myths about vaping.

Question: rate your agreement or disagreement with the following statements about vaping	Nonexpert (n=25)		Expert (n=4)	
	Rating[a], average (SD)	Disagree or strongly disagree, n (%)	Rating, average (SD)	Disagree or strongly disagree, n (%)
Vaping or electronic cigarette use is a good option for smokers trying to quit (correct answer is 1-2, strongly disagree or disagree).	1.8 (0.94)	14 (56)	1.8 (0.96)	3 (75)
Vaping tetrahydrocannabinol is the main problem. Vaping of nicotine and flavored liquids is not significant clinically (correct answer is 1-2, strongly disagree or disagree).	1.8 (0.75)	22 (88)	1.5 (0.58)	4 (100)
Helping patients who vape is just like helping smokers or drug users (correct answer is 1-2, strongly disagree or disagree).	3.5 (0.85)	3 (16)	2.2 (1.26)	3 (75)

[a]Likert rating: 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree.

In response to 3 Likert-type agreement–style knowledge questions, both vaping expert and nonexpert participants were fairly knowledgeable about several common myths about vaping. Their responses aligned with the correct answer, which was to disagree with the inaccurate statements (Table 3). Experts disagreed more strongly with the statements. Differences were not statistically significant on average. However, 1 statement, “Helping patients who vape is just like helping smokers or drug users,” had a relatively larger difference (1.3 out of 5) between

nonexperts and experts, suggesting a larger gap in the knowledge about this topic.

Participants were also asked, "Compared to quitting cigarettes, quitting vaping of nicotine is (easier, same, harder)." Most participants (24/31, 77%) said it was the same; 19% (6/31) said it was harder, and 6% (2/31) said it was easier to quit vaping. The ratings for experts and nonexperts were similar.

Discussion

Principal Findings

To confirm and prioritize health care professional training gaps in clinical skills and knowledge related to vaping and e-cigarette use, we conducted a needs analysis with health care professionals and experts in vaping. We asked about their need for training in clinical skills and their interest in related topics. To explore whether there was a knowledge gap, we also asked whether they agree with common myths regarding vaping.

Most health care professionals participating in this study agreed that they needed training in key clinical skills on helping patients with vaping, as identified via a literature review. A majority were also interested in learning about a list of key topics related to vaping culled from the literature review. Participant responses to myths about vaping not only showed some awareness of their inaccuracy but also identified areas of misunderstanding. Together, these results suggest that health care professionals perceive a need for training in vaping-related clinical skills, are interested in learning about related key topics, and have a gap in some related knowledge. Results from experts confirmed the need for the clinical skills training and education in key related topics.

The clinical skills that participating health care providers agreed they need involve providing brief interventions, including counseling and motivating on quitting and prevention, recommending treatments, and evaluating and treating the health effects. The finding that training is needed across the range of skills identified in this study highlights the broad training needs of health care professionals in the evolving patient use of vaping and e-cigarettes and associated health concerns.

Experts more strongly agreed that health care professionals need training in each of the clinical skills needed to help their patients with vaping when compared with health care professionals who were not experts on vaping. The reasons for this difference might include health care professionals not being as aware of a training need, providers being better prepared than experts realize, or other reasons, which would require further research to understand.

A majority of participating health professionals who were not experts on vaping were interested in nearly all the vaping-related topics listed in this study. This indicates widespread agreement on what general areas to cover in a vaping training program. The topics with the highest rate of interest, *Pros and cons of vaping versus smoking* (20/25, 80%), *Health effects of second- and third-hand vaping* (19/25, 76%), and *Risks of vaping* (18/25, 72%) can be emphasized.

Further research could explore the reasons for high and low ratings for need and interest to distinguish between lack of interest, lack of relevance for their practice, or already having a particular skill or knowledge.

Participants' relatively higher agreement with a myth that there are no differences between interventions for vaping and other substance use points to an understanding of the similarities but a knowledge gap about the differences that do exist. This confirms knowledge and skills gaps identified in the literature review. Nonexperts in vaping need a better understanding that there are some differences in clinical treatment for vaping and e-cigarette cessation versus smoking cessation to respond to the reinforcing effects of flavoring, different patterns of use, peer influence, and the ability to vape or use e-cigarettes discretely and in more environments [9,10,17,66,67].

The topics physicians were most interested in differed somewhat from those of participating health care professionals as a whole. They showed greater interest in the health effects of vaping and e-cigarettes, recommending treatments, and providing brief interventions for vaping THC. As might be expected from their patient population, primary care physicians rated the need for training higher than nonprimary physicians (average 4.3, SD 0.34 vs 3.9, SD 0.37, out of 5; P=.01). They also indicated more interest in vaping-related topics, endorsing an average of 5.5 versus 3.6 topics (P=.02).

The results support a training for health care professionals on vaping and e-cigarettes that emphasizes the primary care setting and the identified skills and topics. However, fairly low SDs throughout the study, despite over half of the participants being nonphysicians and nonprimary care, support the development of a universally applicable training. The training activities must be flexible enough to address the minor differences in needs based on the health care professionals' work setting and patient population.

Applications

Subsequent to this research, a few more clinical practice guidelines on vaping and e-cigarettes emerged. For example, in 2021, the American Academy of Pediatrics published an e-cigarette curriculum and poster for pediatricians only accessible to members [63]. As adolescents and young adults use these products more than other age groups, and as that young demographic is less likely to see the physician than older individuals, nonphysician health care professionals need this training in addition to pediatric physicians.

Although our work was specific to vaping cessation, some takeaways can be applied to continuing education development for health care professionals in general. Programs on substance use should include content related to health impacts to increase physician engagement and interest. In addition, content related to clinical skills should focus on specific areas where this research demonstrated gaps between the health care professionals' self-perceived understanding of their training needs and real-world outcomes, such as the need to adapt counseling and interviewing techniques to the specific substance and cultural, racial, ethnic, and socioeconomic differences. In addition, health care professionals may need to be persuaded

that topics favored more highly by experts on a topic are relevant to their practice and patient population.

After identifying health care professionals' training needs and practice gaps, we developed 3 case-based web-based training activities focused on the clinical skills identified. These activities are currently available in the studies by Rossie [68-70]. In an early evaluation of that program with 78 health care professionals, most users indicated improvement in their knowledge (74/78, 95%) and competence (66/78, 85%). The learners gave high ratings for their vaping-related self-efficacy (4.3 out of 5), intended behavior (4.3 out of 5), and attitude (4.3 out of 5) following the completion of the program. An analysis of the educational impact of the activities is ongoing.

e-Cigarettes and vaping are not the *safe alternative* to cigarette use, as initially presented by the industry. Patients who vape, use e-cigarettes, or are considering using them will benefit from health care professionals who are able and ready to intervene with prevention, evaluation, and cessation strategies. Health care professionals who are adequately trained regarding patient vaping and e-cigarette use will decrease the burden of nicotine, THC, and harmful chemicals used in these products on patient health.

Key Findings

Most participants agreed that clinicians need more training on vaping across a list of clinical skills commonly used to address substance use. However, experts' agreement was stronger.

Health care professionals without expertise in vaping understood their need for training in clinical skills related to vaping, as was evident by selecting similar needs to what experts selected. However, expert agreement on needs was significantly stronger, on average.

Health care professionals agreed most strongly that they need clinical skills training in recommending treatments for patients who vape or use e-cigarettes and evaluating and treating health effects in patients who vape or use e-cigarettes.

There was strong interest by most participants who were not experts in vaping in learning about most topics on a list of key topics about vaping. The strongest interest was in the pros and cons of vaping versus smoking and the health effects of second- and third-hand vaping.

Physicians in primary care more frequently expressed interest in topics related to vaping and e-cigarette use than those not in primary care. Physicians had greater interest in the health impact of vaping than other health care professionals.

Participants showed a moderately good understanding of myths about vaping from a clinical perspective but need better awareness of the differences between treating a patient for vaping and other substance use.

Limitations

This research was limited by searching only 3 major databases of journals in our literature review, PubMed, Google Scholar, and PsycIINFO. For example, we did not search for Scopus and CINAHL, which have relevancy because of the clinical nature of this topic. We may have missed some topics mentioned in articles indexed only in the sources not used.

Limitations related to sampling may have affected the results. We elected to use a convenience sample owing to the time frame and funding available. Thus, the participants may not represent the health care professionals as a whole.

Several limitations are related to study participants. We directed half of our recruitment efforts to a list of health care professionals who had taken our other substance use courses because we wanted to understand the needs of our typical audience. Consequently, participants may have more interest in and knowledge about substance use than the average health care professional. An honorarium provided to participants may have introduced a bias toward participation or more positive feedback. The small number of experts in this study limits comparisons of experts with nonexperts. Although we had participant recruitment efforts that specifically sought to increase the diversity of the sample, African American health care professionals were not represented.

Finally, questions were not randomized owing to limitations of the software used, which may have resulted in items near the top of the checklist being chosen more often than they would have otherwise.

Conclusions

Using a survey derived from a literature review and expert knowledge, we identified health care professionals' perception of their need for training in clinical skills, their interests, and their knowledge related to vaping and e-cigarette use by patients. The list of clinical skills training needed and topics of interest for health care professionals identified in this study confirms the need identified in the literature and adds prioritization according to which skills and topics had the greatest need and interest. This information can contribute to the effective focus of the growing body of training on helping patients who vape or use e-cigarettes or considering use. Combining literature review with expert opinion and health care professionals' interest enabled us to develop a targeted curriculum to address the clinical skills gaps and the evolving health concerns of vaping and e-cigarette use. The results suggest that vaping and e-cigarette use is an area where health care professional training would benefit.

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Conflicts of Interest

The authors are employees of Clinical Tools, the small business that received the National Institute on Drug Abuse grant to perform this needs analysis. BT is the principal investigator of the grant and owner of Clinical Tools, Inc. Clinical Tools may profit from products created as a result of the grant.

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Abbreviations

FDA: Food and Drug Administration
THC: tetrahydrocannabinol

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Original Paper

Medical-Blocks A Platform for Exploration, Management, Analysis, and Sharing of Data in Biomedical Research: System Development and Integration Results

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Abstract

Background: Biomedical research requires health care institutions to provide sensitive clinical data to leverage data science and artificial intelligence technologies. However, providing researchers access to health care data in a simple and secure manner proves to be challenging for health care institutions.

Objective: This study aims to introduce and describe Medical-Blocks, a platform for exploration, management, analysis, and sharing of data in biomedical research.

Methods: The specification requirements for Medical-Blocks included connection to data sources of health care institutions with an interface for data exploration, management of data in an internal file storage system, data analysis through visualization and classification of data, and data sharing via a file hosting service for collaboration. Medical-Blocks should be simple to use via a web-based user interface and extensible with new functionalities by a modular design via microservices (*blocks*). The scalability of the platform should be ensured through containerization. Security and legal regulations were considered during development.

Results: Medical-Blocks is a web application that runs in the cloud or as a local instance at a health care institution. Local instances of Medical-Blocks access data sources such as electronic health records and picture archiving and communication system at health care institutions. Researchers and clinicians can explore, manage, and analyze the available data through Medical-Blocks. Data analysis involves the classification of data for metadata extraction and the formation of cohorts. In collaborations, metadata (eg, the number of patients per cohort) or the data alone can be shared through Medical-Blocks locally or via a cloud instance with other researchers and clinicians.

Conclusions: Medical-Blocks facilitates biomedical research by providing a centralized platform to interact with medical data in collaborative research projects. Access to and management of medical data are simplified. Data can be swiftly analyzed to form cohorts for research and be shared among researchers. The modularity of Medical-Blocks makes the platform feasible for biomedical research where heterogeneous medical data are required.

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KEYWORDS

biomedical research; data sharing; data handling; data science; platform; software; translational medical research; medical informatics; PACS; DICOM

Introduction

Health care institutions are increasingly challenged by the need to balance the increasingly complex clinical pathways and socioeconomic costs. Digital transformation in health care is expected to address this challenge [1]. More accurate and rapid diagnosis, management, and treatment are anticipated through personalized and precision medicine [2,3]. However, combining health care data with biomedical research proves to be difficult and cumbersome for health care institutions, even if the researchers are based at the institutions itself.

Most health care data are available at the level of the health care institutions, often only accessible by clinical personnel and not by biomedical researchers themselves. The availability of data is even more complicated for multicenter research, which is preferable because of the increased sample size, statistical power, and improved generalizability of research [4]. Even if data are available, regulations make data sharing difficult and hinder collaborative research. Although federated learning promises to alleviate the challenge of data sharing, it is a rather new concept that requires expert knowledge, and it is not straightforward to implement. Therefore, the accessibility and sharing of data originating from single or even multiple centers to biomedical research would be advantageous for today's evidence-based medicine [2,5,6].

Besides the availability of data, the complexity and heterogeneity of data in health care make data-driven biomedical research even more difficult [7-10]. Answering research questions and characterizing diseases often involves diverse and interdisciplinary data [11], ranging from metadata (eg, demographics), clinical information (eg, clinical history and cognitive scores), biological specimens (eg, blood samples), physiological data (eg, electroencephalography), and imaging data (eg, magnetic resonance) to other auxiliary data; that is, multi-omics research. Using such diverse data, a more comprehensive understanding of the diseases and drawing stronger conclusions might be possible [9,12]. However, preparing, handling, and curating heterogeneous data can be tedious and costly [2] before even a single hypothesis can be tested. Knowledge of the available data and means of simple and fast extraction and management of the data from health care institutions are, therefore, key to successful biomedical research.

The development of software platforms facilitating data exploration, management, analysis, and sharing for biomedical research is ongoing, as some previous reviews [9,10,13-15] summarize. Among the numerous existing platforms, those that are most relevant to this work, which are presented on the use case of medical imaging, are summarized hereafter. XNAT (Extensible Neuroimaging Archive Toolkit) [16] is a platform that allows the storage, processing, and sharing of data in biomedical research, with an emphasis on medical images. The virtual skeleton database [17] allows sharing of data in a web-based repository. GIFT-Cloud (Guided Instrumentation for Fetal Therapy and Surgery) [18] is a data sharing and medical image–sharing platform that simplifies the transfer of data from clinics to research. JIP (Joint Imaging Platform) [19] tackles data sharing using a federated approach, which enables the decentralized use of medical images for algorithm development. KETOS [20] is a platform for data analysis, training, and deployment of artificial intelligence (AI) methodologies in health care settings. PRISM (Platform for Imaging in Precision Medicine) [21] handles medical images and associated clinical data, allows the creation of cohorts, and provides image curation functionalities in the setting of the Cancer Imaging Archive. However, most of the available platforms require data to be extracted and curated beforehand and are nonmodularizable; that is, the platforms usually do not provide support if researchers want to use uncommon types of data.

We present Medical-Blocks, a platform that enables exploration, management, analysis, and sharing of data in biomedical research. On the basis of the increasing demand to share and analyze health care data for research, we hypothesize that Medical-Blocks enables swift and secure data exchange. Medical-Blocks can be used as a cloud application or a network of local instances in multi-institutional research, or as a local instance at a single institution, depending on the data sharing and protection regulations. It is adaptable and modularizable to the needs of the particularities of the biomedical research conducted and, hence, the required data.

Methods

Overview of Medical-Blocks

Medical-Blocks allows the exploration of data available at clinical systems, management and analysis of these data for research, and sharing of data between institutions for collaborative research. To this end, Medical-Blocks can be connected to data sources of clinical systems (eg, databases such as electronic health records [EHRs] and picture archiving and communication system [PACS]) at health care institutions by blocks. Users can explore the data in the clinical systems through Medical-Blocks, without interfering with the clinical workflow. After identifying data that are suitable for further investigation (eg, within a clinical study), the data can be imported to and managed within Medical-Blocks. Medical-Blocks allows analysis of the data through data visualization, editing, and (automatic) classification by labeling the data such that it becomes research-friendly. By classification of the data, metadata of the data becomes available to the users (eg, number of patients and number of images of a certain type). Therefore, Medical-Blocks allows swift exploration and management of the available data for biomedical research at health care institutions. Furthermore, the metadata or data can be shared through Medical-Blocks from instance to instance or via the cloud in research collaborations.

An exemplary use of Medical-Blocks in a research collaboration between hospitals is illustrated in Figure 1. Medical-Blocks operates both in the cloud and locally at an institution. In both cases, it features the same functionalities. The cloud instance allows users to connect to Medical-Blocks and to perform management and analysis of data from all over the world. Metadata and data can be shared to this cloud instance either from local instances of Medical-Blocks at health care institutions or data can also be imported directly to the cloud, if compliant

with the legal regulations (eg, only anonymized data). At health care institutions, Medical-Blocks can be directly connected to the data sources of the clinical systems.

Medical-Blocks is implemented as a web application that relies on a client-server model. The implementation of the front end is illustrated in Figure 2. The React library [22] is used to build the user interface (UI) with its web components (tables, combo boxes, etc), which are based on the Material-UI library [23]. The Redux library [24] oversees variables that are used by the web components of the UI and notifies them upon changes in the data. The Axios HTTP client library [25] is used to query, upload, and download data between the web components and the back end's application programing interfaces (APIs) such as GraphQL and representational state transfer (REST) APIs.

The back end is based on the ExpressJS framework [26] that exposes two end points (Figure 3): a GraphQL and REST download end point. The GraphQL [27] end point is implemented using the Apollo server library [28], which handles the query, mutations, and upload events triggered by the clients. Owing to the limitations of the Apollo server library in handling file download events, a download end point was created. The implementation of the download end point was based on the RESTful API. GraphQL ensures communication with the local SQL server through the Sequelize NodeJS library [29]. Files were redirected to an internal files system using NodeJS [30]. To notify clients about events (variables, messages, and new files), we used the subscription system of GraphQL in conjunction with a Redis database [31]. A NodeJS Docker API was implemented to handle the communication to the Docker containers [32]—the so-called blocks. The Docker containers can connect to the APIs of the clinical systems. Details on the technical implementation, such as the PACS and EHR connections, are provided in Multimedia Appendix 1 [27-30,32-38] and referenced accordingly in the subsequent sections.

Figure 1. Illustration of the use of Medical-Blocks in a research collaboration between 2 health care institutions via the cloud or direct connection. At each health care institution, a local instance of Medical-Blocks is set up, which accesses the data sources of the health care institution (eg, electronic health records and picture archiving and communications system). Researchers and clinicians can explore, manage, and analyze the available data through Medical-Blocks. For collaboration, metadata (eg, number of patients per cohort) or the data itself can be shared through Medical-Blocks via a cloud instance with other researchers and clinicians. Metadata and data can also be shared directly between local instances of Medical-Blocks from institution to institution.

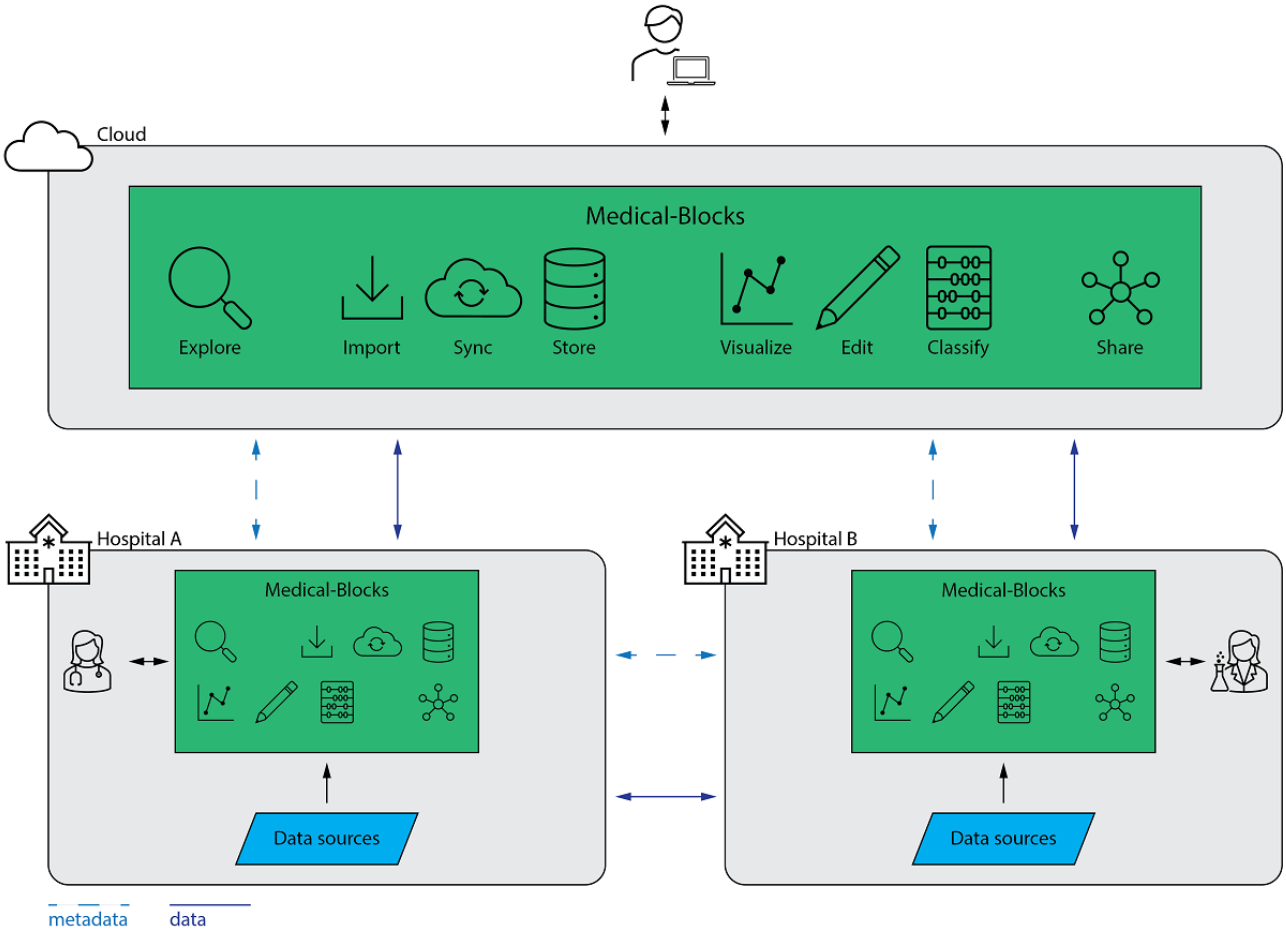


Figure 2. The front end of Medical-Blocks is built using the React library with Material-user interface web components. An Axios HTTP client communicates with the back end of Medical-Blocks. UI: user interface.

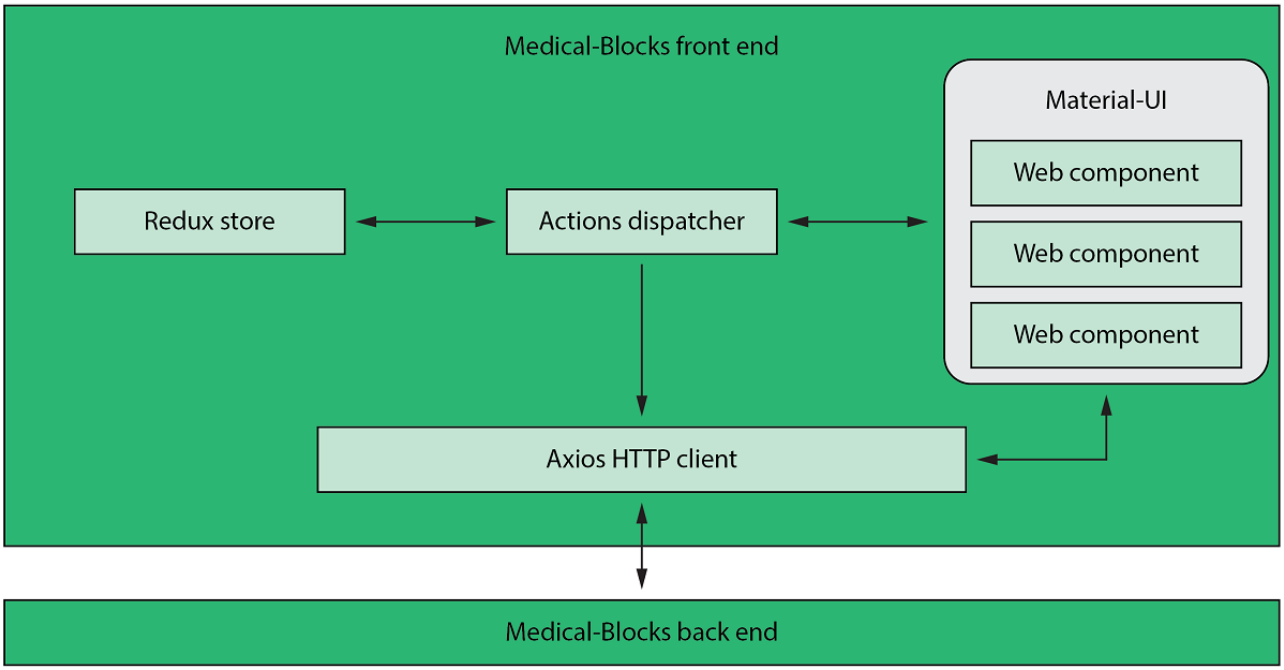
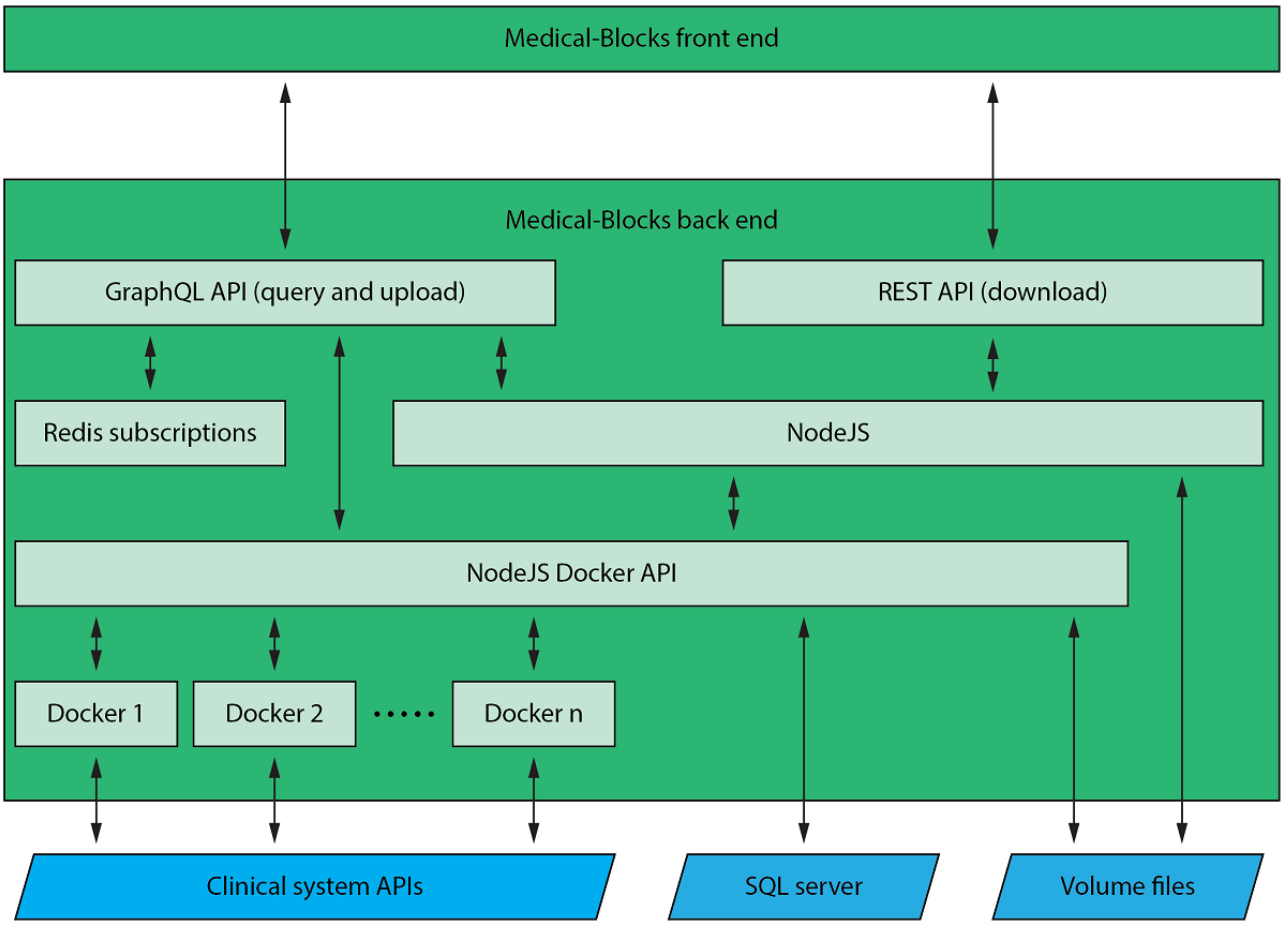


Figure 3. The back end of Medical-Blocks is based on ExpressJS and exposes a GraphQL and download end point. NodeJS is used to communicate with Docker containers—the so-called blocks—that can connect the clinical systems. API: application programming interface; REST: representational state transfer.



Main Features

The main features of Medical-Blocks can be broken down into data exploration, data management, data analysis, and data sharing.

Data Exploration

Medical-Blocks can be connected to the data sources of clinical systems, which allows users to explore the data available within an institution. The type of connected data sources, that is, systems and databases, depends on the type of research being conducted. Currently, Medical-Blocks is connected to PACS, EHR, and electroencephalography data sources (section S1 in Multimedia Appendix 1). The connections to the individual systems of the data sources are established through the APIs of these systems by Docker containers (*blocks*) specific to each connected clinical system.

Data Management

Medical-Blocks allows the management of data for research, which includes the import of data from data sources to its internal storage system. Data import is possible in three ways: manually by a user over the web UI, semiautomatically using standalone applications (through MB-Connect and MB-Sync described later), or automatically via blocks triggered upon new data being available. For example, the clinical PACS automatically sends a copy of the data (medical image in Digital Imaging and Communications in Medicine [DICOM]) format) to Medical-Blocks. The block processes data into the required format, such as anonymization (eg, removing patient-related information) and conversion to another data format (eg, DICOM to MetaImage conversion). For uncommon data types, the modular architecture of Medical-Blocks allows the integration of new blocks (section S2 in Multimedia Appendix 1).

Medical-Blocks stores data files and information in its own internal system (SQL server and volume files in Figure 3). Storing the data separately allows modification of data such as anonymization and conversion without altering the original data in the institution's system. The platform provides permanent storage of data prepared for research, which makes the data easily accessible for future research and, therefore, lowers the effort of data collection and preparation. This is in line with the FAIR data principles [39]; that is, findability, accessibility, interoperability, and reusability. Furthermore, the importation to Medical-Blocks lowers the number of requests to the institution's systems to the minimum, which is only accessed during data exploration and import.

Data Analysis

Medical-Blocks allows the analysis of stored data through metadata. Metadata becomes available through analysis blocks that automatically classify and label newly stored data upon import or by manual triggering. Such metadata could be, for instance, the type of disease or the imaging sequence, which is described further in section S3 in Multimedia Appendix 1. As the analysis depends on blocks and the modularity of Medical-Blocks allows the integration of new blocks (section S2 in Multimedia Appendix 1), the type of analysis performed, and therefore the metadata, is user- and project-specific. If an automatic extraction through blocks is not possible, metadata can also be added by the user manually. Data can also be visualized and inspected using the built-in viewers in the platform (eg, image viewer for images).

The metadata provides a research-friendly summary of the available data via a dashboard. This summary might facilitate the creation of potential cohorts for research, which is often a time-consuming process. Therefore, metadata offers the potential to explore the available data in a more research-driven manner. Such exploration is usually not provided by clinical systems, which rarely come with features that facilitate research, as they function at the level of individual patients rather than cohorts.

Data Sharing

Data sharing is one of the core features of Medical-Blocks. A built-in file hosting service via the cloud permits sharing of data, similar to well-known file hosting services such as Dropbox. The extent of sharing is freely configurable by providing individual users, groups of users, and even users from other institutions access to the cloud. Therefore, Medical-Blocks meets the requirements of biomedical research, where collaboration is often key to success.

The data can be shared on two levels: (1) sharing of metadata and (2) sharing of full data. The sharing of metadata allows the exchange of summaries of the available data based on the data analysis performed in Medical-Blocks. Therefore, researchers can explore the available data without sharing the actual underlying data. In research involving multiple groups and multicenter research, sharing metadata allows exploring potential collaborations regarding aspects such as data set size and data composition. As only metadata are shared, the potential abuse of data is prevented. As soon as all stakeholders agree, Medical-Blocks then allows researchers to exchange the full data that underlies the metadata.

Design Principles

The design of Medical-Blocks adheres to five principles: (1) simplicity, (2) flexibility, (3) modularity, (4) scalability, and (5) security.

Simplicity and Flexibility

Medical-Blocks is accessible via a web UI, which allows researchers to interact with various data formats available at health care institutions within one interface. Domain knowledge regarding clinical systems and access to software specific to data formats (eg, PACS use and access) is not required for researchers. Furthermore, the web UI makes the platform agnostic to specific hardware and operating systems requirements.

Metadata simplifies the exploration of potential cohorts for research through a dashboard view of the UI. This contrasts with accessing different clinical systems to search for potential cohorts, which can be a tedious process depending on the number of clinical systems involved. Beyond the dashboard, technically versed users can also use the GraphQL playground for exploration (section S4 in Multimedia Appendix 1).

Data sharing and access to data are further facilitated by standalone sync applications that can be installed on PCs, which

reduces interactions with the web UI and allows files to be uploaded to Medical-Blocks via the file explorer. Their functionality is very similar to well-known file hosting services; that is, shared data are directly synchronized to the file system and are accessible via the file explorer of the operating system. There are two versions of the sync application: a full version (MB-Sync) and a lightweight version (MB-SyncLight). The lightweight version works only unidirectionally; that is, data are only synced from the platform to the client. This also allows sharing of data with users who are not registered users of Medical-Blocks by providing a token for access. The full version works bidirectionally; that is, data can be synced from Medical-Blocks to the client, and vice versa. The sync applications are available for the operating systems Windows, macOS, and Linux. Details of the technical implementation are provided in section S5 in Multimedia Appendix 1.

Medical-Blocks offers various features that facilitate project management, as synchronizing the communication between multiple researchers and keeping track of the current state of a research project are often cumbersome. This is further complicated if multiple institutions and researchers are involved in multiple projects. Medical-Blocks facilitates project management through a communication, notification, and activity logging system. Users can access the status of a project and review what other users have been doing in the project, if new data are available, among others. Using the communication system, users can communicate with each other and with the teams to which they are assigned.

Modularity

Medical-Blocks is modularizable to adequately cope with the complexity of the information technology (IT) ecosystems of modern hospitals, such as multiple vendors, different APIs, and security restrictions. Individual patient data are typically stored in various systems at an institution (eg, clinical, laboratory, and radiology). To obtain an entire view of the electronic medical record of a patient, the data needs to be pooled from these individual systems, which can be a cumbersome process for researchers because of the different interfaces to access the systems. Medical-Blocks simplifies access to data by using blocks tailored to connect to the clinical systems through their APIs. These blocks allow a flexible adaptation of Medical-Blocks to the IT ecosystem of the health care institutions and for different research projects. Depending on the type of research project, a block can be integrated to access data from a previously unconnected clinical system.

Scalability

Medical-Blocks is intended for use at various levels of operations. The first level is the use as a cloud instance or local instance at a health care institution without any connection to clinical systems; that is, data are imported manually through the web UI. The next level is the connection to the clinical systems of the health care institution. Further levels are then the connection to other Medical-Blocks; that is, from institution to institution and to the cloud. The connection to the clinical systems is possible in two ways: (1) by directly connecting a Medical-Blocks instance and (2) by using MB-Connect. Connecting Medical-Blocks necessitates a local instance running on a server, which may not always be desired and feasible. Therefore, MB-Connect, a software plug-in, can be used at health care institutions as a bridge to a cloud instance of Medical-Blocks (section S6 in Multimedia Appendix 1). Therefore, the use of Medical-Blocks can be adjusted depending on the requirements of the health care institutions and the size of the research collaboration.

Scalability is directly linked to the available resources Medical-Blocks runs on. To ensure scalability, Medical-Blocks leverages operating system virtualization; that is, the main core of Medical-Blocks is designed as containers that store and run their corresponding functionality. Using Kubernetes (Cloud Native Computing Foundation), the containers can be scaled according to the live demand of resources. Depending on the estimated maximum resource requirements, Medical-Blocks can run on low-cost hardware such as Raspberry Pi (Raspberry Pi Foundation) to enterprise products such as Google Cloud (Google Inc). Hardware can be locally installed, virtualized, and cloud-based. Easy scalability is especially important as big data and data-driven methods are becoming more prevalent in biomedical research [3,5,10], which will result in an increased demand for the storage and management of data. Furthermore, having the possibility of running instances at a smaller scale allows the inclusion of smaller institutions and their data owing to relatively flexible hardware requirements.

Security

Security is a key requirement for software that interacts with health care data. The security and privacy of health care data are usually regulated at the national or international level; for example, in the United States through the Health Insurance Portability and Accountability Act of 1996 and in the European Union through the General Data Protection Regulation. Therefore, software interacting with health care data must adhere to the regulations of the countries in which the software is being deployed. In Switzerland, the management of health care data for research requires at least three main security features (Ordinance on Clinical Trials in Human Research 810.305; Article 18): (1) restricted access, (2) user rights, and (3) traceability of operations.

Medical-Blocks provides restricted access, user rights, and traceability of operations performed on data. Restricted access is enforced by a secure log-in to the platform (section S7 in Multimedia Appendix 1). Rights can be assigned at the user level to prevent unwanted import, access, and modifications. All operations (ie, import, access, and modifications) performed on the data by the system and users are logged and saved for a potential audit. Therefore, Medical-Blocks adheres to the common legal and ethical regulations in biomedical research. It must be noted that such features are not necessarily implemented in clinical systems (eg, clinicians often have access to all patients without specific restrictions).

The user management of Medical-Blocks allows to define roles from the level of projects to teams, down to the level of single users. The principal investigator can define the data, teams, and users involved in a project. To simplify user management, teams of users can be formed with team-wide rights, which can be assigned to projects. Rights can also be defined at the user level;

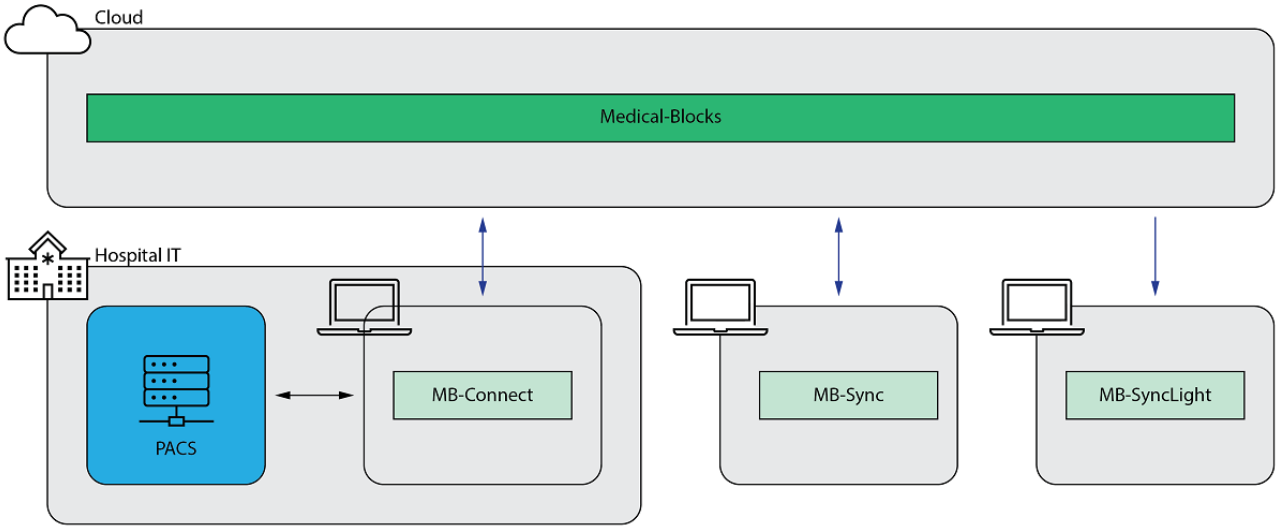
for instance, clinicians can access deanonymized data, whereas researchers can only access anonymized data. Generally, data imported into Medical-Blocks gets assigned to the user who performs the import, which is the first measure to prevent abuse of data as it is only accessible by this user. Furthermore, data exploration and import are restricted to specific users to prevent unauthorized access to clinical systems. Users can be restricted to only see metadata instead of the true underlying data. Similar to exploration and import, data sharing is also restricted to specific users.

Medical-Blocks at the Inselspital

We present Medical-Blocks on the use case of medical imaging and how the platform is currently being used at the Inselspital (University Hospital of Bern, Bern, Switzerland). This use case encompasses mostly research in the field of quantitative medical image analysis, involving the processing of medical images using AI developed to extract quantitative imaging biomarkers for monitoring of treatment response and as an outcome measure. To do so, researchers need to have access to medical images acquired in daily clinical routine to develop and evaluate AI methodologies on real-world data. To date, this process has been tedious because it involves accessing the PACS of the hospital to query and retrieve medial images of potential cases in the DICOM format. Subsequently, researchers had to anonymize and convert the DICOM images to a regulatory-complying and research-friendly format. Furthermore, the medical images had to be linked to complementary (clinical) information such as demographic variables and diagnoses extracted from other clinical systems.

Medical-Blocks was integrated into the IT imaging ecosystem at our hospital (Figure 4). We opted to use Medical-Blocks as a cloud instance, which does not necessitate the installation of Medical-Blocks at the hospital but, in turn, necessitates that all data contained in Medical-Blocks must be anonymized to comply with the legal regulations of the responsible authorities. Therefore, we use MB-Connect to access the unanonymized data of the PACS, anonymize the data, and send the data to Medical-Blocks in a semiautomatic manner. MB-Connect was integrated into an in-house DICOM viewer as a plug-in (MB-Viewer; section S6 in Multimedia Appendix 1). Upon import, the users of Medical-Blocks can access the data via the web UI from anywhere. Furthermore, the data can be synchronized and shared with any computer by two synchronization applications: MB-Sync and MB-SyncLight.

Figure 4. Overview of Medical-Blocks as used at our hospital. Owing to legal regulations, the picture archiving and communications system cannot be directly connected to Medical-Blocks as patient-identifying would be shared over the internet. Therefore, we use the MB-Connect plug-in within an in-house Digital Imaging and Communications in Medicine viewer for uploading anonymized medical images to Medical-Blocks. Users of Medical-Blocks can access the data via the web user interface. Synchronization of data to the user's file systems is possible by two synchronization applications (MB-Sync and MB-SyncLight). IT: information technology; PACS: picture archiving and communication system.



Results

We present the results of the development of Medical-Blocks separated into the main features of data exploration, data management, data analysis, and data sharing.

Data Exploration

The dashboard with a summary of the metadata is presented to the user upon log-in into Medical-Blocks (Figure 5). The number of cases, studies, and series available become directly visible to the user. It also presents summaries on anatomical regions, sequence, and the type of pathology. Furthermore, the dashboard presents the latest activities within the project to the user. Moreover, only the metadata and activities of the project or projects to which the user has access are shown.

Exploring available data in the clinical systems at the institution and in Medical-Blocks is possible in the Query/Retrieve section (Figure 6). Querying of data is similar to that in commercial PACS software: querying by patient name, patient ID, accession number, date of birth, study description, unique identifiers, and image properties. The query can be refined by date, image modality, and image properties options. A query will list all results that match the search criteria. If Medical-Blocks is not directly connected to the PACS of the hospital, it only retrieves results from the data contained within the platform. If Medical-Blocks is connected to a PACS, a query lists the results

from the PACS that can be explored and imported without the need of having access to the actual clinical systems (the PACS viewer in this case). This feature can be limited to certain users of Medical-Blocks to prevent abuse. Medical-Blocks further ensures that all queries and imports are logged.

Figure 5. Dashboard of Medical-Blocks shown upon log-in to the platform. The dashboard visualizes the metadata; that is, it provides a concise summary of the available data.

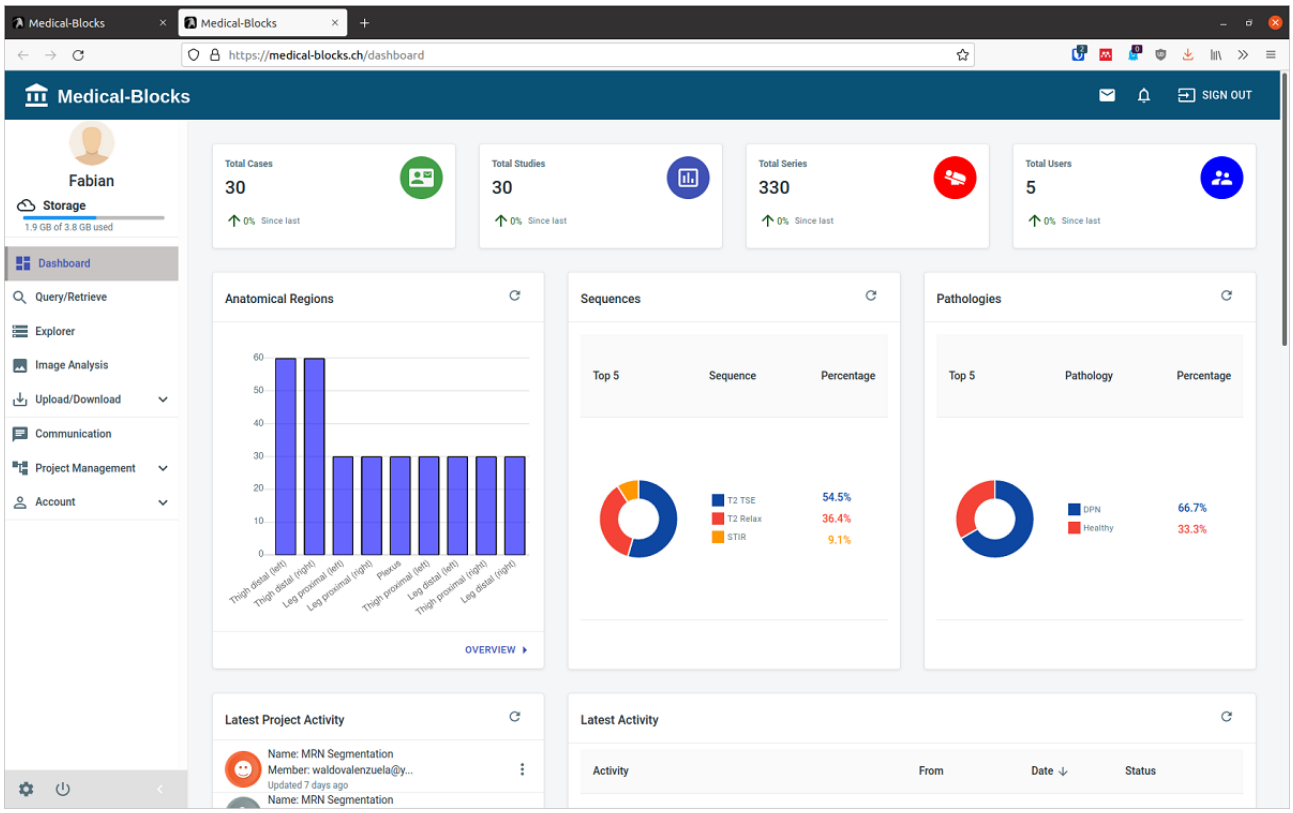
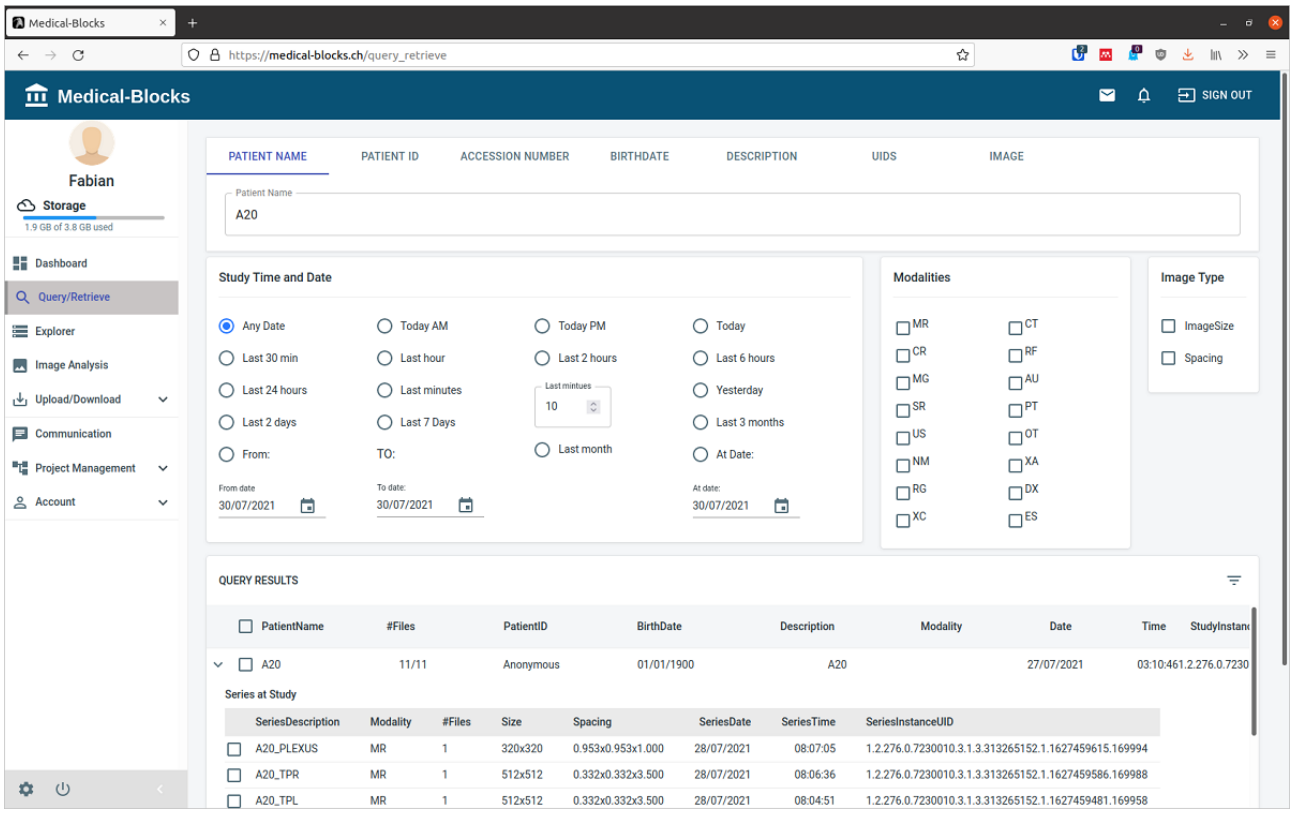


Figure 6. Data exploration through the Query/Retrieve section. Upon entering a patient name, the available data in Medical-Blocks search for matching entries, which are listed in the query results. The query can be refined by restricting it to a certain date or a range of dates, imaging modalities, and image properties.



Data Management

The Explorer section of Medical-Blocks allows the inspection of available data in the platform (Figure 7). The Explorer section works like explorers known from today's operating systems. It allows the user to rearrange files into folders, copy files, cut files, paste files, and remove files. The explorer is agnostic to the type of data; that is, electroencephalography or text documents are also displayed in the Explorer section. Furthermore, the explorer has a drop feature that allows users to import a file directly in the Explorer section, facilitating the way of moving files to Medical-Blocks for sharing.

Import of data to Medical-Blocks is possible through the Query/Retrieve section (if Medical-Blocks is connected to a clinical system), MB-Connect, MB-Sync, and manually. The manual Upload/Download section (Figure 8) extends the import capabilities of the explorer to multifile import. The file or files to be imported can be selected from the file system of the computer by a file system dialogue or directly imported by dropping to the Upload/Download section. Once imported, the files become visible in the explorer.

Figure 7. Overview of the available data in Medical-Blocks through the Explorer section. The explorer allows files to be managed in a manner similar to that of file explorers in current operating systems. Here, 30 folders containing image data, 1 CSV file, and 8 electroencephalography files are present.

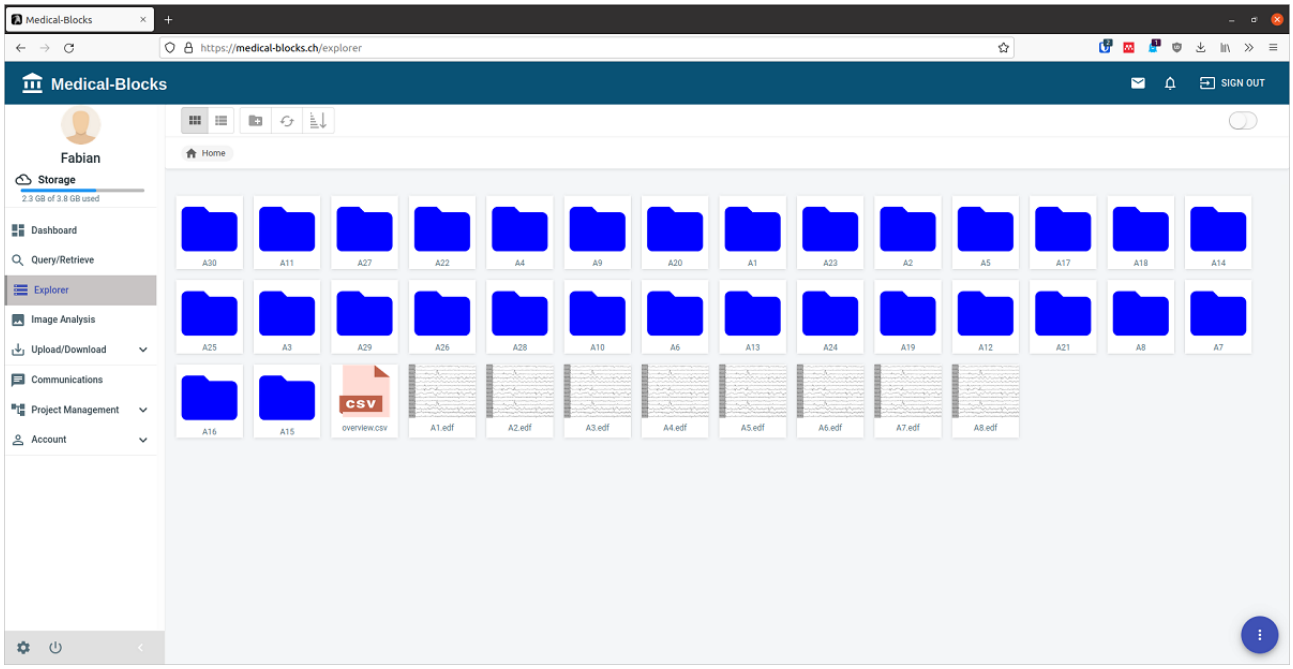
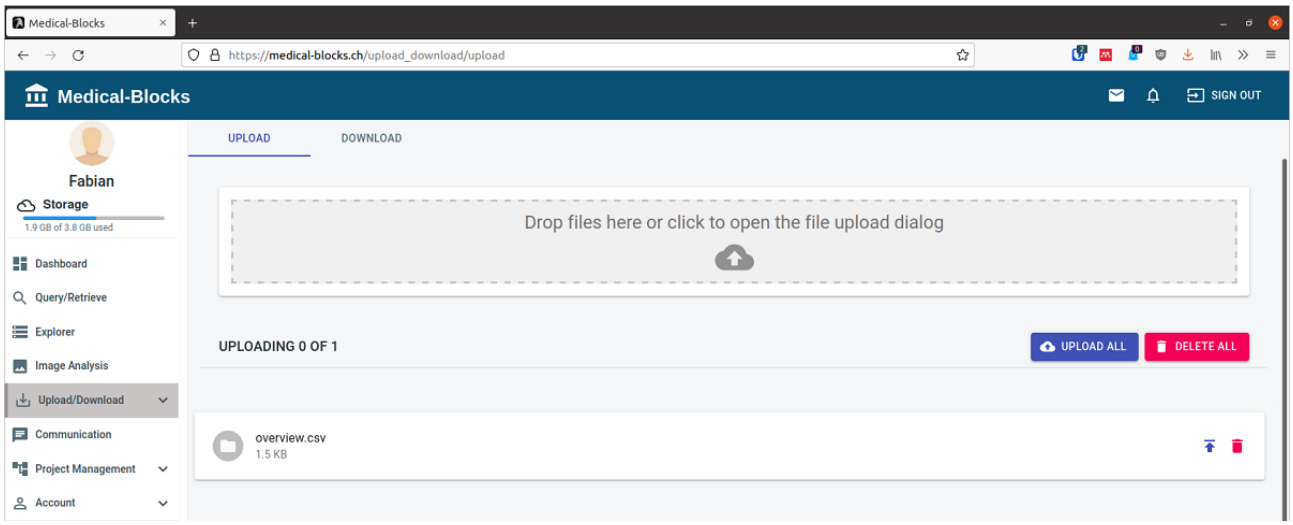


Figure 8. Manual import of data to Medical-Blocks. Files to be imported can be selected using a file system dialogue or by dropping the files to the user interface of Medical-Blocks.



Data Analysis

Medical-Blocks presents a summary of the data available in the form of metadata in the dashboard of Medical-Blocks (Figure 6), which allows a high level of automation in the data analysis. Furthermore, the built-in viewer allows, for example, the inspection of medical images directly via the web UI (Figure 9). A section for manual classification appears when selecting a file (Figure 10). This section allows to correct wrong classifications and to add user-defined classifications that are not automatically extracted by the blocks.

Figure 9. The built-in viewer allows to inspect the different image slices of a medical image within Medical-Blocks.

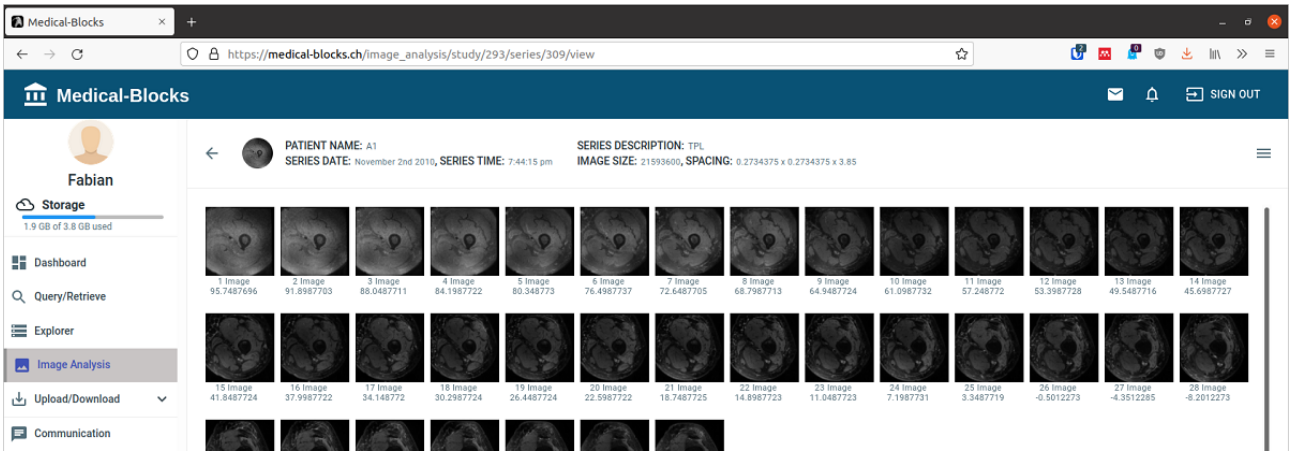
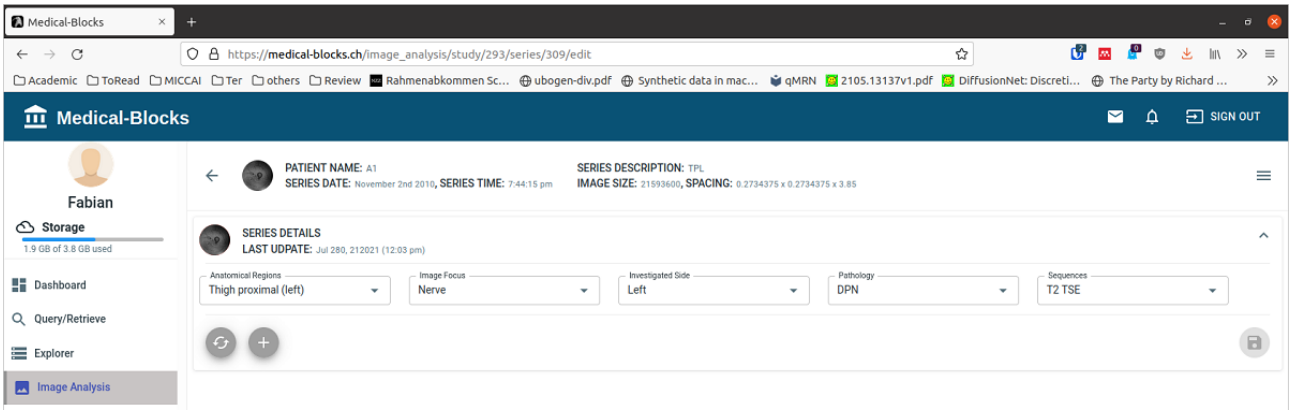


Figure 10. The process of manually classifying data in Medical-Blocks. By selecting a medical image, it can be classified according to anatomical region, image focus, investigated side, pathology, and sequence.



Data Sharing

Sharing of data via Medical-Blocks is possible in multiple ways. First, users see the metadata of the available data in Medical-Blocks on a project-level in the dashboard by default (Figure 5). Second, the owner can provide access to the data to other users or projects in a corresponding dialogue of the explorer or by generating a share link, as shown in Figure 11. As soon as access rights are granted, data will appear in the explorer of the other user or users. Third, synchronization applications MB-Sync and MB-SyncLight can be used for sharing.

Using the synchronization applications, data from Medical-Blocks can be synchronized to any computer's file system, as shown in Figure 12. Access to data can be granted on a folder level in the explorer; that is, by sharing a link to a user of the synchronization application (Figure 11). Data access can also be granted to people who are not users of Medical-Blocks by generating a SYNC CODE (Figure 12). This code can be used with MB-SyncLite to retrieve data from Medical-Blocks without being a user of the platform.

Figure 11. The sharing of data in Medical-Blocks. (A) The owner of the data within the explorer gives read access to the data to another user (Waldo Valenzuela) and a project (MRN Segmentation). The files will now appear in the explorer dialogue of the user Waldo Valenzuela and for all users assigned to the project MRN Segmentation (with appropriate user rights to view data). (B) Share links for direct sharing of data can be automatically generated.

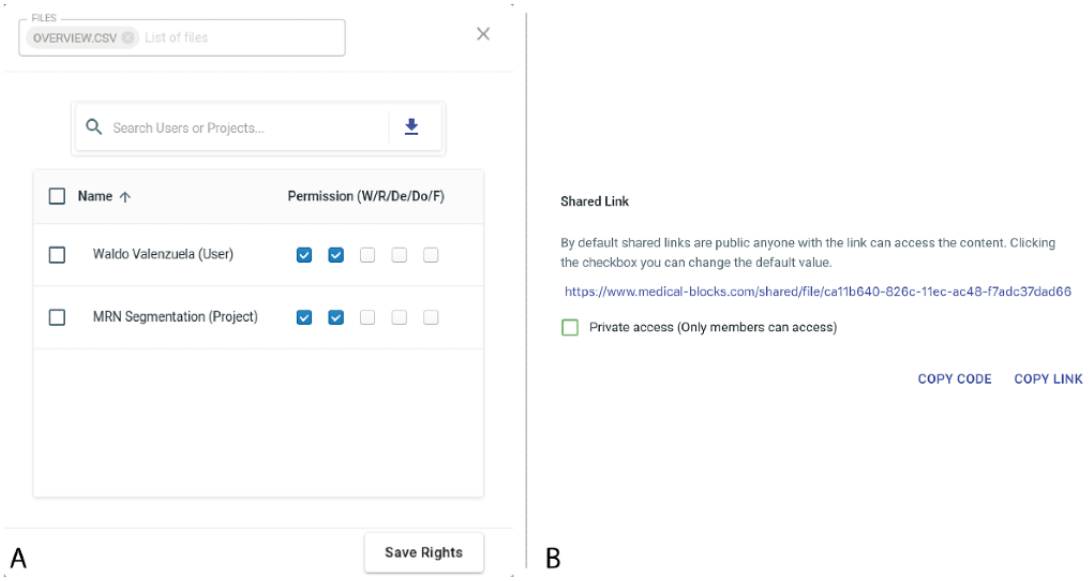
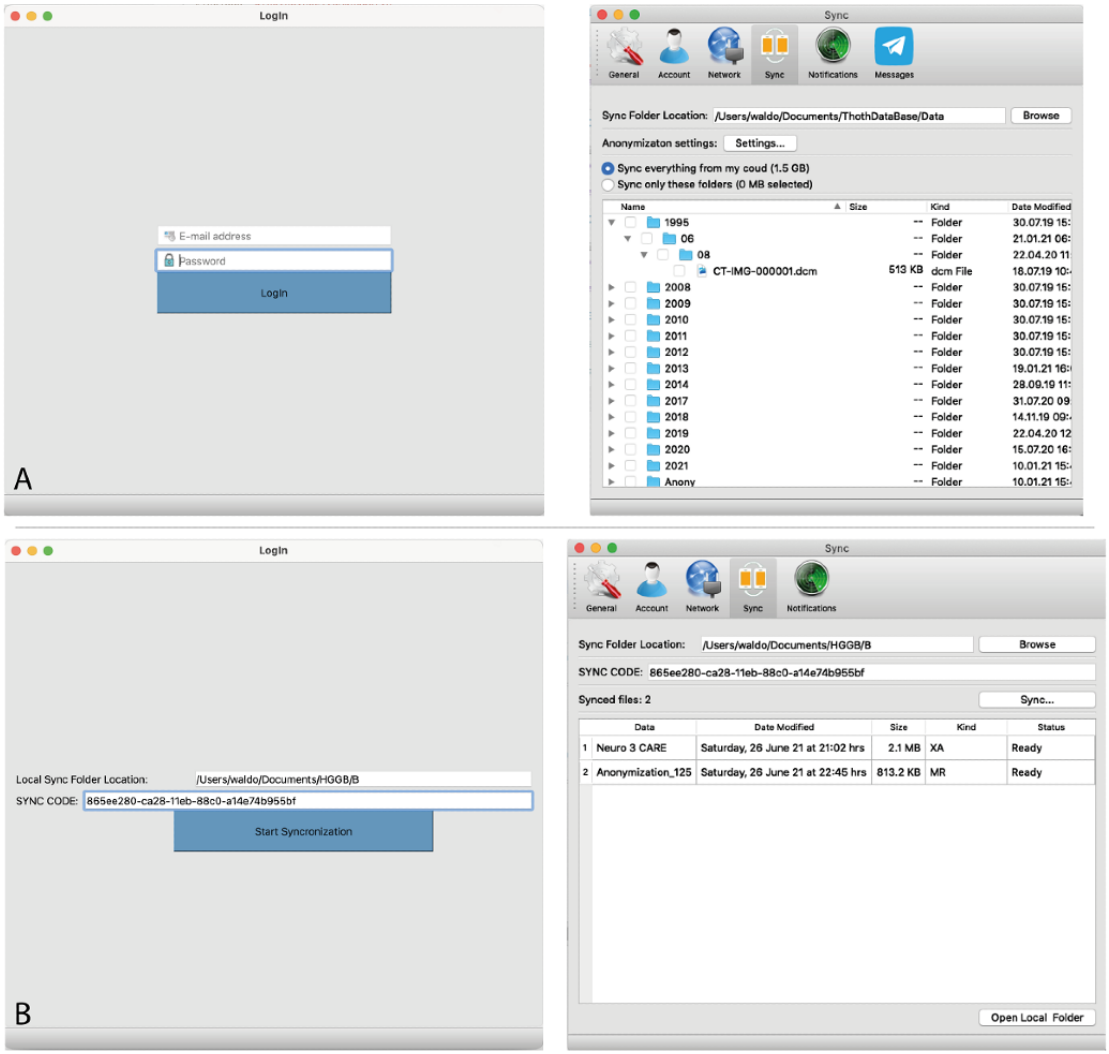


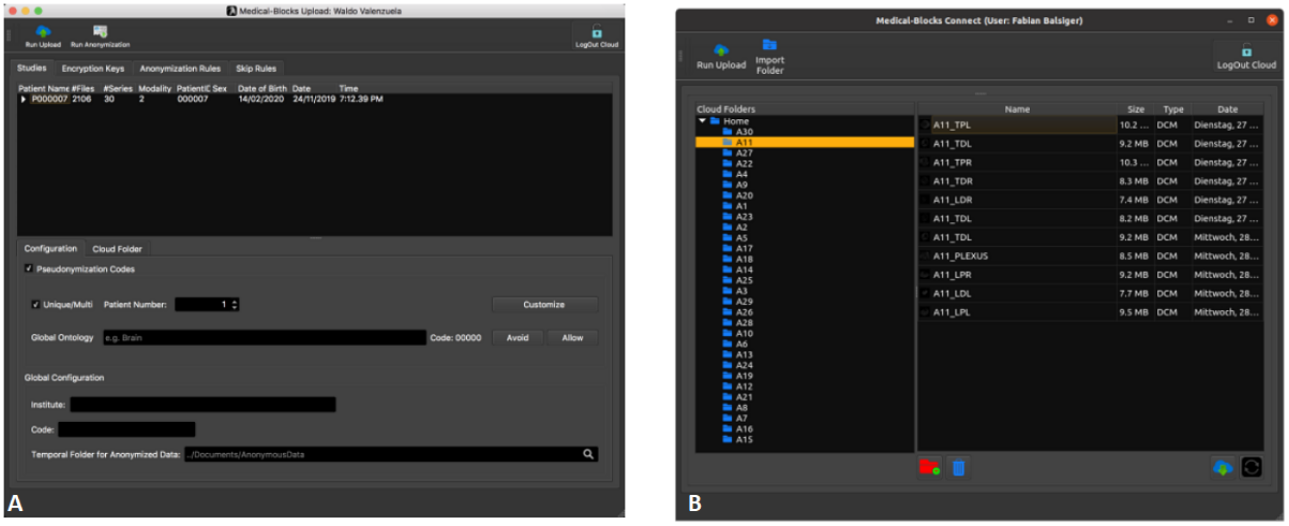
Figure 12. The synchronization applications MB-Sync (A) and MB-SyncLite (B). For MB-Sync, the user uses the log-in credentials of Medical-Blocks and selects which data to sync and to which location. For MB-SyncLite, a person receives a synchronization code (SYNC CODE) that grants access to a specific folder (here HGGB). In both cases, the data are synced to the file system and are accessible via the explorer of the operation system.



MB-Connect

MB-Connect is used to import data to the cloud instance of Medical-Blocks (Figure 13). MB-Connect was integrated as a plug-in into an in-house DICOM viewer called MB-Viewer (section S6 in Multimedia Appendix 1). By default, the DICOM files to be imported are anonymized using a predefined template (eg, the date of birth is set to January 1, 1900). If required, the user can edit and modify the anonymized information, that is, which DICOM tag fields will be anonymized according to what rules, through the anonymization dialogue (Figure 13A). For the import to Medical-Blocks, the user can select the directories to which the medical image or images will be imported (Figure 13B). By default, the medical images will be uploaded to the user's home directory, as with the Upload/Download section in the web UI (Figure 8). The directories on Medical-Blocks can also be directly modified within the upload dialogue such as editing the directory name as well as creating and deleting directories. Anonymization is mandatory before the upload of medical images to Medical-Blocks such that no patient-identifying information is being uploaded to the cloud instance of Medical-Blocks.

Figure 13. The anonymization (A) and upload (B) dialogues of MB-Connect integrated into our in-house Digital Imaging and Communications in Medicine (DICOM) viewer MB-Viewer. Before the upload of medical images to Medical-Blocks, the DICOM tag fields need to be anonymized by using the dialogue shown (A). The user specifies to which directories on Medical-Blocks the medical images are uploaded to by using the dialogue shown (B).



Discussion

We conceptualized and devised Medical-Blocks to enhance the exploration, management, analysis, and sharing of data in collaborative biomedical research. The platform can be connected to clinical systems for direct exploration of data for potential research. Data imported into and managed by Medical-Blocks are available to other researchers for further analysis. Visualization and classification of data allow the formation and analysis of potential cohorts for research. As Medical-Blocks can run as a cloud application, sharing of metadata and data with collaborators is easily possible, enabling multicenter research. An ecosystem of complementing software such as MB-Connect and synchronization applications MB-Sync and MB-SyncLight further extend the applicability and usability of Medical-Blocks. Medical-Blocks is accessible for use on the web [40]. New users must register, and access is granted upon reasonable request.

Data analysis and data sharing are two key features of Medical-Blocks. The automatic analysis of data allows the convenient exploration of data to form new cohorts for research through metadata. This metadata allows further exploration of potential collaborations with other researchers by sharing the type and extent of data available without sharing the underlying data. Once cohorts are defined, the underlying data can easily be shared with collaborators. The synchronization applications MB-Sync and MB-SyncLight make sharing and synchronizing data to the file system straightforward.

By connecting the medical systems of a health care institution, medical data become accessible to researchers who usually do not have direct access to such systems. This allows the exploration of available data for potential research without interfering with the clinical workflow. By managing the data with Medical-Blocks, the data are handled in a standardized manner independent of proprietary data formats. Researchers are likely to spend less time on converting and managing data because the platform can automate such processes.

The integration of computational blocks into Medical-Blocks is a feature that is currently lacking. In the use case of medical imaging, computational blocks can, for instance, leverage AI for medical image analysis. Such computational blocks can be used in different ways to classify data for metadata and research purposes. For the classification of metadata, AI can automatically predict the investigated side, which would further automate the data analysis if not simply possible through DICOM tag fields. For research purposes, AI is used for medical image analysis such as segmentation [41,42], brain morphometry [43], and reconstruction [44,45]. By executing such blocks when new data are synchronized from the PACS and when a user imports new files, AI can be tested on real clinical data acquired in everyday clinical practice. Therefore, a novel AI can be

deployed in a shadow-mode–like environment for the continuous validation of AI [46].

A major hurdle in developing Medical-Blocks was its integration into the hospital IT infrastructure. Directly connecting Medical-Blocks to the PACS of the hospital underlies legal restrictions related to cloud-based data transfer. Running Medical-Blocks as a local instance and connecting it to the PACS was possible without any problems, as the use of MB-Connect highlights. Nevertheless, to develop and leverage data sharing—a key feature of the platform—we opted to use Medical-Blocks as a cloud instance. We believe that this was the right trade-off; that is, fully leveraging data sharing while restricting the connection to clinical systems. This setting also shows that Medical-Blocks can be used without having a local instance running, but only by using MB-Connect integrated into a DICOM viewer for the data exploration and upload of data from the PACS to a cloud instance of Medical-Blocks. This setting might further make it simple to convince smaller institutions to participate in a multicenter research project, as no local instance of Medical-Blocks needs to be run in the institution's IT infrastructure.

We will address several shortcomings with the next release of Medical-Blocks. First, we aim to certify the platform such that it can manage unanonymized medical data in the cloud; that is, a certification as a medical device. A direct connection to the clinical systems at our hospital without intermediate software such as MB-Connect might then be possible. Having unanonymized data available for multicenter research might benefit the classification, cohort exploration, and ultimately the conclusions of the research projects. Second, we aim to apply Medical-Blocks beyond the use case of medical images. A first step in this direction was already made by starting a project involving electroencephalography data, but a more diverse set of types of data would be favorable for research involving multiple medical disciplines. Third, the integration of computational blocks involving AI is a key strategy for future releases (section S2 in Multimedia Appendix 1). Researchers should be able to add their AI as blocks to the platform and run these blocks directly on the newly imported data. Such a possibility could hopefully facilitate the application of novel AI in shadow mode before translating it to clinical practice. Finally, we believe that the ongoing and increasing use of Medical-Blocks will likely reveal several aspects we currently do not think about but are key to better user experience and more accurate and faster biomedical research.

In conclusion, we introduced Medical-Blocks that facilitates biomedical research by providing a centralized platform to interact with medical data in collaborative research projects. Medical-Blocks simplifies access to and management of medical data. Data can be analyzed swiftly to form cohorts for research. Finally, data can be shared among researchers. The modularity of Medical-Blocks makes it possibly applicable to various types of biomedical research involving heterogeneous medical data.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Technical implementation details.
[PDF File (Adobe PDF File), 653 KB - formative_v6i4e32287_app1.pdf]

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Abbreviations

AI: artificial intelligence
API: application programing interface
DICOM: Digital Imaging and Communications in Medicine
EHR: electronic health record
IT: information technology
PACS: picture archiving and communication system
REST: representational state transfer
UI: user interface

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Original Paper

Lessons Learned Through Two Phases of Developing and Implementing a Technology Supporting Integrated Care: Case Study

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Abstract

Background: As health care becomes more fragmented, it is even more important to focus on the provision of integrated, coordinated care between health and social care systems. With the aging population, this coordination is even more vital. Information and communication technology (ICT) can support integrated care if the form of technology follows and supports functional integration. Health TAPESTRY (Teams Advancing Patient Experience: Strengthening Quality) is a program centered on the health of older adults, supported by volunteers, primary care teams, community engagement and connections, and an ICT known as the Health TAPESTRY application (TAP-App), a web-based application that supports volunteers in completing client surveys, volunteer coordinators in managing the volunteer program, and primary care teams in requesting and receiving information.

Objective: This paper describes the development, evolution, and implementation of the TAP-App ICT to share the lessons learned.

Methods: A case study was conducted with the TAP-App as the case and the perspectives of end users and stakeholders as the units of analysis. The data consisted of researchers' perspectives on the TAP-App from their own experiences, as well as feedback from other stakeholders and end user groups. Data were collected through written retrospective reflection with the program manager, a specific interview with the technology lead, key emailed questions to the TAP-App developer, and viewpoints and feedback during paper drafting from other research team members. There were 2 iterations of Health TAPESTRY and the TAP-App and we focused on learnings from the second implementation (2018-2020) which was a pragmatic implementation scale-up trial using the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework at 6 primary care sites across Ontario, Canada.

Results: TAP-App (version 1.0), which was iteratively developed, was introduced as a tool to schedule volunteer and client visits and collect survey data using a tablet computer. TAP-App (version 2.0) was developed based on this initial experience and a desire for a program management tool that focused more on dual flow among users and provided better support for research. The themes of the lessons learned were as follows: iterative feedback is valuable; if ICT will be used for research, develop it with research in mind; prepare for challenges in the integration of ICT into the existing workflow; ask whether interoperability should be a goal; and know that technology cannot do it alone yet—the importance of human touch points.

Conclusions: Health TAPESTRY is human-centered. The TAP-App does not replace these elements but rather helps enable them. Despite this shift in supporting integrated care, barriers remained to the uptake of the TAP-App that would have allowed a full flow of information between health and social settings in supporting patient care. This indicates the need for an ongoing focus on the human use of ICT in similar programs.

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KEYWORDS

integrated care; information and communication technology (ICT); program evaluation; older adults; primary care

Introduction

Background

Currently, health care is provided by multiple providers across various disciplines and through different organizations. With patients receiving care from multiple people, it is crucial to have a system that can integrate providers and information horizontally and vertically across the health care system. The concept of integrated care is to deliver coordinated care that brings together services from across health and community-based social systems [1]. This type of care also aims to close the gap between health and social care [2] as it is seen as a way to bridge the gap among acute care, primary care, and community and social services [3]. Evidence shows that integration, coordination, and person-focused care are core features by which primary care achieves better population health outcomes [4]. To effectively integrate care, providers must ensure the continuity of sharing information about patients while allowing patients to remain at the center of their own care [5]. Therefore, this type of care relies on infrastructure to support the bridging of these traditionally siloed services and the centering of the patient in any intervention.

Information and communication technology (ICT) is an important enabler that supports the delivery of integrated and coordinated primary care [6,7]. ICT includes any health information technology that aids in the collection of health information and its processing, storage, and exchange [8]. There is evidence that ICT can support integrated care systems by fostering greater care efficiency and enhancing information exchange [9-11].

With the growing population of older adults in Canada and globally, the need to provide care that wraps around patients is even more important. In shifting to more integrated care, the changes that organizations make will need to be supported using all available resources. ICT can connect users across organizations and disciplines to share information. Appropriate communication to enhance these connections is critical for successful integrated care systems [5]. However, there are knowledge gaps in the literature describing the processes of introducing ICT into existing health and social care settings and in understanding how ICT changes work and information flows. Given the challenges that the introduction of anything new can present when incorporated into existing systems, careful planning and evaluation of these infrastructures are necessary.

Health TAPESTRY (Teams Advancing Patient Experience: Strengthening Quality) offers an opportunity to describe the development and evolution of ICT as part of a pragmatic complex intervention rooted in primary care. The program creates connections among trained community volunteers, interprofessional primary health care teams, novel technology, and community engagement and connections through improved system navigation [12,13]. The aim is to help older adults stay healthier for longer in the places where they live. A total of 2 evaluations have been completed through a randomized controlled trial. The study showed that patients who received Health TAPESTRY walked more (mean difference 1.13, 95% CI 0.31-1.95), had fewer hospitalizations (incidence rate ratio 0.37, 95% CI 0.18-0.77), and saw their primary care team more (mean difference 1.52, 95% CI 0.84-2.19) [12,13].

The key ICT within Health TAPESTRY is the Health TAPESTRY app (TAP-App), a web-based application that has 3 interfaces (briefly described below). In Health TAPESTRY, trained volunteers conduct visits in older adults' homes to discuss the clients' health and life goals, while identifying their health and health-related social needs using validated tools or surveys adapted by the research team. These surveys were administered by volunteers, facilitated by and recorded in the TAP-App on tablets through the volunteer interface. During the visits, the volunteers had the opportunity to answer client questions and provide relevant information on community programs and services that may be of interest to the client. After visits, volunteers write *social context* information on the TAP-App about their own perspectives of the client. Volunteers were also invited to write narratives on the TAP-App, which were stories of their own experiences with the potential to be used for research or program development purposes, as needed. A volunteer coordinator at each site handled the management and scheduling of volunteer and client visits through the TAP-App (ie, the volunteer coordinator interface).

The TAP-App creates an automated PDF TAP-Report that is shared with the huddle team at the patient's primary care site through a huddle interface. The huddle is a subgroup of people within the primary care team who meet weekly to discuss with clients in the program. The huddle is composed of at least 3 providers from different disciplines (eg, physician assistant, occupational therapist, nurse, and physician). The huddle members view TAP-Reports from their own interprofessional lens and work together to create individualized plans of care for clients based on the information collected. The huddle teams are then able to document a summary of their review and plan of action on each TAP-Report through the huddle interface. They also have the option to send volunteers back to clients through the huddle action checklist, which contains a list of options for engaging volunteers in the plan of action, including discussing changes in clients' health needs, planning the achievement of goals, or connecting clients to community-based health and social services. These recommendations are communicated to volunteers via volunteer coordinators who receive this information on the TAP-App. After volunteers follow-up with clients, they communicate any new information back to the huddles through the Follow-Up Report, another automated PDF report created by the TAP-App. A detailed description of Health TAPESTRY is in the published protocol [12].

Objectives

In this paper, we describe the development and evolution of a specific ICT in Health TAPESTRY, the TAP-App. This story

is presented as a case study to share the lessons learned during its development, evolution, and implementation.

Methods

Design

The case under study is the TAP-App itself, and the units of analysis are the perspectives of end users and stakeholders [14]. We used the Stake understanding of case studies [15], including a focus on qualitative results, involvement of researchers' impressions as key sources of data, detail provided to assist in naturalistic generalization, and lack of a specific start or end time of data collection and analysis. Although our case was partly bounded by the start and end dates of the randomized controlled trial that was conducted (described elsewhere), the TAP-App went beyond these temporal boundaries; hence, we describe development and vision both before and after. The settings that bound our case were numerous and are described in the *Setting* section below.

Data Collection

The data in this study came from the direct perspectives of key members of the research and implementation team, who are also represented as authors in this paper. The lessons learned in this paper constitute the key themes from the team's perspectives in implementing the TAP-App in Health TAPESTRY. Specific data sources to understand how the TAP-App was implemented in its 2 phases were a written retrospective reflection from the program manager, an interview with the technology lead (facilitated by SD and JG), and key questions administered via email to the software developer.

Although the lessons learned in this paper came directly from the program team, their understanding of the implementation of the TAP-App was informed by the feedback that the team received from many other stakeholders and end users (including Health TAPESTRY clients, community volunteers, volunteer coordinators, primary care providers, and administrative or other primary care team members). This feedback came to the team via email, volunteer *lunch and learns*, volunteer narratives submitted via the TAP-App, and during verbal debriefs with volunteer coordinators. Furthermore, we gathered viewpoints and feedback from other research team members who developed and implemented the TAP-App at each of the 2 main stages. SD and JG collected this information and combined it with the direct observations of the research team to add detail and clarity to understanding the lessons learned in this work.

Data Analysis

Although there was no traditional qualitative data set for this study's data because of the structure of data collection, the project team members (ie, the authors and key informants) discussed lessons learned throughout and after project implementation. LL and SD developed the initial *Lessons Learned* section in this paper based on the key themes that continued to arise in these project conversations and their own perspectives as implementers. JG and SD then edited the lessons learned after collecting more information from key informants (ie, the interview with the project lead and key questions to the developer). Throughout this process, member-checking was continued, that is, feeding back the written lessons learned to the key informants, to ensure that the written representation fit their understanding of the process.

Methods to Improve Rigor

We used several methods to enhance rigor in this case study. We worked to enhance credibility and confirmability through triangulation of various data sources (ie, respondents), data collection methods, and individual interpreters of the data [16,17]. We further enhanced credibility by prolonged engagement of respondents while ICT was used in a multi-year program [16]. Finally, although this case study focused deeply on a specific ICT, we used a thick description that may aid in understanding the potential for transferability or naturalistic generalization of the results to other settings and ICTs [15,16].

Setting

The TAP-App was developed, hosted, and driven by an academic university department, McMaster University's Department of Family Medicine. The department includes subgroups—2 of which are devoted to information technology and research—and were the 2 areas of the department that managed the TAP-App. During the implementation of Health TAPESTRY–Ontario (2018-2020), which is the period of focus of this study, the TAP-App was used in 6 family health teams (FHTs) across the province of Ontario, Canada to support older adult clients. FHTs are primary health care teams that bring traditional family physician–led practices together with an array of interprofessional providers such as nurses, social workers, dietitians, pharmacists, and others [18]. Interprofessional providers in an FHT may be colocated or located at different sites. The FHTs, as well as the communities they serve, vary in size, with populations ranging from 2710 to 536,917 as of the 2016 Census [19,20]. In addition to its use by FHTs, as described above, the TAP-App was used by trained community volunteers working in clients' homes and by the organizations and individuals that supported both these volunteers and the communication exchange among elements. A national humanitarian charitable organization supported 4 of the 6 sites with 4 volunteer coordinators. A coalition of multiple agencies focused on community health supported the final 2 sites with 1 volunteer coordinator.

Development and Evolution of the TAP-App

TAP-App (Version 1.0)

The first version of the TAP-App was programmed in-house at McMaster University's Department of Family Medicine, using Java. The technology was still in active development at the start of implementation, which led to an iterative nature of development and the opportunity to integrate feedback from users. During the initial implementation of Health TAPESTRY that took place at just 1 FHT in Ontario (2014-2015), the technology was a single log-in webpage with different interfaces for volunteers and administrators (ie, volunteer coordinators and research staff) and for the 2 clinical sites within this FHT. The volunteer interface was where surveys for each client could be accessed during home visits. Upon completion, the automatically generated PDF TAP-Report was not shared with the primary care team via a huddle interface; instead, the

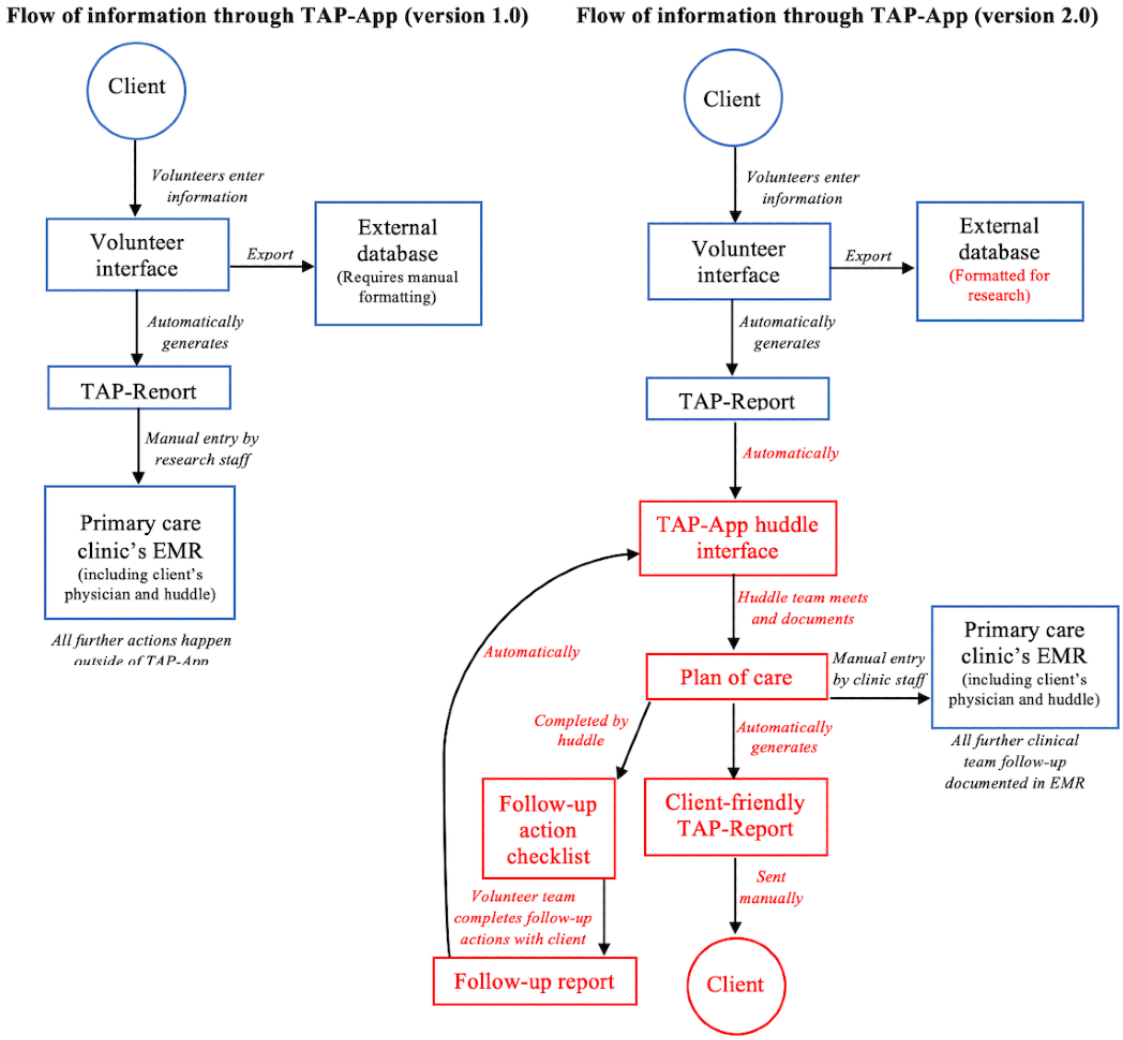
research staff uploaded the TAP-Reports to the clients' electronic medical records (EMRs) for the primary care team to review. Therefore, they also did not have the huddle action checklist, nor did volunteers have the follow-up visit or Follow-Up Report options, though volunteers did conduct preplanned 3-month follow-up visits which were not a part of the second implementation of Health TAPESTRY. As in the second version of the TAP-App, the volunteer coordinator interface held client and volunteer information but also had a scheduler for coordinating volunteer availability and visit times. The question data could be extracted from the TAP-App for research purposes, although it was not in the ideal format for data analysis.

TAP-App (Version 2.0)

Building on the initial Health TAPESTRY experience, the McMaster University Department of Family Medicine invested in a new iteration of the technology that would be supported on Research Enterprise Management of Information (REMI), a new multi-tenant software platform built using Java and Angular to facilitate collaborative research initiatives. The second large-scale implementation of Health TAPESTRY at 6 sites (2018-2020)—enabled by the TAP-App—was the first department project to use REMI, with modifications specific to the program.

There were several advancements in the existing technology with the goal of establishing a 2-way versus 1-way flow of information between clients and interprofessional huddle teams (Figure 1). First, a huddle interface was created, which allowed TAP-Reports to be generated directly in the huddles. This new interface provided huddle a place where a client's plan of care could be documented. From here on, the huddles could use the new huddle action checklist. The huddle interface also allowed huddles to create a client-friendly version of the TAP-Report, including a plan of care that could be mailed to clients. Finally, to improve the flow of information, this iteration of the TAP-App enhanced the functionality of exporting data to allow them to be uploaded to other data storage locations (eg, REDCap [Research Electronic Data Capture; Vanderbilt University] electronic capture tools) and be easily reported to sites to support quality improvement, quality assurance, or research purposes.

Figure 1. Health Teams Advancing Patient Experience: Strengthening Quality (TAPESTRY) application—TAP-App (version 1.0) versus TAP-App (version 2.0). EMR: electronic medical record; TAP-App: Health TAPESTRY app.



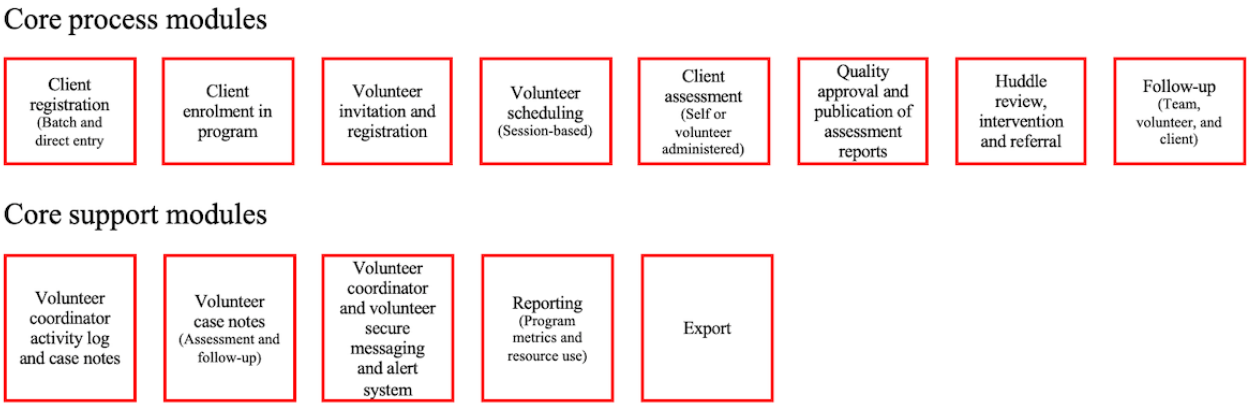
Note: The text boxes in red represent what was added to TAP-App (version 2.0) compared to TAP-App (version 1.0)

The design was again iterative and implementation was stepwise in nature, as rollout of the program and technology did not occur in all 6 FHTs simultaneously. Each site was able to customize its survey packages based on community or clinic needs and preferences. The TAP-App was still in active development when implementation began on the first site, which allowed the team to solicit and receive feedback from users (as described in the *Data Collection* section).

The Tap-App ICT: Bringing a Vision to Life

Although the TAP-App was first introduced as a tool to schedule volunteer and client visits and collect survey data with tablet use in focus, a broader vision underpinning this ICT was further developed during implementation. As outlined earlier, within the department, there was a desire to create a *program management tool* that could underpin all aspects of a complex intervention such as Health TAPESTRY. This shift led to the creation of a tool (the TAP-App hosted on REMI) that provided organizational support, management of clinicians and community partners, logic in data collection, and the opportunity for information to flow among users in a scalable and customizable tool that could support research and education enterprises (see Figure 2 for a detailed look). At the time of writing, the vision for the technology included some elements that had not been fully introduced, such as enhanced volunteer management and tracking and the opportunity for others in the department to use the technology.

Figure 2. Research Enterprise Management of Information (REMI): powering the Health TAPESTRY (Teams Advancing Patient Experience: Strengthening Quality) app and more.



Contributing to Integrated Care Through the TAP-App

Models of integrated care are centered on the values of *collaborative*, *coordinated*, *comprehensive*, and *holistic care* [21]. By the end of the implementation, we were able to design a technology that made strides toward supporting these core values of integrated care through ICT. The TAP-App provided a platform that enabled communication between primary care providers and 2 community-based volunteer agencies, as well as their community volunteers, to support *collaboration* between the health and social sectors. This technology allows for the *coordination* of information within and across teams by using trained volunteers to collect data for clinicians and volunteer agencies, allowing for the expanded coordination of services for clients. The follow-up action component of the TAP-App was not extensively used by primary care teams to request volunteer support, in part because some of the items on the follow-up checklist did not mirror real-life patient needs; for example, items did not include specialist or hospital referrals as the primary care teams managed those themselves. Regardless, some clients experienced the *comprehensiveness* of having multiple providers and services across disciplines involved in their plan of care in a more integrated and less fragmented manner. Finally, this technology was embedded into a person-centered program with a focus on what mattered most to clients rather than what was the matter with clients. This introduced components of a *holistic* approach, as the TAP-App was used to support this aim and collect health as well as social, socioeconomic, emotional, and other dimensions to create a plan of care that would reflect client needs across the health and social spectrums.

Results and Discussion

Participants, Positionality, and Reflexivity

The authors of this paper were the participants from whom the themes of the lessons learned came. The roles they held in Health TAPESTRY were research assistant, research associate, technology (digital health) lead, program manager, research coordinator, practice model lead, software developer, data manager, executive lead, and evaluation lead. Of the 10 authors, 5 (50%) were women, 4 (40%) were men, and 1 (10%) was gender nonbinary. Of the 10 people, 7 (70%) were present in both phases of the Health TAPESTRY program, and 3 (30%) were present only in the second phase.

As developers, implementers, and evaluators of the technology under study, we had an implicit bias in the shared hope for program success. However, the 2 phases of project work allowed us to reflect on our unique position and further develop the app to overcome barriers and maximize its success. Beyond that, we aimed to take a pragmatic approach to understanding our lessons learned, considering both what worked and what did not work.

Lessons Learned

Iterative Feedback Is Valuable

The introduction of any new technology will inevitably have both expected and unexpected effects on operations and workflows, even beyond the initial implementation. Therefore, continuous iterative feedback is necessary from users throughout. Given the many end users (or, in some cases, stakeholders who did not actively use the technology themselves) involved in a complex program such as Health TAPESTRY, there is a need to develop a process for managing feedback. It is also important to prioritize suggestions into high-, medium-, and low-priority categories. Some potential questions and guidelines that we found helpful—and encourage others to consider using in determining the end users' needs—during our implementation are as follows:

1. Would this alter the mechanisms in which data moved among users?
2. Would this require retraining for end users?
3. Would this change the way in which a client experienced the program?
4. Was this outside of the scope and capacity of the technology?

A key to the successful implementation of ICT is the involvement of end users. Buntin et al [10] highlighted the *human element* being a critical component of health technology implementation, which emphasizes the importance of provider feedback and *buy-in*. As the literature has identified, it is important to plan ICT early and deliberately, with monitoring and end user involvement throughout [8]. The involvement of end users appears to be a necessary element for the successful implementation of technology [5] because the implementation of ICT will create new tasks and processes. Iterative feedback will help move the implicit experience of an end user into explicit knowledge as ICT will likely introduce new ways of working at various levels by numerous people. See Table 1 for an overview of the 5 key lessons learned from our implementation of the TAP-App.

Table 1. Five key domains to consider when implementing a new information and communication technology (ICT) to support integrated care.

Domain	Why is it important	When is it important
Iterative feedback	Iterative end user feedback is vital for successful implementation of an ICT as different stakeholders involved have different needs and workflows that need to be considered.	Throughout implementation
Purpose of the ICT	An ICT that will be used for research, in addition to program implementation, must consider the needs of both purposes.	Development of the ICT
Integration into existing workflow	The ICT should support and enable existing workflows to facilitate the normalization of the ICT into practice.	Throughout implementation
Interoperability	Interoperability has both advantages and disadvantages. There is a need to consider the feasibility and practicality of an ICT being interoperable with other software; it is also possible that interoperability should not be the goal.	Development of the ICT
Limitations of technology	On the basis of the program being implemented; an ICT may be unable to complete all tasks within a program or the ICT may not be the best option to complete those tasks; a human element may be required.	Development of the ICT

If ICT Will Be Used for Research, Develop it With Research in Mind

Computer-assisted data collection for research use has been considered acceptable and has been widely adopted for at least 25 years [22]. However, when developing an ICT with the key purpose of being part of a program (rather than a research study), the research needs to evaluate whether the program can sometimes be overlooked. This is exactly what happened within the development of TAP-App (version 1.0), which made it very difficult to manage the spreadsheet of data as the output. We identified the problem and remedied it during the development of TAP-App (version 2.0) by including an embedded researcher (LL) in the ICT development team. The only way to scale a technology that may be used for research purposes (eg, understanding pre–post changes in participant outcomes or for general program evaluation) is to have a usable downloadable file (or way to develop summary reports), ideally one that can be converted into the appropriate file types for statistical software programs. Although this is not a common key learning in the literature in this field, other authors have emphasized the importance of being aware of concurrent changes to other systems when implementing a new ICT system [23]. Although these authors referred to technology systems, it is just as important to consider any system of work, including program versus research needs.

Prepare for Challenges With Integration of ICT Into Existing Workflow

The integration of ICT into existing practices and workflows takes time and requires an understanding that there will be challenges until it becomes a normalized part of the regular experience. This is not a new learning on its own; the literature in the field describes how introducing new ICT introduces new ways of working, which organizations and providers may be resistant to and often, an inadequate understanding of the clinical work environment causes new ICT systems to fail [5,24,25]. We have worked to understand how to manage these barriers. Although the normalization process theory was not fully used as an underpinning for this project, we considered the elements of normalizing a new technology into the existing workflow as we implemented the TAP-App. Normalization process theory states that new interventions must interact with the service organization, practices, and ways in which providers engage

with patients to be successful [26]. Along with existing work processes, implementation must interact with the existing *information ecology*, the activities in which users are already served by technology, such as the current channels of communication and storage of information [5].

Therefore, technology needs to support and enable the workflow of clinicians and not dictate it. By developing a new iteration of the TAP-App on REMI, the technology's ability to achieve a level of flexibility and scalability allows the technology to be implemented in multiple existing contexts. However, despite including flexibility, scalability, and the human element of feedback within our development of the TAP-App in both iterations, there were still some difficult areas when fitting it into the usual practice. One of these was the log in to a secondary website by providers, that is, the use of the huddle interface. This additional step added time, already at a premium for health care providers, and an issue that can be a major constraint in introducing new ICT into practice [8].

It is also important to implement ICT that is flexible enough to change per the local context, but neither the technology nor the end users can be too rigorous in the application of the technology. Although end users need to see value in adopting a new ICT [23], its developers and implementers cannot expect too many users and users cannot expect too much ICT. Steele Gray et al [24] recommended that adopting ICT into integrated care models requires a balance between a user-focused model and disruptive innovation, as ICT will inevitably introduce new ways of working for each user. However, the literature on innovation adoption suggests that users are likely to only support components that reflect practice as usual [27], a contradiction that can be difficult to navigate. Implementation of the TAP-App resulted in similar findings, as providers ended up adopting components of the technology that were useful to them and not the parts that added work or changed the workflow.

Ask Whether Interoperability Should Be the Goal

In the adoption of ICT, the concept of interoperability, specifically between external software and EMRs, will likely always need to be considered and is often seen as the end goal for any new health-related technology [28]. Interoperability is "the ability of health information systems to work together within and across organizational boundaries" [29]. Although there is evidence to support the benefits of ICTs that are interoperable with EMRs [30], the TAP-App was not intended to be fully interoperable during this implementation. It was not feasible, given the sheer number of EMR systems currently in use across Canada, including the 6 sites for this study. This may be a common barrier when implementing ICTs and may make them interoperable with EMR systems. This barrier is even larger with the implementation of programs such as Health TAPESTRY, which would require information systems that spanned the health and social sectors. The lack of interoperability among systems has been considered a key barrier in other studies [24]. However, because it was not feasible to fully integrate the TAP-App into an EMR, it does not mean that more integration would not be appreciated by providers. If providers have something similar to an embedded link in their EMR that takes them only a single click to access, they may not see it as a distinct site or different from their usual workflow.

Even if we had pushed for full interoperability between the TAP-App and EMRs, it may have addressed some of the disruptions in workflow. However, it has been shown that providers need to first see a great enough value in the ICT to fully integrate it into their work. In Health TAPESTRY, the value of ICT is not only the TAP-App itself but also the program elements that the huddle can access with the TAP-App, which introduces an additional barrier to access, as the primary care team should see a great enough value in the information contained in the TAP-Report and in the work of volunteers who are following up with their patients. In observing the challenges of integrating new health ICT, Planitz et al [23] found that the adoption of health ICT relied on providers identifying the functionality of new systems and that they were reluctant to change work processes during adoption. Therefore, the consideration of how well human factors are considered in introducing new ICT, and how well the ICT's functions are suited to end users may actually provide more value than the consideration of the interoperability of an ICT into an EMR. The human element is the key.

Know That Technology Cannot Do it Alone...Yet

There are inherent benefits and growing knowledge of the importance of developing human-centered ICT, including both the uptake and usability of the technology, which has been described in this case study and in other literature [31,32]. At the core of Health TAPESTRY are community volunteers administering surveys directly to clients, building rapport, and viewing clients in their own spaces, with their visits and questions facilitated by the TAP-App. This element is a benefit of the program and it would be remiss to suggest that technology could do this *instead*. Technology as the solution is not a true solution, as a human element is important in programs such as this; form should follow the function for an ICT to be successful.

Another human touch point within Health TAPESTRY was the addition of volunteer coordinators to interprofessional huddles, which further enabled the practice of integrated care, helping reach out to the community beyond the volunteer organizations themselves. While the TAP-Report to the huddle team provided necessary information, the volunteer coordinator was able to provide further narrative. In addition, this connection allowed the huddle teams to liaise directly with volunteer coordinators about possible follow-up actions for volunteers and resources to connect with patients. It also allowed the volunteer coordinator to remind the huddle teams of the community-based health and social-service options within their context and the role volunteers can play in connecting patients to these, as well as helping with any TAP-App–related issues. However, although this was an in-person activity, the volunteer coordinators' connections to the huddles were fully internet-based. As the entire world shifted to a more internet-based environment during the COVID-19 pandemic, we have seen many fields turn to more internet-based methods of connection. Through internet-based inclusion of community-based partners in interprofessional primary care huddles, we could keep the human element of connection, using it to further humanize the use of

technology [33], while still working to provide personalized, wrap-around care for clients.

Limitations

We acknowledge several limitations to this study. First, the authors of this paper understand the development and implementation of the TAP-app were themselves the developers and implementers of this ICT. This may introduce bias. However, we were not aiming for an entirely unbiased picture. Instead, we were directly looking to further understand perspectives of the people closest to the technology. We also practiced reflexivity in understanding our position in the project. Another limitation was that there was no direct data set with actual quotes that could be used. This was a restriction of the way we set up the evaluation. Finally, while there were a great number of stakeholders who provided perspectives to the authors throughout implementation, these perspectives were filtered through authors' understanding and positionality.

Conclusions

Although ICT systems are used to support coordinated and integrated care through information sharing, access to care, and continuity of services [5-7,24,34], there is a limited understanding of the process of introducing ICT into existing health and social care settings [24]. We have contributed to reducing this gap in the literature by describing the development and implementation of a specific ICT, the TAP-App, within the Health TAPESTRY program. The TAP-App helped enable the human-centered elements of Health TAPESTRY. However, despite the advancements made in the design of the TAP-App, there remain barriers to achieving the uptake of technology to allow for a fully improved flow of information between health and social settings. The key lessons for introducing ICT to enhance information exchange across sectors are that a system of iterative feedback to inform the design is important and that introducing a new ICT will inevitably cause implicit and explicit changes to existing workflows. In addition, human perspectives, interactions, and relationships may be more vital than ensuring interoperability between ICTs and EMRs. Maintaining a human-centered approach to integrated care is still key, whether a human-centered approach can also be brought in through internet-based communications or other technology.

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Conflicts of Interest

None declared.

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Abbreviations

EMR: electronic medical record
FHT: family health team
ICT: information and communication technology
REDCap: Research Electronic Data Capture
REMI: Research Enterprise Management of Information
TAPESTRY: Teams Advancing Patient Experience: Strengthening Quality
TAP-App: Health TAPESTRY application

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Original Paper

Use and Effect of Embodied Conversational Agents for Improving Eating Behavior and Decreasing Loneliness Among Community-Dwelling Older Adults: Randomized Controlled Trial

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Abstract

Background: Embodied conversational agents (ECAs) have been proposed as a promising interaction modality for the delivery of programs focused on promoting lifestyle changes. However, it is not understood what factors influence the health effects of ECAs or their use.

Objective: We aimed to (1) identify whether ECAs could persuade community-dwelling older adults to change their dietary behavior and whether ECA use could decrease loneliness, (2) test the pathways to these effects, and (3) understand factors influencing the use of ECAs.

Methods: A randomized controlled trial was conducted. The intervention group received access to the PACO service for 8 weeks. The waitlist group started PACO use after waiting for 4 weeks. Two primary outcomes (eating behavior and loneliness) were assessed via online questionnaires at intake, upon joining the waitlist, after 4 weeks, and after 8 weeks. The third primary outcome (use) was assessed via data logs. Secondary outcomes were measured at the same time points, via questionnaires or an optional interview.

Results: In total, 32 participants completed the intervention. We found a significant correlation between use in minutes on the one hand, and perceived usefulness (r=0.39, P=.03) and enjoyment on the other (r=0.38, P=.03). However, these did not predict use in the full regression model ($F_{2,29}$=1.98, P=.16, R^2=0.12). Additionally, PACO use did not lead to improvement in eating behavior (χ^2_2=0.34, P=.85) or a decrease in loneliness (χ^2_2=0.02, P=.99).

Conclusions: Our study did not provide any concluding evidence about factors that are linked to the use or health effects of ECAs. Future service design could benefit from either creating a functional design catering to the predominant stage in the precaution adoption process model of the targeted population, or by personalizing the service based on an intake in which the end user's stage is determined.

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International Registered Report Identifier (IRRID): RR2-10.2196/22186

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KEYWORDS

eHealth; online intervention; embodied conversational agent; lifestyle change; older adult; user experience; eating habits; eating behavior

Introduction

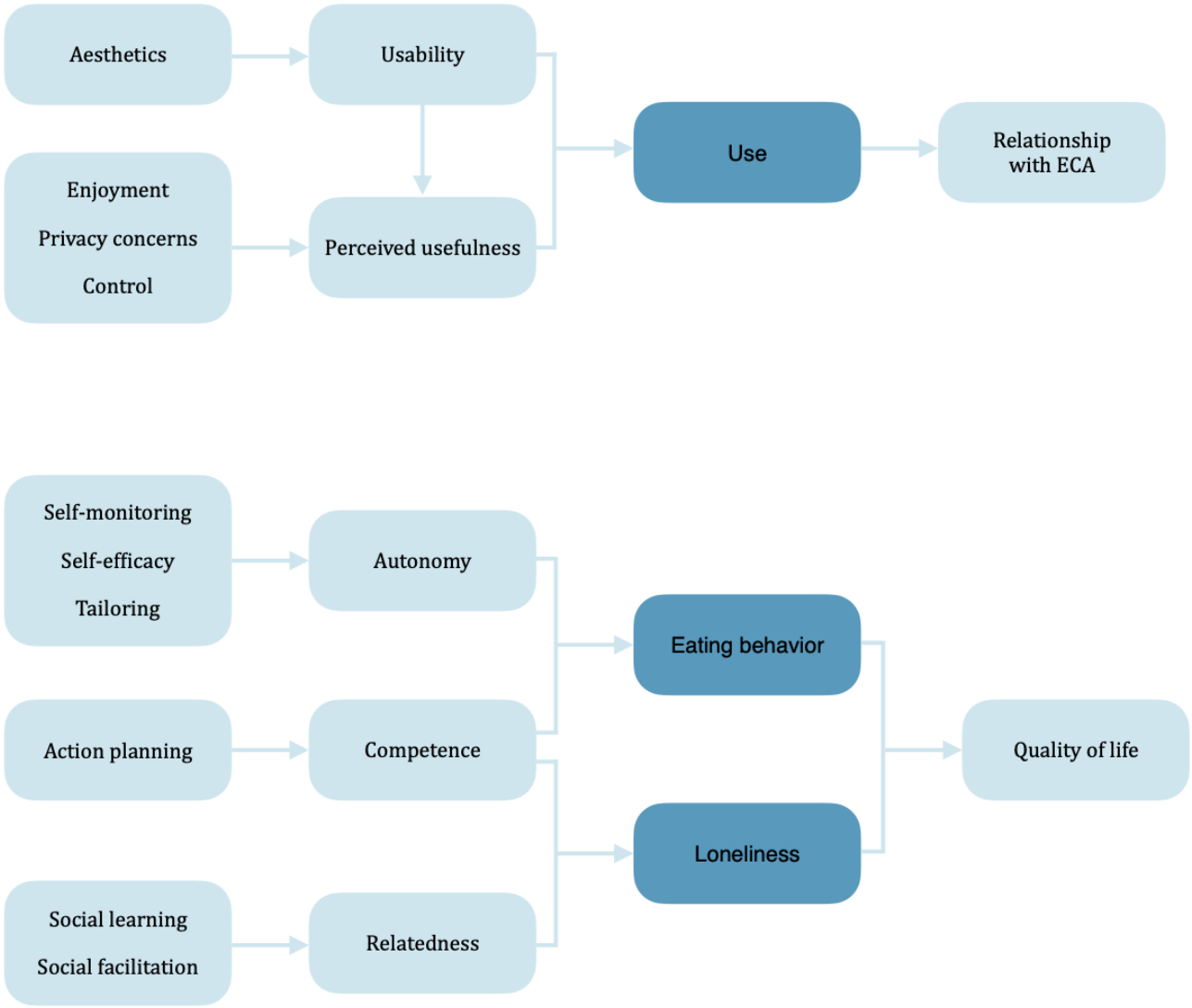
Background

Embodied conversational agents (ECAs) have been proposed as a promising interaction modality for the delivery of programs focused on promoting lifestyle changes [1], such as physical activity [2-4] and nutrition [5,6], and preconception care [7,8]. ECAs often have a human-like appearance and communicate via prewritten dialogue. They also have the ability to establish and maintain an empathic relationship by using empathic behavior, both verbal, via text or speech, and nonverbal, via facial and gaze expressions and hand and body gestures [9]. These behaviors may make them more engaging than traditional eHealth interventions [10,11]. Results are promising, as ECA interventions have been found to be easier to use [5] and used more frequently [5,11-13] than interventions without an ECA. Nonetheless, ECA use does decline over time, limiting long-term health effects [1,14-17]. Moreover, it is unknown what factors influence use of an ECA. When designing an ECA, designers are advised to select the right role for the ECA, combine the most important personality characteristics, and use informational, nonjudgmental language [18]. In addition, a scoping review identified which use-related factors were assessed when evaluating the effect of ECAs on promoting healthy lifestyles. These factors included usability and user satisfaction, further specified as factors including liking and trusting the ECA and the desire to continue using the ECA. However, evidence for the effect of these factors on ECA use is limited. Furthermore, there is scarce and inconclusive evidence for the health effects of ECAs and the pathways to these effects [1].

In order to assess the pathways to effects and understand ECA use when evaluating an ECA, conceptual models can be used (as shown in Figure 1; further details were reported in the research protocol for this study [16]). The conceptual model explaining ECA use is based on existing human-computer interaction literature, including the technology acceptance model (TAM) [19]. The key variables in TAM are perceived usefulness and perceived ease of use. Systematic reviews have shown that these 2 variables typically explain about 40 percent of an individual's intention to use a technology in a variety of contexts [20-22]. However, there is mixed evidence regarding whether intention predicts actual use [23,24]. Since actual use, rather than intention to use, is deemed necessary to achieve any health benefits, use is at the center of the conceptual model. Increased use is expected to improve the intensity of the relationship with the ECA, because of the capacity of ECAs to establish and maintain an empathic relationship. Usability and perceived usefulness are hypothesized to act as antecedents for use, whereas increased usability is expected to result in increased perceived usefulness.

The conceptual model explaining health effects occurring after the use of an ECA starts with behavioral change techniques (see Multimedia Appendix 1), which are expected to lead to an improvement in the 3 basic psychological needs: autonomy, competence, and relatedness. [25]. Ultimately, improved health behaviors will lead to a better quality of life. This model is primarily based on self-determination theory [25] and has an explorative character. By contrast, the classification system of Teixeira et al [26,27] is used to form hypotheses to explain which techniques improve which needs. Hence, the objectives of this study were to (1) identify whether ECAs could persuade community-dwelling older adults to change their dietary behavior and decrease their loneliness, (2) assess the pathways to these effects, and (3) understand ECA use.

Figure 1. Conceptual models explaining embodied conversational agent (ECA) use and health effects.



Methods

Study Design

This study used a randomized controlled trial design. Participants in the first cohort received access to the 8-week intervention immediately, while participants in the second cohort served as a control group, receiving access to the intervention after being placed on a 4-week waiting list.

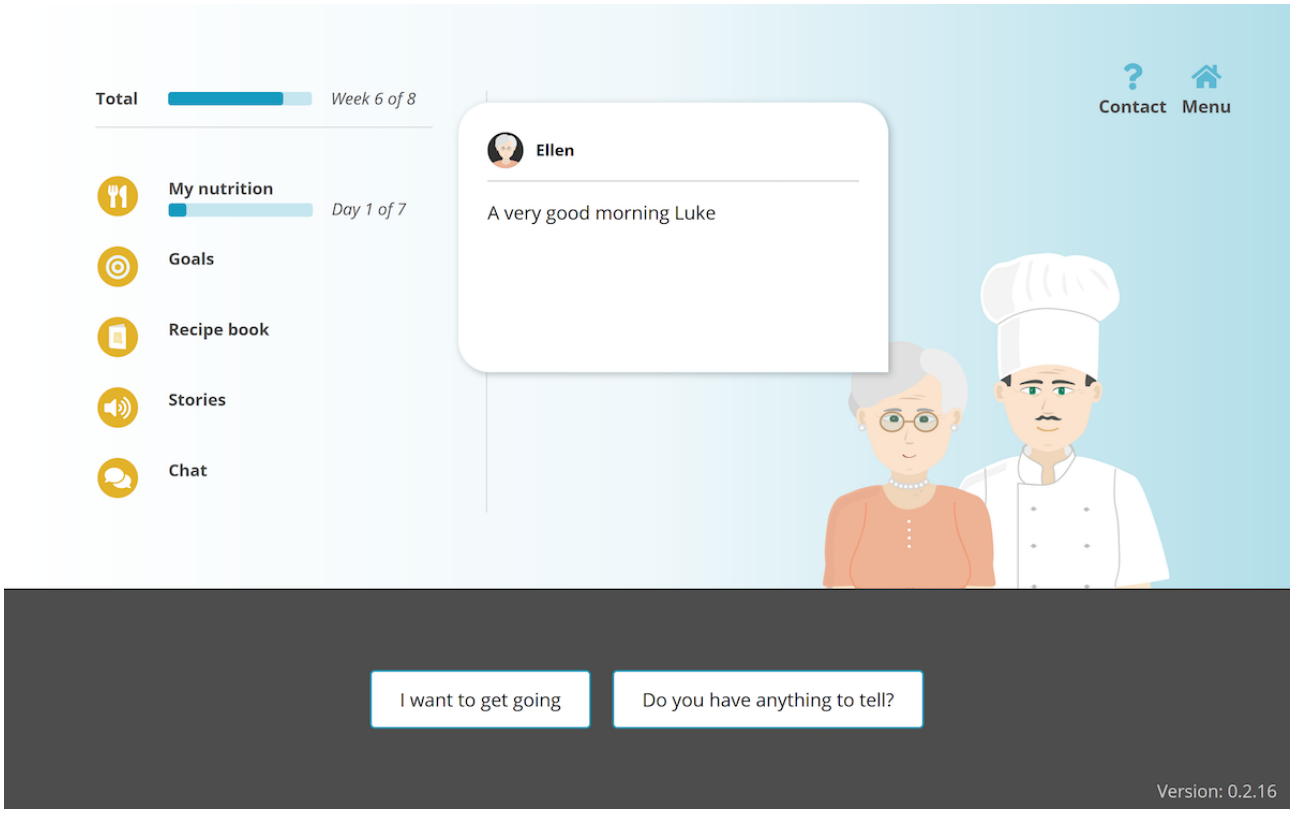
Participants and Procedure

We aimed to include a total of 60 participants with a 1:1 ratio of participants per cohort. Participants were deemed eligible if they were aged 65 years or older, not in paid employment, and lived alone and independently at home. In addition, participants needed to speak Dutch, be able to use a tablet or computer by themselves, and have a wireless internet connection. The project members recruited participants via research panels, flyers, newspapers, and social media. After providing informed consent, the participants were invited to complete the intake questionnaire. They were asked to report their demographics (gender, age, educational level, health conditions, risk of malnutrition [28], and eHealth literacy [29]), their possession of a device to use for the study, and their motivation to participate. All participants were asked to complete the baseline questionnaire (T0) after creating an online account and complete another questionnaire after 4 (T1) and 8 (T2) weeks of use. Participants in cohort 2 were asked to complete an additional waitlist questionnaire (Tw) 4 weeks before T0. In the last questionnaire, participants were asked whether they were open to an interview by phone.

Intervention

The intervention, PACO, is a web-based eHealth service in which 2 ECAs engage in dialogue with an older adult to provide motivation for improving eating behavior and decreasing loneliness. The service consists of 5 modules, each one applying a different behavioral change technique (Figure 2, Multimedia Appendix 1). The user can engage in dialogue with Herman (the cook, who provides nutritional advice) and Ellen (the peer, who provides social advice). The ECAs are represented as 2D humans in cartoon style, are not animated, and use text as the means of communication. During the onboarding process, the ECAs introduce themselves and explain the PACO program.

Figure 2. PACO home screen.



Outcomes

The primary outcomes include use of the service, eating behavior, and loneliness. Use was assessed via log data collected on the PACO back end. Eating behavior was self-assessed by 3 open questions about the previous day's fruit, vegetable, and liquid intake and loneliness was assessed via a validated questionnaire (Table 1 shows further details). The experience and the willingness to pay for PACO were measured via a self-compiled scale. All other outcomes were measured via validated online questionnaires. In an interview of approximately 30 minutes, participants were asked further questions about their experiences with PACO and any behavioral changes.

Table 1. Study outcomes measured via questionnaires in each study phase.

Outcome	Scale	Tw	T0	T1	T2
Use-related outcomes					
Relationship with ECA[a]	Rapport scale [30-32]	N/A[b]	✓	✓	✓
Usability	System usability scale [33]	N/A	N/A	N/A	✓
Enjoyment	Affect scale [34]	N/A	N/A	N/A	✓
Aesthetics	Classic aesthetics [35]	N/A	N/A	N/A	✓
Privacy concerns	Concern for privacy scale [36]	N/A	N/A	N/A	✓
Control	Active control [37]	N/A	N/A	N/A	✓
Perceived usefulness	Perceived usefulness scale [19,38]	N/A	N/A	N/A	✓
Health-related outcomes					
Eating behavior	N/A	✓	✓	✓	✓
Loneliness	De Jong Gierveld loneliness scale [39]	✓	✓	✓	✓
Quality of life	Brief older people's quality of life questionnaire [40]	✓	✓	✓	✓
Autonomy, competence, and relatedness	Basic psychological need satisfaction and frustration scales [41-43]	✓	✓	✓	✓
Other outcomes					
Experience	N/A	N/A	N/A	✓	N/A
Willingness to pay	N/A	N/A	N/A	N/A	✓

[a]ECA: embodied conversational agent.

[b]N/A: not applicable.

Data Analyses

We created a single score for each scale and checked the test assumptions. Due to the violation of the linearity assumption, we deviated from the original protocol by using nonparametric tests. Relationships between demographics and the main study outcomes were calculated using Spearman ρ and, for gender, Mann-Whitney *U*. Differences between Tw and T0, and in health-related outcomes over time, were compared using the Friedman test. Differences in the strength of the relationship with the ECA over time were compared with a repeated-measures ANOVA. Spearman ρ was used to calculate the correlations between use- and health-related outcomes. Linear regression analysis was used to calculate the multivariate relationships between use, eating behavior, loneliness, and significant outcomes. The statistical significance level was $P<.05$. Recordings of the interviews were transcribed and thematically analyzed by LLK and BCM.

Ethics Approval

This study was preregistered at ClinicalTrials.gov (NCT04510883) and approved by the medical ethics committee of Wageningen University (number NL73121.081.20). We refer to the study protocol article for all details on the protocol, the development process of the intervention, and the conceptual models [16].

Results

Drop-out, Baseline Characteristics, and Motivation

In total, 51 participants met the inclusion criteria. Nineteen participants did not use the PACO service for 14 consecutive days and were treated as dropouts. Among participants who dropped out, 7 did not respond to emails or telephone calls, 3 dropped out due to illness, 3 due to lack of time, 2 due to lack of motivation, 2 due to difficulties with the service, and 1 due to internet issues. Eight participants who dropped out had created an account, of whom 4 had completed T0. The mean age of the 32 participants was 73.00 years (SD 5.33, range 65-85); 18 (56%) were women. In total, 12 (38%) had completed high school or an associate degree and 19 (59%) had completed college or university. The mean eHealth literacy score was 29.25 (SD 4.36, range 15-34), and the risk of malnutrition was 9.69 (SD 1.35, range 7-11). None of the demographic characteristics were significantly associated with use, eating behavior, or loneliness, and there were no significant differences in health-related outcomes between Tw and T0. During intake, participants stated that they were mainly motivated to participate because they were interested in research and in new developments and thought it was important to contribute. Some participated because they were interested in nutrition and wanted to stay healthy or improve their habits.

Health Effects

The ECAs were not able to persuade users to change their fruit, vegetable, or liquid intake ($\chi^2_2=0.34$, $P=.85$) or decrease

loneliness (χ^2_2=0.02, *P*=.99). There were also no significant differences over time in quality of life (χ^2_2=2.99, *P*=.22), autonomy (χ^2_2=0.34, *P*=.85), competence (χ^2_2=2.32, *P*=.31), or relatedness (χ^2_2=2.46, *P*=.29). Table 2 shows all descriptive health outcomes.

During the interviews, most participants indicated that they thought they had a healthy diet. Nonetheless, a majority mentioned that the food diary helped them to become aware of their food intake. Some people were even shocked by the observation that they had such a fixed eating pattern and described PACO as a wake-up call. About half of the participants mentioned that they did introduce changes into their diet, such as cooking with more fresh ingredients, baking bread, eating more fruits and vegetables, and eating less meat. With respect to loneliness, most participants mentioned that they already had ample social contacts, even though some stated that they were feeling rather lonely. Apart from the unfortunate timing of the pandemic, 4 participants mentioned making changes in their social network because of PACO. For example, 1 participant created a list of everyone he knew and contacted them occasionally. Also, the chat connected a few people with each other and resulted in one-on-one contacts.

Table 2. Descriptive health outcomes.

	Scale	Tw, mean (SD)	T0, mean (SD)	T1, mean (SD)	T2, mean (SD)
Eating behavior	0-300	237.04 (45.33)	215.84 (72.12)	215.70 (65.92)	223.01 (71.28)
Loneliness	1-5	2.27 (1.71)	2.47 (1.78)	2.62 (1.91)	2.44 (1.92)
Quality of life	13-65	54.93 (4.93)	56.09 (5.60)	55.47 (6.56)	54.78 (5.85)
Autonomy	1-5	4.11 (0.42)	3.99 (0.54)	4.05 (0.60)	4.07 (0.56)
Competence	1-5	4.24 (0.37)	4.05 (0.58)	4.19 (0.52)	4.22 (0.57)
Relatedness	1-5	4.21 (0.38)	4.33 (0.56)	4.31 (0.53)	4.34 (0.51)

Pathways to Effects

Following our conceptual model for health, we expected to find a significant correlation between minutes spent on the different modules and eating behavior. However, this was not the case (*P*>.05, see Table 3 for all correlations). With respect to the other pathways, we found that competence correlated with eating behavior (*r*=–0.38, *P*=.03) and that it predicted eating behavior over time ($F_{1,30}$=4.30, *P*=.047, R^2=0.13). Quality of life (*r*=–0.60, *P*<.001), autonomy (*r*=–0.38, *P*=.03), relatedness (*r*=–0.59, *P*<.01), and number of chat messages (*r*=0.72, *P*=.03) correlated with loneliness, but did not predict loneliness ($F_{4,8}$=1.32, *P*=.40, R^2=0.14).

Table 3. Spearman correlations for health-related outcomes and PACO modules.

Variable	Eating behavior	Loneliness	Quality of life	Autonomy	Competence	Relatedness	Food diary	Goals	Recipes	Stories	Chat
Eating behavior											
Spearman correlation	1	0.10	–0.21	–0.11	–0.38	–0.01	0.19	0.12	–0.27	0.04	0.01
P value	—[a]	.57	.28	.57	.03	.94	.30	.53	.13	.81	1.00
Loneliness											
Spearman correlation	0.10	1	–0.60	–0.38	–0.16	–0.59	0.01	–0.09	–0.23	–0.13	0.72
P value	.57	—	<.001	.03	.39	<.001	.98	.62	.21	.48	.03
Quality of life											
Spearman correlation	–0.21	–0.60	1	0.75	0.47	0.67	0.13	0.20	0.14	0.36	–0.45
P value	.26	<.001	—	<.001	.007	<.001	.48	.28	.45	.046	.22
Autonomy											
Spearman correlation	–0.11	–0.38	0.75	1	0.55	0.60	0.09	–0.02	–0.03	0.16	–0.31
P value	.57	.03	<.001	—	.001	<.001	.62	.92	.88	.37	.41
Competence											
Spearman correlation	–0.38	–0.16	0.47	0.55	1	0.43	0.06	–0.32	–0.24	–0.01	0.06
P value	.03	.39	.007	.001	—	.014	.74	.08	.18	.99	.89
Relatedness											
Spearman correlation	–0.01	–0.59	0.67	0.60	0.43	1	0.12	0.13	0.20	0.24	–0.29
P value	.94	<.001	<.001	<.001	.01	—	.51	.49	.28	.20	.45
Food diary											
Spearman correlation	0.19	0.01	0.13	0.09	0.06	0.12	1	0.02	–0.14	–0.13	–0.27
P value	.30	.98	.48	.62	.74	.51	—	.92	.46	.49	.48
Goals											
Spearman correlation	0.12	–0.09	0.20	–0.02	–0.32	0.13	0.02	1	0.34	0.44	–0.37
P value	.53	.62	.28	.92	.08	.49	.92	—	.06	.01	.33
Recipes											
Spearman correlation	–0.27	–0.23	0.14	–0.03	–0.24	0.20	–0.14	0.34	1	0.11	–0.21
P value	.13	.21	.45	.88	.18	.28	.46	.06	—	.54	.59
Stories											
Spearman correlation	0.04	–0.13	0.36	0.16	–0.01	0.24	–0.13	0.44	0.11	1	0.03
P value	.81	.48	.046	.37	.99	.20	.49	.01	.54	—	.93
Chat											
Spearman correlation	0.01	0.72	–0.45	–0.31	0.06	–0.29	–0.27	–0.37	–0.21	0.03	1
P value	1.00	.03	.22	.41	.89	.45	.48	.33	.59	.93	—

[a]Not applicable.

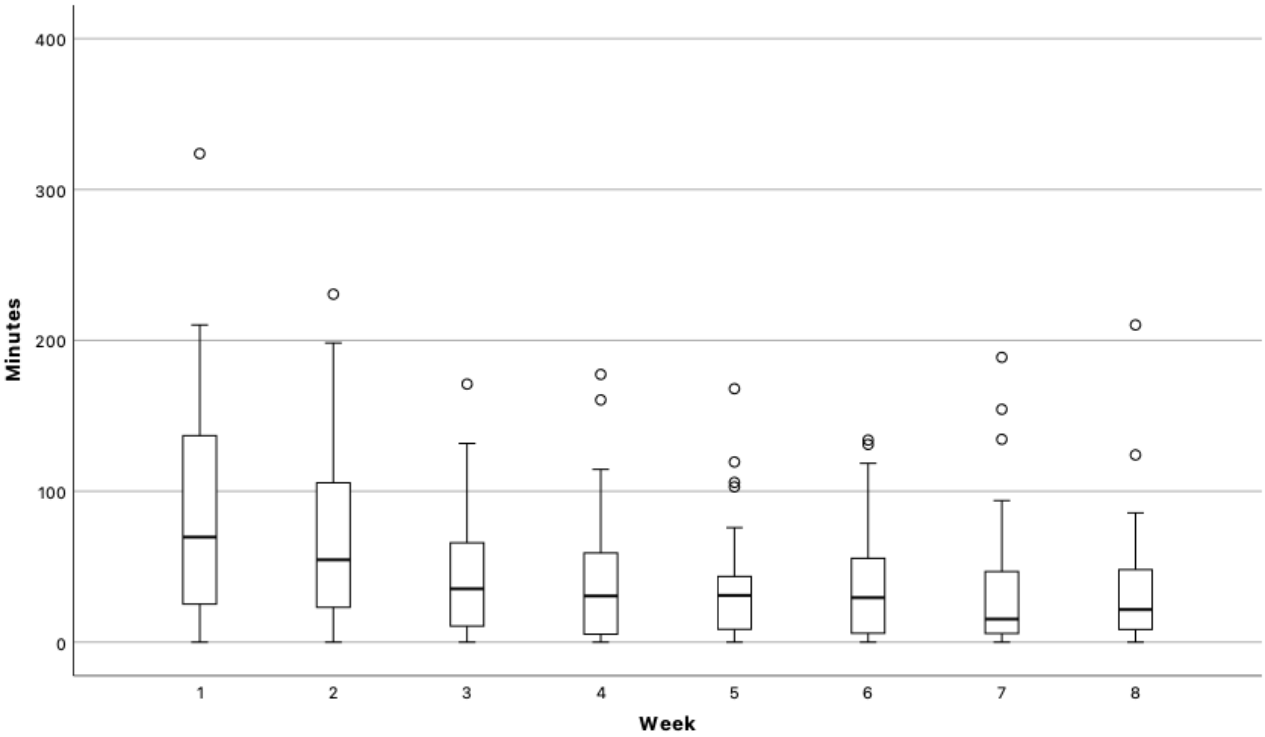
Understanding ECA Use

Use of PACO and Trends Over Time

On average, participants logged in 39.97 times (SD 37.38, range 10-197). Minutes per week decreased from a median of 69.66 in week 1 to 21.57 minutes in week 8 (Figure 3). The Friedman test confirmed this decline over time, showing a significant difference in use between weeks (χ^2_7=31.46, *P*<.001). The median time for using PACO was 15 h, 15 min, and 05 s. The average total time spent on PACO was 6 h, 30 min (SD 05 h, 54 min, 01 s), and the time spent per session was 11 h, 10 min (SD 05 h, 44 min). The average number of modules used per session was 2.39 (SD 0.34). The most time was spent on the food diary (85.45%), followed by the recipes (6.36%), goals (4.58%), and stories (3.61%). In total, 11 participants signed up for the chat. They sent a mean of 27.78 messages (SD 15.55, range 13-67). During the final interaction, the module used most

often was the food diary (41.67%), followed by the chat (25.00%), goals (16.67%), recipes (12.50%), and stories (4.17%).

Figure 3. Minutes per week.



Use-Related Outcomes

Usability, aesthetics, privacy concerns, and perceived control were rated above the midpoint of the scale (Table 4). The enjoyment and usefulness of PACO were rated below the midpoint of the scale, and perceived usefulness was rated relatively low. In total, 30 (94%) participants indicated that they were not willing to pay for PACO. With respect to the amount they would be willing to pay, results were contradictory, with 28 (88%) not willing to pay anything, and 4 (13%) willing to pay €5 (US $5.50). Following our conceptual model for ECA use, we found that aesthetics correlated significantly with usability (r=0.44, P=.01) and enjoyment correlated with perceived usefulness (r=0.48, P=.005). Although we found that perceived usefulness (r=0.39, P=.03) and enjoyment (r=0.38, P=.03) correlated with use in minutes (Table 5 shows all correlations), in the full regression model, these did not predict use ($F_{2,29}$=1.98, P=.16, R^2=0.12).

During the interviews, participants stated that although they read the module content, they did not truly engage and often reported that the content was not helpful. For example, participants listened to stories and read recipes, but did not act. In some cases, this was due to issues of tone, such as storytellers being seen as patronizing or the discomfort of endorsing dining alone. In other cases, such as the chat, participants simply did not wish to speak to people they did not know, or, if they did do so, the conversations felt shallow.

Table 4. Descriptive use outcomes.

	Scale	Outcome, mean (SD)
Usability	0-100	64.53 (17.98)
Enjoyment	1-7	3.26 (0.81)
Aesthetics	1-7	4.82 (1.21)
Privacy concerns	1-7	5.14 (1.28)
Control	1-7	4.78 (1.20)
Perceived usefulness	1-7	2.56 (0.99)

Table 5. Spearman correlations for use and use-related outcomes.

Variable	Use	Relationship with ECA[a]	Usability	Perceived usefulness	Aesthetics	Enjoyment	Privacy concerns	Control
Use								
Spearman correlation	1	–0.13	–0.05	0.39	0.34	0.38	0.30	–0.01
P value	—[b]	.47	.80	.03	.06	.03	.09	.99
Relationship with ECA								
Spearman correlation	–0.13	1	–0.01	0.31	0.28	0.28	0.01	0.32
P value	.47	—	.96	.08	.13	.12	.96	.07
Usability								
Spearman correlation	–0.05	–.01	1	–0.13	0.44	0.23	0.35	0.48
P value	.80	.96	—	.47	.01	.21	.05	.005
Perceived usefulness								
Spearman correlation	0.39	0.31	–0.13	1	0.27	0.48	0.09	0.01
P value	.03	.08	.47	—	.13	.005	.64	.95
Aesthetics								
Spearman correlation	0.34	0.28	0.44	0.27	1	0.78	0.54	0.51
P value	.06	.13	.01	.13	—	<.001	.001	.003
Enjoyment								
Spearman correlation	0.38	0.28	0.23	0.48	0.78	1	0.32	0.38
P value	.03	.12	.21	.005	<.001	—	.07	.04
Privacy concerns								
Spearman correlation	0.30	0.01	0.35	0.09	0.54	0.32	1	0.48
P value	.09	.96	.05	.64	.001	.07	—	.005
Control								
Spearman correlation	–0.01	0.32	0.48	0.01	0.51	0.38	0.48	1
P value	.99	.07	.005	.95	.003	.04	.005	—

[a]ECA: embodied conversational agent.

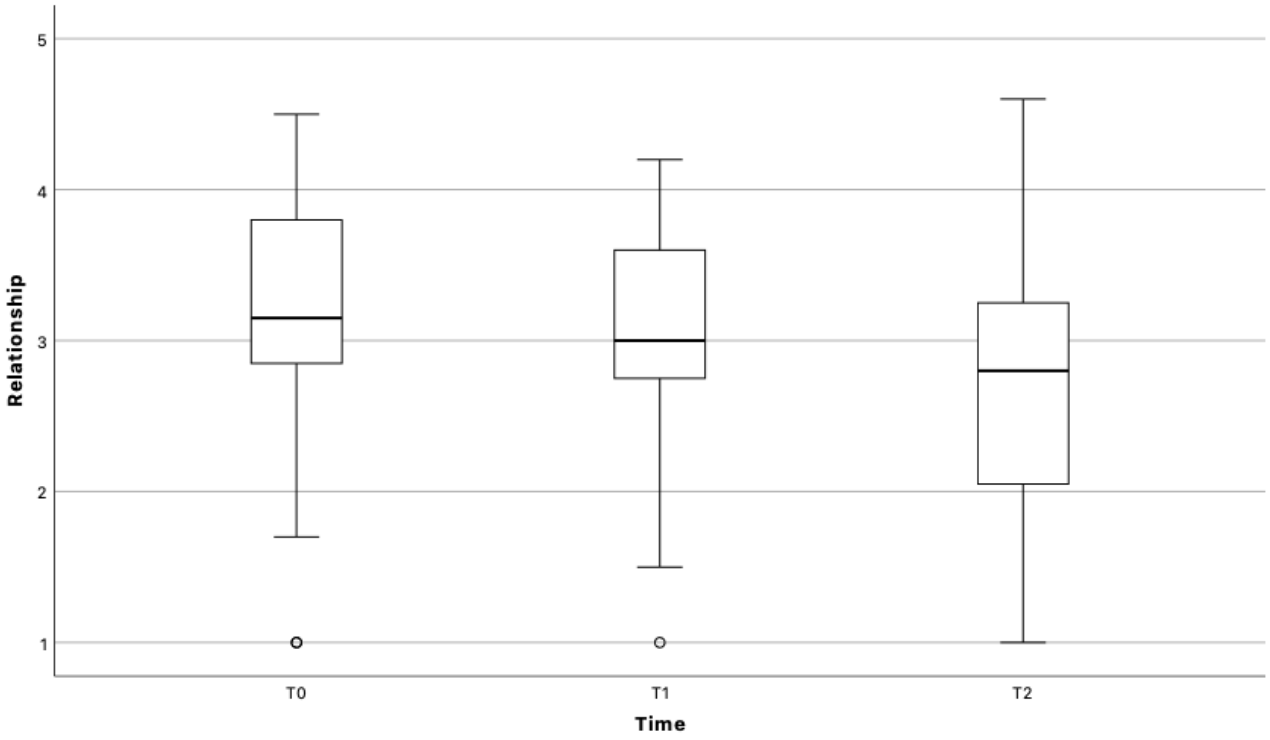
[b]Not applicable.

Relationship With the ECAs

The strength of the relationship with the ECAs decreased over time ($F_{1.72,53.33}$=4.22, *P*=.02; more details shown in Figure 4). Posthoc analysis with Bonferroni correction showed that the difference between T1 and T2 was significant (*P*=.047). Contrary to our expectation, the relationship did not correlate with use (*r*=–0.13, *P*=.47).

During the interviews, most participants were neutral about the ECAs, or reported not having noticed them. Six participants mentioned that the ECAs made PACO easier to use, more engaging, or more enjoyable compared to plain text, or even described them as “fantastic.” On the other hand, 3 participants found the ECAs to be childish and unreal and the participants considered themselves too rational to regard the ECAs as actual people.

Figure 4. Relationship with the embodied conversational agents over time.



Discussion

This study used a randomized controlled trial to investigate the effectiveness, the pathways to effects, and the mechanisms that underlay the use of an ECA targeting eating behavior and loneliness among older adults. The results showed that neither the ease of use of the PACO service nor the user experience explained the extent to which it was used. Furthermore, the use of PACO did not result in improved fruit, vegetable, or liquid intake or reduced loneliness. Our findings might, on first sight, contradict our hypotheses, and add to the mixed evidence base on nutritional ECAs [5,6,44]. On the other hand, we can also take these results as valuable lessons for the future design of eHealth services.

Participants did become more aware of their eating behavior due to the self-monitoring tool, and thus also became more aware of behaviors they could improve. In the terms used in the precaution adoption process model (PAPM) [45], they were "deciding about acting." However, in the interviews, participants expressed high self-perceived health and no need for change. This suggests users might well have been in the stage of "decided not to act." It is known that the PAPM stage plays a significant role in the perceived persuasiveness of different behavioral change techniques [46]. Hence, different needs should have been nurtured in our participants, as they were still in an earlier stage of the model. If this was the case, then the design of future services could benefit from either creating a functional design catering toward the predominant stage of the targeted population or personalizing the service based on an intake process that considers the stage of the end user.

To our knowledge, we are among the first to study factors that help understand ECA use. Surprisingly, we found that the use of PACO could not be explained by its usability, privacy concerns, perceived usefulness, or level of enjoyment. Furthermore, positive ratings on aesthetics and perceived control were not associated with time spent using PACO, although these factors did have a positive correlation with usability. Instead of arguing that these factors are not relevant for the development of an ECA, we argue that a certain threshold might be necessary for a service to be used. This is in line with other work on ECAs among older adults, which has shown that technical problems have a negative impact on use, adaptiveness, usefulness, and trust [47]. It has yet to be determined what factors positively influence the use of an ECA. Instead of focusing on traditional use-related factors, as we did in our conceptual model explaining ECA use, future research might benefit from examining certain threshold scores in earlier stages of development. Furthermore, the PAPM might help understand ECA use. If users do not intend to change their behavior, for example, it can be expected that they will not engage with the ECA. Research has indeed shown that this is true for the adoption of nutrition and fitness apps among the general population [48].

This study has limitations. First, we received a very low response to our flyers, social media posts, and advertorials. Newspaper interviews and phone calls to potential participants by the research panels resulted in a greater, yet still limited, response. Because of this nonresponse, we do not know why more older adults did not want to participate in this study. In total, 5 potential participants indicated that they did not want to participate on the consent form. One unintended effect of this method of obtaining informed consent could have been that people who were unable to provide consent were excluded. As a result of the small sample size, the overall power of this study was low. We consider that not measuring the PAPM stage was a second limitation of this study. We suspect that PAPM stage

is a factor that might provide more insight into both the use and effectiveness of the service (ie, participants who use the service more frequently and report health-related effects might be more likely to act). Finally, the ongoing COVID-19 pandemic might have influenced our results. We did rewrite the content of PACO to match the current situation and focused on online alternatives for engaging in social interactions. Nonetheless, participants felt they were not able to be more socially active due to government restrictions. Indeed, loneliness increased in our target group during the pandemic [49]. This might have counteracted the decrease in feelings of loneliness that we expected.

In conclusion, this study illustrates how to use a conceptual model to guide the evaluation of an ECA service in terms of both its level of use and its health effects, although it did not provide us with any conclusive evidence of its actual effectiveness. Nonetheless, our results provide valuable directions for future studies in this emerging field.

Acknowledgments

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Conflicts of Interest

LvV works at Roessingh Research and Development, the company that developed PACO. There are no other conflicts of interest.

Multimedia Appendix 1
The modules of the PACO service.
[DOCX File , 20 KB - formative_v6i4e33974_app1.docx]

Multimedia Appendix 2
CONSORT e-HEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 372 KB - formative_v6i4e33974_app2.pdf]

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Abbreviations

ECA: embodied conversational agent
PAPM: precaution adoption process model
TAM: technology acceptance model

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Original Paper

Developing a Mobile Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events Administration System to Capture Postradiation Toxicity in Oncology: Usability and Feasibility Study

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Abstract

Background: Accurate self-reported symptomatic toxicity documentation via the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) is essential throughout cancer treatment to ensure safety and understand therapeutic efficacy. However, the capture of accurate toxicities from patients undergoing radiation therapy is challenging because this is generally provided only at the time of scheduled visits.

Objective: This study seeks to establish the usability and feasibility of a mobile PRO-CTCAE Administration System (mPROS) to capture toxicities related to radiation therapy.

Methods: English-speaking adult patients who were undergoing radiation therapy for cancer were enrolled and given a brief demonstration of the Say All Your Symptoms (SAYS) and Symptom Tracking Entry Program (STEP) interfaces of the mPROS app, followed by a patient-use phase where patient actions were observed as they navigated mPROS to enter toxicities. Patient feedback was captured via a semistructured interview and brief questionnaire.

Results: We enrolled 25 patients (age: mean 60.7 years; females: n=13, 52%; White patients: n=13; 52%; non-Hispanic patients: n=19, 76%; college graduates: n=17, 68%). Patients almost equally preferred the SAYS (n=14, 56%) or STEP (n=11, 44%) interfaces, with 21 patients (84%) agreeing that they would use mPROS to report their symptoms to their health care team and 19 patients (76%) agreeing that they would recommend mPROS to others.

Conclusions: The mPROS app is usable and feasible for facilitating the patient reporting of radiation therapy–related symptomatic toxicities. A revised version of mPROS that incorporates patient input and includes electronic health record integration is being developed and validated as part of a multicenter trial.

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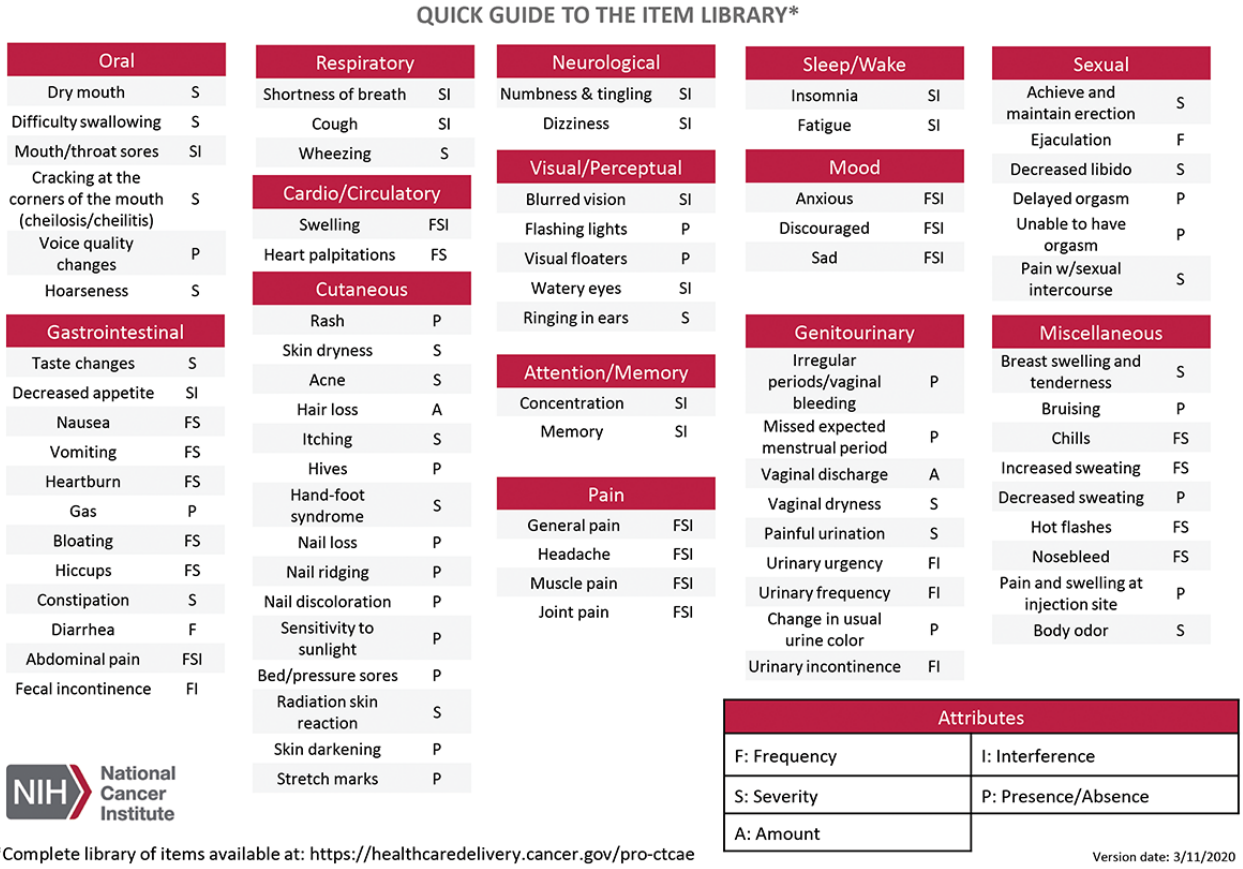
KEYWORDS

neoplasms; patient outcome assessment; radiation oncology; toxicity; public health informatics; mobile apps; mobile health; mobile administration system; radiation therapy; eHealth

Introduction

Toxicity reporting via the Common Terminology Criteria for Adverse Events (CTCAE) of the National Cancer Institute (NCI) is mandatory in oncology clinical trials to monitor patient safety and to understand the toxicity profiles of treatments [1]. Several studies have shown that symptomatic toxicities associated with anticancer treatments (eg, nausea and vomiting) are frequently underreported by health care providers, even when prospectively collected within clinical trials [2-5]. To address the issue of underestimating symptom toxicities related to cancer treatment, the NCI supported the creation of the Patient-Reported Outcomes (PRO) version of the CTCAE (PRO-CTCAE), referred to as PRO-CTCAE [6-10]. Version 1.0 of the PRO-CTCAE item library can be administered electronically [11] and includes 124 individual items representing the 78 toxicities, with multiple attributes captured for a given toxicity attribute question (eg, frequency, severity, and interference with usual or daily activities), as shown in Figure 1.

Figure 1. Patient-Reported Outcomes of the Common Terminology Criteria for Adverse Events item library version 1.0.



Although the PRO-CTCAE has preliminarily demonstrated promise in several areas [12-17], with the broad electronic delivery of the PRO-CTCAE showing clinical utility [18-21], this tool has not yet enjoyed widespread use in the radiation oncology setting [22-24]. The exposure of surrounding healthy tissue to the radiation field is largely unavoidable for patients with cancer who are treated with radiation therapy, making patient reports of symptomatic toxicities particularly important for this population. One barrier to using the PRO-CTCAE is that each radiation oncology clinic must develop infrastructure and support to administer a PRO-CTCAE assessment [25]. For example, administrative personnel in clinics creating custom PRO-CTCAE assessments using paper forms require additional time to enter the patient responses into digital systems. If the PRO-CTCAE is administered on a clinic-provided digital platform (eg, tablets), administrative support is required to answer questions from patients who do not routinely use technology (eg, for changing passwords) [26,27]. Although these complications are manageable, they may be reduced or eliminated through the development of mobile apps that do not require clinics to provide digital assessment platforms.

Categories of PRO-CTCAE items have not yet been established for commonly used cancer radiation treatments, necessitating that radiation oncologists select PRO-CTCAE items for a given treatment based on their clinical experience rather than a uniform standard. Additionally, the current practice is such that PRO-CTCAE assessments are not tailored to patient characteristics, previous assessment responses, or the area(s) of their body where they are receiving radiation therapy. Such patient-centered specificity in toxicity reporting would provide clinicians with crucial context that will assist in their interpretation of this patient-reported information. Further, for patients reporting PRO-CTCAE toxicities between visits or otherwise outside of the clinic setting, there is currently no means to remotely deliver relevant self-care information and suggestions (eg, strategies for treating mild skin symptoms). Patients may be more likely to engage in and complete the

assessments if they know that they will learn something about their symptoms and how to treat them.

Despite the importance of leveraging the electronic capture of between-visit PRO information that can be incorporated directly into the electronic health record with respect to improving medical decision-making and prolonging overall patient survival [28-30], there are no cancer-specific mobile health apps available for this purpose [31,32]. Therefore, this study sought to complete a cross-sectional assessment of the usability and feasibility of the Mobile PRO-CTCAE Administration System (mPROS), an iOS- and Android-based smartphone app designed to address the aforementioned barriers through the tailoring of PRO-CTCAE assessments specifically to patients undergoing radiation therapy for cancer.

Methods

Recruitment

Patients with appointments in the radiation oncology clinics at Memorial Sloan Kettering Cancer Center (MSK), a tertiary NCI-designated Comprehensive Cancer Center in New York, NY, were screened by a clinical research coordinator (CRC) for initial eligibility. Patients were originally eligible for approach if they spoke English; were receiving radiation therapy in the head/neck, breast, or pelvic areas; and were aged 18 years or older. Delays related to patient accrual required the expansion of participant enrollment to those receiving radiation therapy for any disease type, despite mPROS only being equipped to address symptoms related to radiation in the head/neck, breast, and pelvic areas. The physicians attending to the patients were contacted for permission to approach patients who were determined to be eligible. Enrolled patients were given the option to end the study session at any time. Documented informed consent was not collected, as this study was deemed exempt by the Institutional Review Board at MSK.

Mobile App

The mPROS app uses 2 PRO-CTCAE assessment interfaces to collect data. The structured interface, called the Symptom Tracking Entry Program (STEP), delivers multimedia-supported PRO-CTCAE items relevant to the patient's radiation therapy (Figure 2). The second interface, Say All Your Symptoms (SAYS), leverages a virtual clinical assistant in the form of a chatbot to engage the patient in a text-based conversation to elicit patient responses to relevant PRO-CTCAE items in a comforting manner (Figure 3). Both interfaces are programmed to be responsive to symptoms related to radiation in the head/neck, breast, and pelvic areas for male and female patients.

Figure 2. Symptom Tracking Entry Program interface.

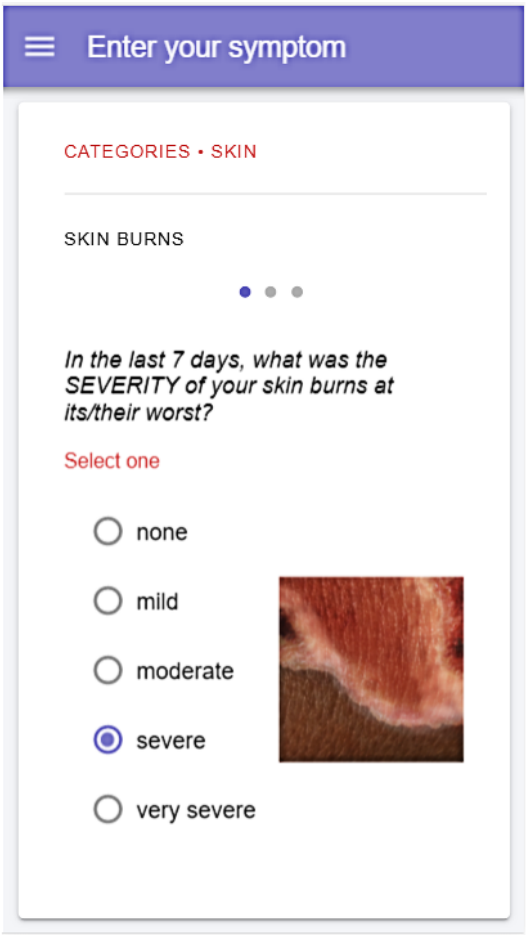
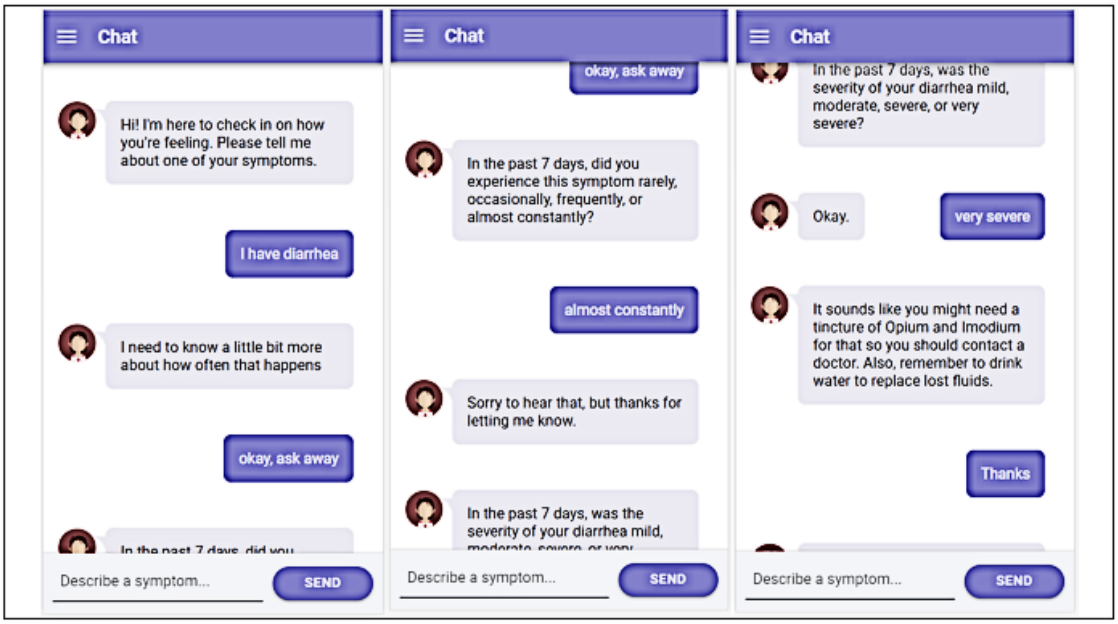


Figure 3. Chatbot on the Say All Your Symptoms interface.



Procedure

The interactions during this research session took place in a quiet, private space in the MSK radiation oncology clinics and were audio-recorded to support the generation of a summary report. The CRC confirmed eligibility and determined if the patient was able to use a study-provided iOS- or Android-based smartphone on which the mPROS app was installed. Upon enrollment, the CRC collected demographic and treatment characteristics (eg, gender, age, education, race and ethnicity, the radiation treatment region, and the frequency of mobile phone app use) and provided an explanation about how mPROS works. Patients were then asked about their preferred operating system (ie, iOS or Android), the part of the body where they were currently being administered radiation, and 1 to 3 symptoms that they were currently experiencing or had recently experienced. This was followed by a brief (8-10 minutes) demonstration on how to use both interfaces of mPROS, with the CRC using symptoms not mentioned by the patient to avoid redundancy. Patients were given the opportunity to ask questions about mPROS and request a repeat demonstration of either mPROS interface.

Following the completion of the demonstration, patients were provided with the study smartphone based on their preferred operating system (ie, iOS or Android) and asked to use the mPROS app for approximately 5 to 10 minutes. The patients were asked to choose which interface they wanted to use first (ie, STEP or SAYS). The CRC guided the patients to progress through each interface but was instructed to provide additional assistance only when requested by the patients.

The patients' explicit and implicit actions were observed and documented by the CRC (eg, the ability to switch between interfaces without assistance, issues related to progression through the app, app crashes, etc), and any aspects that appeared to be frustrating or time consuming were noted for the follow-up interview. All patient interactions with the mPROS app (ie, click location and time per page/interface in milliseconds) were captured by the mPROS system.

Upon completing the patient-use portion of the study within mPROS, the CRC conducted a semistructured interview in which patients were asked the following questions: (1) What features of mPROS did you like the most? (2) What features of mPROS did you like the least? (3) What suggestions do you have to improve mPROS? (4) Which mPROS interface did you prefer and why? (5) What symptoms or features of symptoms did you want to report in mPROS but could not? (6) How frequently do you think you would use the mPROS application? (7) What could we add to the mPROS application to make it more useful to you? (8) How would an application like mPROS help you in discussing your symptoms with your doctors? (9) Is there anything else that you would like to tell us about your experience with the mPROS application?

Patients were then asked to complete a brief 7-item questionnaire to indicate the degree to which they agreed with the following statements: (1) I would use the mPROS application to report symptoms to my health care team. (2) I would recommend mPROS to others. (3) I use other smartphone applications to track my symptoms. (4) I use other smartphone applications to track my daily activity and experiences. (5) I would be interested in connecting with other radiation patients through the mPROS application to share experiences. (6) I would like for the mPROS application to show me my symptom history over time. (7) I would like for the mPROS application to give me an option to use the phone camera to take a picture of my symptomatic area (eg, skin, mouth) to send to my doctor.

After the research interaction, patients were thanked for their participation, reimbursed US $50 for their time, and given the opportunity to spend additional time using the mPROS app if it was of interest to them. All audio recordings were destroyed within 48 hours of the research interaction.

Results

Patient Characteristics

A total of 124 patients were screened for eligibility between May and August 2019. Among them, 91 patients (73.4%) were found to be eligible; the CRC approached 65 (71.4%) of these 91 patients (Figure 4). The primary reason for not approaching patients was due to the rescheduling of appointments (n=20). Of the 65 approached patients, 29 (23.4%) accepted enrollment in the study, with a total of 25 patients (20.2%) completing the research interaction session. Further, 20 patients who were eligible did not show up for their scheduled appointment and thus could not be approached for participation, whereas 19 patients were approached and agreed to participate if they could complete the session during a future visit. The reasons for refusal included not enough time for the study (n=11, 64.7%), not interested/irrelevant (n=4, 23.5%), not using a smartphone (n=1, 5.9%), and not keen to use an app like mPROS (n=1, 5.9%).

The enrolled patients (age: mean 60.7 years; range 34-80 years) comprised 52% females and were mostly highly educated (68% college graduates or postgraduates), White (52%), and non-Hispanic (76%). The radiation regions included the brain (n=4), breast (n=4), chest/thorax (n=4), head/neck (n=4), lungs (n=2), lymph nodes (n=2), adrenal gland (n=1), liver (n=1), pelvic region (n=1), spine (n=1), and thighs (n=1), of which only 9 (ie, breast, head/neck, and pelvic region) were the targets for the current version of mPROS. All but 3 (12%) of the 25 patients indicated that they sometimes used smartphone apps, with 12 patients (48%) indicating that they “always” used smartphone apps. Furthermore, 20 patients (80%) currently use and prefer the iOS operating system, whereas 5 patients (20%) preferred using Android devices. The sample characteristics are included in Table 1.

Figure 4. CONSORT (Consolidated Standards of Reporting Trials) diagram. appt: appointment; CRC: clinical research coordinator; MSK: Memorial Sloan Kettering Cancer Center; mPROS: Mobile Patient-Reported Outcomes.

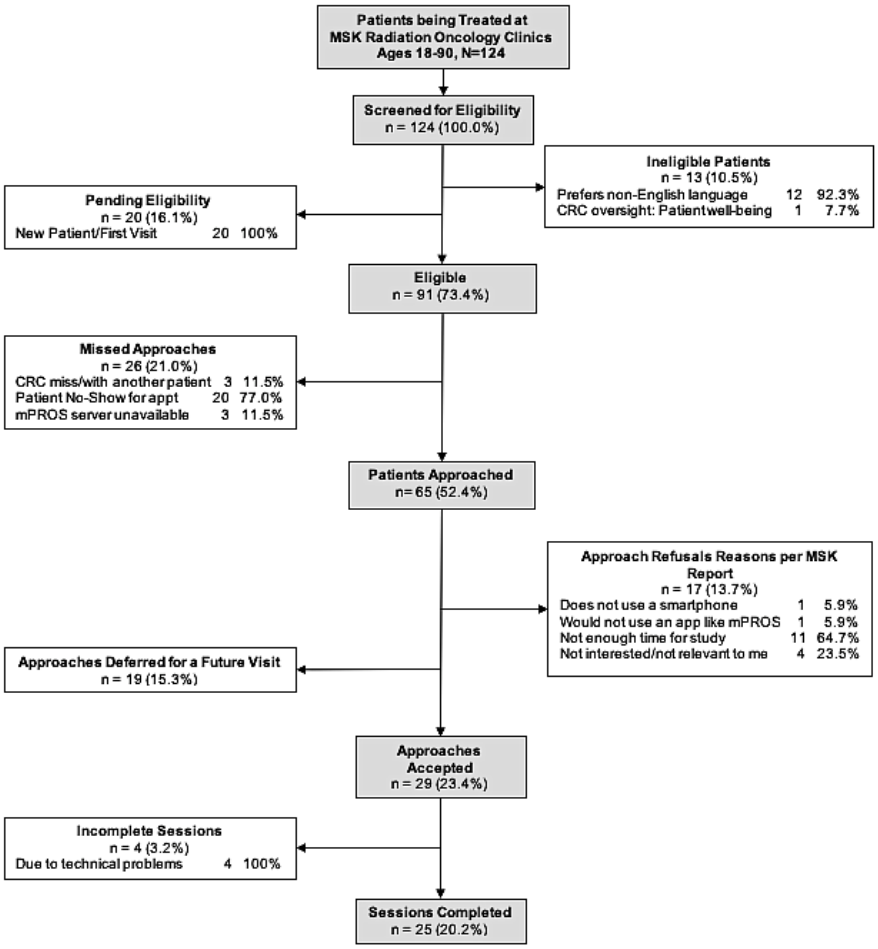


Table 1. Demographic and clinical characteristics of the patients (N=25).

Characteristics	Value
Age (years)	
Mean (SD)	60.7 (12.7)
Median (range)	63.5 (34-80)
Gender, n (%)	
Female	13 (52)
Male	12 (48)
Race, n (%)	
White	13 (52)
Asian or Pacific Islander	3 (12)
Black or African American	2 (8)
Asian Indian	1 (4)
Native American	1 (4)
Mixed race	2 (8)
Preferred not to answer	3 (12)
Ethnicity, n (%)	
Non-Hispanic	19 (76)
Hispanic	1 (4)
Chose not to answer	5 (20)
Education, n (%)	
High school graduate or less	5 (20)
Post high school training/some college education	3 (12)
College graduate/postgraduate	17 (68)
Use of smartphone apps, n (%)	
Never	3 (12)
Sometimes	4 (16)
Often	6 (24)
Always	12 (48)
Cancer type, n (%)	
Breast[a]	4 (16)
Head/neck[a]	4 (16)
Chest/thorax	4 (16)
Brain	4 (16)
Lungs	2 (8)
Underarm lymph nodes	2 (8)
Pelvic region[a] (male)	1 (4)
Spine	1 (4)
Thighs	1 (4)
Liver	1 (4)
Adrenal gland	1 (4)
Pelvic region[a] (female)	0 (0)

[a]Cancer type specifically targeted in the current mPROS (Mobile Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse

Events Administration System) app.

Demonstration Phase

Patients generally understood the use of mPROS during the demonstration phase; no patients requested a repeat demonstration of the mPROS features. However, 3 patients had questions regarding treatment management suggestions (eg, 2 types of ibuprofen suggested for pain rather than 1 type), and 1 patient asked whether text had to be entered into the final open-ended text box for gastrointestinal symptoms for the symptom form to be "complete."

Patient-Use Phase

The mean time to complete the patient-use phase was 19 minutes and 33 seconds (range 7 minutes and 22 seconds to 39 minutes and 17 seconds). All but 2 of the participants were able to navigate between STEP and SAYS without assistance from the CRC.

Semistructured Interviews

Table 2 includes a summary of patient preferences, perceived mPROS benefits, suggestions for mPROS improvement, and general feedback on the app. The majority of the patients indicated they would use mPROS on a regular basis (n=12) or when they noticed a marked change in their symptoms (n=13). Patient statements included "I would use it every day because of my chronic symptoms."

When asked about their suggestions to improve mPROS, 8 patients suggested the addition of a feature to send mPROS communications directly to their doctor, preferring a 2-way confirmation of data sent and received. The addition of a feature for patients to enter lifestyle-related information (eg, current medications, treatments, diet, mental health, and exercise routines) was suggested by 7 patients. Another suggestion given by 4 patients was to have an alert system in place for any instance of a symptom being reported as "very severe," and 3 patients spontaneously suggested adding a feature to upload photographs of their skin. The inclusion of a spell-check feature in the SAYS interface was suggested by 3 patients. Of these 3 patients, 2 suggested having SAYS confirm a symptom entry before advancing to the related questions or having it suggest a symptom if the user's input was not recognized (eg, "you said 'headache' – did you mean head pain?"). Two patients suggested including legal language before reporting symptoms (eg, "If you are experiencing an emergency, please call 911 or contact your doctor"). One patient suggested a "sent confirmation/read receipt" feature be added to the app, and another patient suggested the addition of an option to enter medications or treatments already taken for a given symptom.

With respect to using mPROS to help with discussing symptoms with their doctor, 14 patients mentioned the advantage of being able to record and recall symptoms over time, with 9 patients indicating that mPROS would help them to report symptoms over time, 7 mentioning that using mPROS would help their doctor or treatment team, and 4 stating that they are currently recording and maintaining their own physical set of symptom notes that would otherwise be documented in the mPROS app.

The mPROS app provided artistically rendered images to help patients understand the skin burn severity levels (mild, moderate, severe, and very severe). When asked about the skin severity images, 17 of the 25 patients (68%) found these to be helpful, and 18 patients indicated that the binary (ie, light versus dark) skin tone was insufficient, with 2 patients spontaneously raising this point prior to the interview question. The inclusion of additional context was requested by 3 patients when selecting skin color during patient setup, as the images do not appear until later, and they appear only if skin symptoms are included in the STEP interface. Another patient suggested asking the skin color question only when specifically indicating that a patient is experiencing a skin-related symptom. Additionally, 6 patients did not find the skin images to be helpful, citing that the skin burn images were not relevant to them either because the choices within skin effects did not include burns or because the reference images did not represent their healthy skin color. These patient responses included "I didn't find these to be helpful – I have discoloration, not burns. It would be better to upload pictures of your skin as you go through radiation" and "No – they don't look like skin to me. Light and dark skin was not specific enough. You need more gradations or have us pick from a continuum."

Table 2. Patient preferences, perceived benefits, general feedback, and suggestions for improvement identified from the semistructured interviews (N=25).

Survey items	Value, n (%)
Interface choice	
Used SAYS[a] first	13 (52)
Used STEP[b] first	12 (48)
Interface preference	
SAYS	14 (56)
STEP	11 (44)
Interest in future use	
Would use mPROS[c] on ad hoc basis depending on symptom changes	13 (52)
Would use mPROS on regular basis	12 (48)
Perceived benefits of mPROS	
Ability to record and recall symptoms over time	14 (56)
Assistance with recording symptoms over time	9 (36)
Will assist treatment team	7 (28)
Most liked feature	
SAYS chatbot	9 (36)
Specifying body areas	6 (24)
Speed/convenience of completing symptom reporting using the app versus completing it in the doctor's office	5 (20)
Ability to choose between methods of reporting symptoms	3 (12)
No response	2 (8)
Least liked feature	
mPROS not recognizing symptom	7 (28)
Confusion over when to swipe/tap “next” to enter more attributes	6 (24)
Texting	4 (16)
No response	8 (32)
Patient suggestions to make mPROS more useful	
Ability to send reports directly to clinicians	8 (32)
Ability to enter medications, treatments, diet, mental health, and exercise	7 (28)
Alert system for very severe symptoms	4 (16)
Less verbose questions/chat language	4 (16)
Spell-check for SAYS chatbot	3 (12)
Ability to upload skin photos	3 (12)
SAYS confirmation of symptom entry	2 (8)
Inclusion of legal language before reporting symptoms	2 (8)
Send confirmation/read receipt to clinicians	1 (4)
Specifying skin tone for skin-related symptoms	1 (4)
Use of a 1-5 scale rather than asking patients to type verbal descriptions	1 (4)
Additional safety features for logging into the app	1 (4)
Severity image feedback	
Binary skin tone (ie, light versus dark) insufficient	18 (72)
Images generally helpful	17 (68)
Not relevant due to lack of burns or not representing healthy skin color	6 (24)

Survey items	Value, n (%)
General feedback and issues	
Confused about right-swipe navigation of attribute questions	18 (72)
Helpful completion icons	9 (36)
Attempted to enter symptoms not associated with mPROS radiation sites	7 (28)
Struggled with text entry	6 (24)
Body areas too large to show where symptoms occurred	3 (12)
Problems finding home screen	2 (8)

[a]SAYS: Say All Your Symptoms.

[b]STEP: Symptom Tracking Entry Program.

[c]mPROS: Mobile Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events Administration System.

Patient mPROS Questionnaire

Among the 25 patients, 21 (84%) agreed or strongly agreed that they would use the mPROS app to report their symptoms to their health care team, and 19 (76%) agreed or strongly agreed that they would recommend mPROS to others. Approximately half the patients do not currently use other mobile apps to track their symptoms (n=12, 48%), with the majority indicating they do not use other mobile apps to track other activities (n=16, 64%). When asked whether they would be interested in connecting with other radiation patients through mPROS, only 10 (40%) patients were interested in such a feature. Except for 1 patient, the remaining 24 (95%) would like for mPROS to show symptom history over time and provide an option to send a photograph of their symptomatic area using the phone camera.

Discussion

Principal Findings

The underreporting of symptomatic toxicities throughout the course of radiation treatment can lead to the underestimation of the absolute rate of toxicity, which can immediately impact clinical decision-making. More accurate patient-tailored reporting of toxicities can lead to improved personalized care and quality of life for patients with cancer having difficulty with any treatment. This study sought to establish the usability and feasibility of mPROS, a mobile app that was designed to measure symptomatic toxicities via PRO-CTCAE and was specific to patients undergoing radiation therapy, in a sample of patients from radiation oncology clinics at a tertiary cancer center. The mPROS app was generally liked, with the majority of patients indicating they would use the app to report symptoms to their health care team. Some patients indicated that they liked the speed or convenience of reporting symptoms on their phone versus doing it in the doctor's office. Others liked having a choice of how to report symptoms.

Using mPROS to capture patient-reported toxicities is feasible; only 17 of the original 91 (18.7%) patients who were determined eligible for the study refused to participate (Figure 1). Of the 25 patients who participated, 21 (84%) indicated that they would use this app to report symptoms to their health care team and 19 (76%) stated that they would recommend mPROS to others. Limited training (ie, 8-10 minutes) is required for orienting patients to use mPROS; no patients requested additional demonstrations of the mPROS app prior to initiating the patient-use phase. Despite our patients' median age of 63.5 years and the inclusion of 11 patients aged 65 years or older (range 34-80 years), we observed no age-related challenges in the use of mPROS. This is consistent with recent work that established the feasibility of electronic geriatric health assessment in patients aged 65 years or older in a multi-institutional setting [33].

Using a qualitative methodology to establish the usability of mPROS is a strength of our study [34]. These patient-centered interactions provided important feedback for the refinement of mPROS and demonstrated that there is a need to have a personal app for reporting symptoms; moreover, the SAYS chatbot is desired by patients who are comfortable with texting, and there are symptoms that are not caused directly by radiation that patients still experience and want to report, such as headaches and nausea. Additionally, the majority of patients indicated that the skin severity images were insufficient and did not represent their healthy skin color. Suggestions were made to replace the binary (ie, light versus dark) skin tones with a sliding skin tone scale. The next version of mPROS will contain other recommended features that will make it more useful to the patients.

There are a number of limitations to this study. This was a single-site study completed in a tertiary cancer center with a mostly highly educated study sample with limited Hispanic representation. Additionally, delays related to patient accrual necessitated the expansion of eligibility criteria to any English-speaking patient aged 18 years or older who was receiving radiation therapy for any disease type. The version of mPROS that was used for testing only included body map selections and symptoms related to receiving radiation in the breast, head/neck, or pelvic region. Enrolled patients who were receiving radiation in a different region (n=16) were asked to select a region that was proximal to their radiation site, and several of their suggestions involved expanding mPROS to include their specific radiation sites (n=4). Despite this version of mPROS not including their radiation sites, all but 1 (n=15, 94%) of these participants indicated that they would use this app to report symptoms to their health care team. Finally, as mPROS was evaluated on a study-provided smartphone during a single session with each participant, we did not consider it

appropriate to assess the acceptability of the app at this time; acceptability will be analyzed as part of an ongoing multicenter clinical trial.

Conclusions

The mPROS app is a usable and feasible tailored assessment for patients to report symptomatic toxicities related to their radiation therapy. Using patient input from this study, a revised version of mPROS that includes electronic health record integration is being developed and validated as part of a multicenter clinical trial (National Institutes of Health/NCI Small Business Innovation Research Phase 2 Contract #75N91020C00027). The seamless electronic documentation of these patient-reported symptomatic toxicities will ensure that this information is considered as part of the clinical decision-making process, and this may ultimately improve patient outcomes.

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Conflicts of Interest

JU received funding, and authors SM, AR, and AK each received stipends from the National Institutes of Health and National Cancer Institute for developing the Mobile Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events Administration System (mPROS) through the Phase 1 Small Business Innovation Research contract (HHSN26120180013C).

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Abbreviations

CRC: clinical research coordinator
CTCAE: Common Terminology Criteria for Adverse Events
mPROS: Mobile Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events Administration System
MSK: Memorial Sloan Kettering Cancer Center
NCI: National Cancer Institute
PRO: Patient-Reported Outcomes
PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events
SAYS: Say All Your Symptoms
STEP: Symptom Tracking Entry Program

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Original Paper

Understanding Mental Health Professionals' Perspectives and Practices Regarding the Implementation of Digital Mental Health: Qualitative Study

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Abstract

Background: Despite the potential of digital mental health to provide cost-effective mental health care, its adoption in clinical settings is limited, and little is known about the perspectives and practices of mental health professionals regarding its implementation or the factors influencing these perspectives and practices.

Objective: This study aims to characterize in depth the perspectives and practices of mental health professionals regarding the implementation of digital mental health and explore the factors affecting such perspectives and practices.

Methods: A qualitative study using in-depth semistructured interviews with Portuguese mental health professionals (N=13)—psychologists and psychiatrists—was conducted. The transcribed interviews were thematically analyzed.

Results: Mental health professionals deemed important or engaged in the following practices during the implementation of digital mental health: indication evaluation, therapeutic contract negotiation, digital psychological assessment, technology setup and management, and intervention delivery and follow-up. Low-threshold accessibility and professionals' perceived duty to provide support to their clients facilitated the implementation of digital mental health. Conversely, the lack of structured intervention frameworks; the unavailability of usable, validated, and affordable technology; and the absence of structured training programs inhibited digital mental health implementation by mental health professionals.

Conclusions: The publication of practice frameworks, development of evidence-based technology, and delivery of structured training seem key to expediting implementation and encouraging the sustained adoption of digital mental health by mental health professionals.

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KEYWORDS

barriers; digital mental health; drivers; implementation; internet interventions; psychotherapy; technology acceptance and adoption; mental health professionals; Portugal; European Union; EU

Introduction

Background

Digital mental health may be understood as the use of digital technologies to support and improve mental health conditions and provide mental health care, including screening, health promotion, prevention, early intervention, treatment, and relapse prevention [1-3]. It encompasses a wide range of modalities, including internet research [4], monitoring and assessment [5], videoconferencing counseling and psychotherapy [5], internet interventions [6], and professional training (e-learning and e-supervision) [7]. In this regard, various technologies (telephone, mobile devices, apps, videoconference and chat software, psychological assessment, support and intervention platforms, artificial intelligence, virtual reality, serious games, wearable devices, etc) may be used to improve health outcomes or facilitate health care service delivery [1,2].

Owing to the potential of digital mental health to increase access to mental health care, eliminate disparities, and reduce costs of treatment delivery, interest and research in the field have grown exponentially in the past years [8]. Numerous randomized controlled trials have been conducted, and a strong body of evidence of efficacy has been generated [9,10], particularly in the domains of internet interventions [11] and videoconferencing counseling and psychotherapy [12].

Internet interventions are self-help, guided or unguided, technology-enabled interventions that aim to provide health and mental health–related assistance [11]. They have been found to be more effective than treatment as usual and as effective as face-to-face therapies for various conditions [13] (eg, generalized anxiety disorder [14], depression [15], and cancer-related distress [16]). The impact of guidance on the efficacy of internet interventions has also been examined. Although previous studies suggest that guided interventions are superior to unguided interventions [17], there is still a lack of research comparing the outcomes of blended treatment outcomes with classic face-to-face or nonblended treatments [18]. Internet interventions have also been found to be cost-effective when compared with various control conditions, such as active, attention, or waiting list control groups [19].

With regard to counseling and psychotherapy delivered via videoconference, previous systematic reviews [12,20] have reported that they can be effective across different populations (eg, children, adults, and older adults), geographies (eg, urban and rural), care settings (eg, primary health care settings and clinics), and mental health conditions (eg, anxiety, depression, and distress). Previous studies have reported that the effects are comparable with both in-person treatment and blended care approaches [20], and evidence on videoconferencing counseling and psychotherapy cost-effectiveness is increasing [21]. However, although sound scientific support favors the use of digital mental health approaches for the treatment of mental health disorders, its adoption by mental health professionals has been slow, and its implementation in clinical settings is still limited [22]. In Portugal, despite a significant mental health treatment gap [23,24], digital mental health initiatives are practically nonexistent [25].

Across the globe, various studies have been conducted to identify potential drivers of and barriers to digital mental health adoption (ie, acceptance, uptake, and use) and investigate mental health professionals' attitudes toward such an approach [26]. In general, findings suggest that professionals' attitudes range from neutral to generally positive [27], and there are several factors affecting adoption. Factors that are often identified as expediting adoption relate to the low-threshold accessibility of digital mental health [28,29], professionals' knowledge and training in the field [30,31], the potential to introduce new treatment alternatives (eg, virtual reality and biofeedback) [32], and professionals' positive attitudes toward digital mental health [28]. Conversely, factors frequently appointed as inhibiting adoption relate to the absence of ethical, legal, and regulatory frameworks for providing web-based mental health care [33-36]; professionals' lack of knowledge and training in the field [28,30,31]; potential confidentiality and security breaches associated with digital systems [37]; and negative attitudes toward digital mental health [28]. Furthermore, greater acceptance of blended care approaches was reported across studies [22,32].

Although previous research provides valuable insight into the factors influencing the adoption of digital mental health by professionals, adoption predictors, and their interrelationships are largely unknown. Most studies with health care professionals adopt a quantitative cross-sectional design, capturing the stance of large samples and listing implementation drivers and barriers but failing to provide an in-depth understanding of therapists' experiences, attitudes, and adoption determinants [32]. Moreover, qualitative studies on the topic often focus on cognitive behavioral therapy–oriented interventions [38,39], specific treatment modalities [39,40], and particular mental health conditions [22,29,39] or include participants of specific research programs [22,29,39,41], failing to characterize in depth the perspectives and practices of mental health professionals regarding the implementation of digital mental health or the factors influencing such perspectives and practices.

Objective

The aims of this study are (1) to characterize in depth the perspectives of mental health professionals regarding digital mental health, (2) to characterize in depth the practices of mental health professionals regarding the implementation of digital mental health, and (3) to explore the factors influencing such perspectives and practices in the context of Portugal.

Methods

Study Design

This qualitative study used in-depth semistructured interviews to characterize the perspectives and practices of Portuguese mental health professionals regarding the implementation of digital mental health and explore the factors influencing such perspectives and practices. A semistructured interview guide (Multimedia Appendix 1) was developed based on a literature review and analysis of data obtained from a previous study by the research team [28]. The interview guide included 33 questions and covered five main domains: (1) professional background and digital technology proficiency, (2) knowledge

and use of digital mental health, (3) attitudes toward digital mental health, (4) advantages and limitations of digital mental health, (5) drivers of and barriers to the adoption and implementation of digital mental health, and (6) therapeutic process and alliance in digital mental health interventions. In addition, follow-up questions were used to clarify participants' perspectives and practices. The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist was used as a guideline to structure this paper [42].

Sampling and Recruitment

A nonprobabilistic, stratified purposeful sample [43] of Portuguese mental health professionals—psychologists and psychiatrists—was planned to capture variation and ensure the inclusion of participants in different age groups and work contexts; with different academic degrees and theoretical orientations; and reporting different levels of work experience, knowledge, and use of digital mental health. The sample of participants was identified following referrals from researchers and contacts in the health community. A total of 28 mental health professionals were invited to participate in this study via email or telephone. Of the 28 invited professionals, 15 (54%) replied and agreed to participate. Meaning saturation was established as a stopping criterion, which meant that new participants would not be enrolled once novel fieldwork insights stopped significantly changing the analysis [44]. Data collection ended after 87% (13/15) of participants were interviewed, as meaning saturation was achieved during the last interview.

Study Context

This study was conducted in the context of the iNNOV Breast Cancer project (ClinicalTrials.gov NCT03275727) [45]. During the iNNOVBC project, we realized that mental health professionals' attitudes toward digital mental health were significantly associated with previous use of such interventions, potentially affecting program acceptance and implementation. On the basis of this insight, we decided to further investigate the perspectives and practices of mental health professionals regarding the implementation of digital mental health and explore the factors influencing such perspectives and practices using this qualitative interview study.

Ethical Approval

This study was approved by the ethics review boards of Instituto Português de Oncologia do Porto Francisco Gentil, Unidade Local de Saúde de Matosinhos, Entidade Pública Empresarial, the Portuguese Psychologists Association (Ordem dos Psicólogos Portugueses), and the Portuguese Data Protection Committee (approval number 10727/2017). Written informed consent was obtained from all participants before the onset of study procedures.

Data Collection

Interviews took place face to face between November and December 2019 at Fraunhofer Portugal AICOS meeting rooms to ensure a private and facilitating environment. A total of 2 interviewers participated in the data collection (CMS and Ana Alves or Elsa Oliveira). Although both interviewers were free to pose questions and provide clarifications, each interviewer was assigned a main role (ie, principal interviewer or observer). The first author acted as the principal interviewer in all interviews. Interviews were conducted in Portuguese.

A pilot interview was conducted at the onset of the study to test the interview guide and train all the researchers on the research protocol. In total, 13 mental health professionals were involved, resulting in approximately 10 hours of audio recordings. The average duration of the interviews was 49 (range 26-81) minutes. All interviews were audio recorded and stored in a pseudoanonymized format in a secure, password-protected location. Interview recordings were transcribed verbatim (CMS and Ana Alves) using oTranscribe (MuckRock Foundation) [46], an open-source transcription web app. Transcripts were coded and analyzed in parallel with data collection to enable data collection to be driven by analysis.

Researchers' Characteristics and Reflexivity

The research team comprised outsider, hybrid, and insider researchers with multidisciplinary backgrounds (eg, clinical psychology, engineering, and design). Nevertheless, all data collection team members worked within the field of digital health, which may have influenced the conduction of interviews and analysis. As such, several measures were taken to ensure the validity of the study and promote reflexivity.

Before the start of the study, members of the research team were encouraged to write down their expectations regarding the findings and debate them within the team to elicit preconceptions and prejudiced ideas that could influence the analysis. In addition, data collection co-occurred with data transcription to help reveal areas of the data that required more exploration in subsequent interviews and raise awareness of the potential impact that researchers' relationship with the research topic and participants could have on data collection and interpretation. During the study, frequent meetings were conducted to encourage reflection and debate on management and interview analysis.

Analysis

The analysis followed the thematic analysis method of Braun and Clarke [47]. Coding was performed in parallel by 2 researchers (CMS and Ana Alves). After initial familiarization with data through interview transcription and repeated transcript reading, initial codes capturing salient content were independently generated. Scrivener software [48] was used to support the coding of the interview transcripts and the writing of the memos. Regular discussions between the researchers (CMS, Ana Alves, Elsa Oliveira, and FN) were promoted to discuss the results and coding trees, and comparative analyses were performed to ensure reliability. Data patterns were then identified and iteratively organized into themes by clustering and collapsing codes based on similarities and differences. Thematic maps were then assembled and refined as they were applied to the data. Patterns within and across themes were systematically explored and scrutinized until consensus between researchers was achieved, and no additional insights resulted from the analysis of the data. Preliminary and final reports were submitted for participant validation.

Results

Participants

A total of 13 mental health professionals participated in the study. Of these 13 mental health professionals, 2 (15%) were psychiatrists, and 11 (85%) were clinical psychologists. Most participants were female (11/13, 85%), and the median age was 35 (IQR 11, minimum 25, maximum 56) years. Participants had a median of 11 (IQR 11) years of professional experience, and most held a master's degree or higher (9/13, 69%). Most participants were active (12/13, 92%) and working at different universities or research institutions (5/13, 39%), distinct hospitals of the National Health Service (4/13, 30%), and various private practices or charities (3/13, 23%). Most participants (9/13, 69%) developed some sort of clinical practice at the time of the interviews. Approximately 31% (4/13) of participants worked exclusively as clinical and health psychology researchers in the field of digital mental health. Approximately half of our sample had cognitive behavioral therapy orientation (7/13, 54%). Considering the participants' knowledge and experience using digital mental health, the sample was evenly distributed, including nonusers and occasional and regular users (Table 1). Nevertheless, given the embryonic stage of digital mental health in Portugal [28], half of our sample could be considered as early adopters of digital mental health and thus may not be representative.

Table 1. Participants' sociodemographic characteristics (N=13).

Characteristics	Values, n (%)
Sex	
Female	11 (85)
Male	2 (15)
Age (years)	
23-30	3 (23)
31-40	7 (54)
41-50	2 (15)
51-60	1 (8)
Highest academic degree	
Licentiate degree	3 (23)
Specialization	1 (8)
Master's degree	5 (38)
PhD	4 (31)
Theoretical orientation	
CBT[a]	7 (54)
Psychodynamic or existential	2 (15)
Humanist	1 (8)
Eclectic	2 (15)
None	1 (8)
Work experience (years)	
0-1	1 (8)
2-5	2 (15)
6-10	2 (15)
11-15	5 (38)
≥16	3 (23)
Work context	
Unemployed	1 (8)
Private practice or charities	3 (23)
National Health Service	4 (31)
Universities or research institutions	5 (38)
Areas of specialization	
Clinical psychology	3 (23)
Health psychology	3 (23)
Neuropsychology	2 (15)
Psycho-oncology	5 (38)
Digital mental health self-reported knowledge	
Residual	4 (31)
Moderate	5 (38)
Advanced	4 (31)
Digital mental health self-reported use	
None	6 (46)
Occasional	4 (31)

Characteristics	Values, n (%)
Regular	3 (23)
Technology used in clinical practice	
Videoconference software (eg, Skype, Zoom, FaceTime, and Doxy)	4 (31)
Messaging apps (eg, WhatsApp, Messenger, and Signal)	2 (15)
Email (eg, Gmail and ProtonMail)	3 (23)
Social networks (eg, Facebook, Instagram, Reddit, and Falar sobre Cancro)	2 (15)
Web platforms (eg, Moodbuster, Google Classroom, and Be a Mom)	4 (31)

[a]CBT: cognitive behavioral therapy.

Findings

Digital mental health is not addressed at Portuguese universities, being poorly disseminated in health care institutions and frequently limited to private practice and research organizations. As a result, the participants' understanding of and experience in the field were dissimilar, ranging from sparse to significant and focalized to comprehensive. Although professionals working in private practice were mostly familiar with videoconference counseling and psychotherapy, interviewed researchers had a broader perspective on the various available intervention formats and experience delivering internet interventions and on the web and virtual reality rehabilitation programs. Despite these knowledge and experience decalages, 5 main themes and 16 subthemes became salient in the analysis and characterized the perspectives and practices undertaken by professionals regarding the implementation of digital mental health. These perspectives and practices are listed in the adjacent textbox (Textbox 1) and further described in the following sections.

As the perspectives and practices of participants regarding digital mental health were highly influenced by the purpose of the intervention (psychological assessment, psychotherapy, etc), the selected treatment modality (eg, videoconferencing counseling, internet interventions, etc), and drivers and barriers encountered during the implementation process, the abovementioned practices tended to unfold subsequently but could also co-occur, overlap, be omitted, or assume a recursive nature.

Textbox 1. Themes and subthemes describing participants' salient perspectives and practices.

Themes and subthemes

Indication evaluation

- Assessment of digital mental health uptake drivers
- Appraisal of digital mental health uptake barriers
- Casuistic assessment of the applications and indications of digital mental health

Therapeutic contract negotiation

- Clinicians' credentials presentation
- Therapeutic setting definition
- Therapeutic boundaries framing
- Contingency plan construction
- Privacy, confidentiality, and data protection procedures disclosure
- Legal, jurisdictional, and billing considerations discussion

Digital psychological assessment

- Dealing with the absence of validated technology
- Perceived lack of control over the psychological assessment process

Technology setup and management

- Adapting and conciliating nonclinical software to clinical purposes
- Developing digital mental health technology

Intervention delivery and follow-up

- Appraising the impact of the absence of evidence-based, usable interventions in practice
- Therapeutic alliance establishment
- Perceived lack of control over the therapeutic process

Indication Evaluation

After hearing about digital mental health from a peer, a conference presentation, or a client requesting to be followed remotely, most participants reacted to digital mental health with disquietude. Having received no formal training on digital mental health, participants presented ambivalent predispositions toward this practice, including "apprehension" (P12) and "curiosity" (P1), and felt the need to further explore whether digital mental health could be applied in their practice:

> *I felt that there was a grey area in online psychological interventions because there were many questions that were not being answered [...] my idea was I will not go through with this until it is as transparent as possible* [P5]

Similar to P5, multiple interviewed professionals felt that there was a lack of high-quality guidelines for implementing digital mental health in practice. Professionals had to search thoroughly for legislations and regulations, technical requirements, ethics, and risks of these interventions, and there was an absence of structured intervention frameworks that could be easily adopted. This void required our participants to independently assess who digital mental health could be appropriate for and autonomously delimit digital mental health applications and indications before initiating their digital mental health practice.

According to the participants, digital mental health could be used for prevention, screening, intervention, and rehabilitation purposes. The ubiquitous nature of mobile devices was recognized as an appropriate venue for performing screening and ecological momentary assessments. Complementarily, the low-threshold accessibility, high scalability, and customizable and persuasive design (ie, technology designed for changing users' attitudes or behavior [49]) of digital mental health could potentially leverage prevention (self-care) interventions and rehabilitation programs. Digital mental health was also considered valuable if integrated within a stepped-care health care model, playing an important preventive and supportive role before escalating to more differentiated health care alternatives:

> *[Digital Mental Health] makes sense to me [...] precisely before referral to us [psychiatrists] and not exactly for patients with major disorders. That is, it can and should probably be part of healthcare in [...] early stages of illness [...] I don't want to be too optimistic, but [perhaps] it can effectively prevent future psychiatric illness* [P4]

During the interviews, it became clear that digital mental health was not for everyone; however, the participants believed that many clients could benefit from this approach. Given the accessibility and convenience of digital mental health approaches, implementation was consensual among geographically isolated clients, migrants, and clients at risk of contracting infectious diseases, such as immunodepressed patients. Digital mental health was also considered to support clients presenting mild to moderate psychological disorders or stabilized major disorders and patients with chronic illnesses, as it could support self-care. Conversely, digital mental health was considered generally contraindicated to clients experiencing severe conditions, such as advanced dementia, psychotic outbreaks, borderline personality disorder, suicidal ideation, or history of parasuicidal attempts, because of a high risk of dropout and the difficulties in managing crisis episodes at a distance. According to the participants, special consideration should also be given to clients living in unsafe environments or experiencing domestic violence, as such conditions could not fulfill the minimum setting requirements to establish rapport, compromising the intervention's efficacy and making contingency plans hard to deploy remotely. To be able to benefit from digital mental health approaches, participants considered that potential clients should also present minimal literacy and computer skills, have preserved cognitive function, and be motivated and insightful.

In addition to the abovementioned recommendations, interviewees emphasized that digital mental health implementation should be casuistic, and uptake should depend on the assessment of individual, technological, and contextual factors. In certain situations, digital mental health could configure the unique available alternative to provide first aid psychological support, becoming the indicated approach to even manage situations to which it could be typically contraindicated (ie, suicidal ideation):

> *It's not that I like it very much, but I have several patients [...] who have emigrated [...] and what happens is that it can be crucial and even vital for that person to know that on the other side of the world there is someone who speaks her language, who understands, and who can [...] help her acquire tools to deal with the situation...* [P11]

Awareness of such potential led various health care professionals to consider adoption even when their attitudes regarding such modalities were somewhat negative. According to the participants, complying with their perceived duty to provide psychological support to clients in need was of high importance and often superimposed therapists' preferences, concerns, or digital mental health's identified limitations, being the triggering point for various participants to start delivering digital mental health interventions.

Another important aspect emerging from the interviews was the notion that digital mental health indications could be dynamic and change during the therapeutic process:

> *For example, avoidant people, people with social anxiety [...] we may be reinforcing this way of functioning [using an online medium]. Of course, that if we start like this at an early stage and then afterwards, we bring the person in...but if it's always online and one of the issues is that she's not able to be face-to-face with other people, we are only reinforcing this behaviour with the online intervention* [P13]

As explained by P13, digital mental health interventions could be particularly useful in facilitating access and motivating clients for treatment at some point in the process but could also reinforce dysfunction at a later stage, becoming counterproductive. According to participants, the use of digital mental health implied not only assessing the indication of such an approach at the onset of the intervention but also monitoring the impact that the digital model could have on the therapeutic process.

Therapeutic Contract Negotiation

According to the participants, the delivery of digital mental health interventions should not be a simple transposition of the face-to-face model to the digital format. Appropriate implementations of digital mental health should comply with specific procedural and relational rules that should be clarified and negotiated with clients' ad initium. Although some participants opted to verbally debate with clients on these rules and procedures, others considered this information to be transposed to a written therapeutic contract formalizing the therapeutic relationship being established:

> *You were just asking if there were any rules that were established...I believe that in this type of intervention that's something that should be more demarcated [...] because there is no face-to-face contact. So maybe the intervention should be better delimited, it should be even written, the way things should work [...] the commitment should be established in a more pronounced way.* [P6]

As noted by P6, the high flexibility and informal character of digital interactions could sometimes collide with the structured setting that clinical interventions require, making mental health professionals uneasy. Consequently, participants felt the need to debate with clients about the nature and format of the proposed intervention.

According to the participants, clinicians' credentials should be made available to clients, and the digital setting should be clearly defined. Session or module frequency, structure, and length should be communicated to clients at the onset of the intervention, and the importance of client assiduity and compromise should be emphasized to foster client adherence to the digital therapeutic process. The session's physical space was also a matter of concern. Participants mentioned the importance of guaranteeing a stable and innocuous background environment to underline the professional character of the service being provided. Most participants paid attention to the room dynamic and environmental circumstances in which the session occurred to ensure that no distractions hindered its flow and that confidentiality requirements were met.

Negotiating the therapeutic contract went beyond establishing the setting rules configuring a sort of user manual for both

clients and professionals. According to the participants, when using videoconference, specific guidelines should be followed and provided to clients. Defining who was responsible for establishing the connection was considered important to provide clients with assurance. Complementarily, having a waiting room, as provided in some videoconference software, was perceived as important to welcome clients and mimic the face-to-face model.

Professionals also provided orientations regarding lighting and camera positioning to ensure an adequate assessment of clients' behavior and provided instructions on how to prevent interruptions caused by technology failure. These strategies included turning off other software running in the background and using a cabled network for connection stability. They discussed the diligence to perform in the event of poor audio or image performance, technology failure, or disconnection to avoid impacts on ongoing introspection, ensure adequate therapist feedback, or enable crisis containment. These procedures were perceived as particularly relevant when dealing with crisis situations and became part of a predefined contingency plan. Furthermore, alternative follow-up or communication strategies were identified at an early stage to prevent misunderstandings, promote trust, and make the therapeutic boundaries clear.

Clarifying relationship boundaries during this negotiation phase was capital to most participants:

> *There may be a tendency in some people to think that because it's online...[It] is not really a psychologist-client relationship. The dynamics of power may become slightly blurred. So, to mitigate this problem [...] this initial contract dotted the i's and crossed the t's [...]. Dual relationships...So...How will we treat each other on social networks, you know? "I will not follow you...I advise you not to do it as well to protect your privacy"..."I will not google you..." that sort of...* [P5]

To avoid negatively affecting the therapeutic process, most professionals established strict protocols and boundaries. To avoid dual relationships—situations where multiple relational roles exist between a therapist and a client—most professionals exclusively used institutional accounts or platforms to contact clients and refrained from becoming friends or followers of their clients on social media, thus preserving their clients' privacy and the evolving working alliance.

Professionals also made full disclosures of their data collection and protection procedures, including the storage of personal contacts, health and psychological data, correspondence, or billing data, to assure clients that their privacy was safeguarded. Detailing the costs of each type of interaction (eg, SMS text message, email, and reports) was mentioned as important by participants as it also served the purpose of reinforcing therapeutic boundaries. Finally, our participants discussed the legal and jurisdictional framework that applied to the intervention, especially with clients from abroad and frequent travelers.

Digital Psychological Assessment

Once the therapeutic relationship was framed, therapists were faced with the challenge of case formulation and adaptation of the psychological assessment process to the digital format. In general, interviewees considered the administration of psychological instruments (standardized questionnaires, projective tests, etc) and clinical interviews digitally approachable. Nevertheless, they had reservations about the potential of remote observation and the possibility of performing an accurate and comprehensive psychological assessment using digital mediums.

Regarding testing, most participants expressed high acceptability of systems capable of supporting remote assessment processes and capable of automatically sending, administering, and scoring tests, underlining their time-saving potential. However, none of the participants used such technology in their clinical practice because of the scarcity of dedicated platforms in the market, limited set of instruments, lack of adaptation to Portuguese and digital contexts, or high subscription costs. Having to overcome such barriers significantly affected professionals' practices and possibly the psychological assessment process. While some professionals felt compelled to narrow the scope of the evaluation, relying solely on structured clinical interviews to avoid experiencing a high technological burden in their practice or submitting clients to such a burden, others opted to devise alternative ways of administering psychological instruments remotely:

> *Zoom allowed me to share the screen, so I used to share PQ [a clinical interview] and then clients would see me on the left and the questionnaire on the right and I would fill it out.* [P5]

Professionals commonly used a collaborative approach to administer structured interviews or questionnaires, using videoconference or emailing encrypted questionnaires to overcome distance and software limitations. However, this approach was not considered adequate for all tests (eg, some neuropsychological instruments), and several doubts were expressed regarding the validity of remotely administering paper-and-pencil instruments. In the absence of instruments duly adapted to the digital context, the administration of psychological instruments raised a feasibility dilemma. Participants were often confronted with the conflicting alternatives of trying to administer the assessment protocol they would implement in person versus implementing the most feasible evaluation protocol while considering usability, time, and investment constraints. Moreover, the security and compliance of such procedures with the General Data Protection Regulation and intellectual property rights were questioned, revealing that some participants were uncomfortable with the strategies they implemented.

Regarding observation, some participants expressed concern over the possibility of losing their "clinical sense" (P4) while performing a remote psychological assessment. Owing to limited vision angles and difficulties in assessing nonverbal communication cues, several interviewees rejected this alternative. Other participants recognized that, although this might be a limitation under some circumstances, in other

situations, the digital environment, especially videoconference, could bring an ethnographic dimension to the experience, allowing the therapist to perform a more accurate in loco evaluation of clients' behaviors and contexts:

> *Deep down I completely entered her world, which was a room in a house, in an isolated town. I could see the tidiness and untidiness of her little room [...] Often I could see that she was wearing pyjamas [...] and that was a session mobilizer at times because she was in fact very comfortable, but she was also presenting with depressive symptoms [...] And I was there to watch it like a movie. [...] Well, I believe that we might miss some information, but I also think that there is other information, as in this case, that emerges that perhaps in another face-to-face situation would not appear, right? [...] It ended up being somehow invasive of her privacy...(But) That's right, she was showing it to me.* [P6]

Digital in loco observation, as described by this participant, provided therapists with the opportunity to gather contextual information that is usually unattainable during in-person appointments, such as the hygiene conditions of their clients' homes. It also encouraged clients to behave more naturally and, therefore, facilitated the display of clinically significant signs that otherwise could be hidden. However, as clients' background scenarios and interactions were not under the therapists' control, accessing contextual information passively provided by clients was sometimes felt by professionals as a violation of their clients' privacy. Furthermore, the perception of traveling in an unchartered territory could arise, challenging the therapists' confidence in their web-based assessment capabilities:

> *I get the impression that...I never know the conditions of the environment where the patient is. I don't know if someone is listening to the patient or not, I don't know if what the patient is saying to me is trustworthy or not.* [P11]

As discussed by P11, the impossibility of guaranteeing communication security and discriminating between all environmental factors potentially affecting clients' behaviors during digital appointments sometimes threatened therapists' confidence in using digital mediums for assessment purposes. In addition, the difficulty in discerning if the information conveyed was real or fabricated hindered professionals' perception of control over the digital psychological assessment process. Overcoming such perceptions required adopting a structured assessment framework capable of anchoring professionals' practices and supporting them in providing a comprehensive evaluation of the client.

According to some participants, technology could be helpful in providing such a framework and reinforcing professionals' perceptions of control over this process:

> *It's preferable to have a platform...I would rather be framed by a platform, without a doubt...I prefer to shield myself in a situation like this, than not being safeguarded by a platform. I find it more organized, I find it more coherent, I think it makes a lot of sense to have this type of resource.* [P6]

As mentioned by P6, digital platforms have the potential to integrate several components inherent to the psychological assessment process, facilitate data collection and interpretation, and enable a more comprehensive assessment of the client. Moreover, if designed to comply with data privacy and security requirements, technology could attenuate professionals' concerns about confidentiality and data breaches, increasing therapists' perception of control and security while assessing remotely.

Technology Setup and Management

Being intrinsic to digital mental health, technology plays a determinant role in both psychological assessments and interventions. As each technology (web platforms, mobile apps, chatbots, etc) has its own affordances and characteristics, potentially capturing information and delivering interventions in a distinct way, participants considered that technology should be selected to comply with the characteristics and specific needs of the target population or client. Consequently, professionals were faced with the task of acquiring, adapting, or developing digital technology at some point in the intervention process. The point at which this aspect was addressed depended on the professionals' work context, training, selected approach, and proficiency in the delivery of digital mental health interventions. Although professionals working with more structured approaches, such as internet interventions, usually addressed this requirement at the onset of the intervention process, therapists working in private practice tended to test and adapt various technologies after a preliminary assessment of the client, making adjustments along the intervention process. Regardless of the adopted strategy (ie, purchasing, developing, or adapting technology), pursuing such tasks was often considered a challenge by professionals.

Confronted with the absence of dedicated technology and the obligation to comply with confidentiality, data privacy, and security requirements, professionals were often forced to conciliate and adapt multiple nonspecific software for clinical purposes:

> *I developed, within my limitations because I am not a programmer, an encrypted Excel program...I tried my best to develop something [compliant with GDPR] [...] then I bought a cloud [...] which allowed encryption and stored [the data] there. But I struggled a bit [...] Because there's the excel file and you can put there, some data, but what about the reports? [...] I was forced to handle many different files, all encrypted, with different passwords, then...I had to use a password manager too...And then there's the e-mail part...I subscribed a platform that allows you to encrypt messages without the recipient using [it] as well. But before, we had to share a password. So, in the first session...I asked people to provide a password for the e-mail communications [...] verbally. Okay, so, I was struggling with that and what I would like to have is a platform where I didn't need to manage many passwords, where everything is integrated, where I can communicate with the person in a safe way.* [P5]

Similar to P5, various other participants used nonclinical videoconference software such as Zoom videoconferencing and Skype to conduct remote sessions and administer questionnaires or perform clinical interviews. Encrypted email services were occasionally subscribed to protect therapist-client off-session communication exchanges, and Microsoft Word was used to produce reports. Microsoft Excel was sometimes used to create forms for collecting client data, and some participants mentioned the use of encrypted cloud services for data storage. Implementing and maintaining these technological setups posed a burden on both professionals and clients and compromised therapists' efficiency and satisfaction. Thus, most interviewees agreed on the importance of developing dedicated and comprehensive platforms to implement digital mental health interventions efficiently and cost-effectively.

However, many participants considered that developing digital mental health technology was a "long and challenging process" (P10). According to some participants, there is a tendency to design "one size fits all" (P13) tools and interventions; however, digital mental health technology should capture and portray emotional and relational nuances to fit different clients. Trust and transparency should be embedded in the structure of the software, and empathy should be conveyed through developed assessment and intervention materials. Digital mental health technology should be usable, inclusive, customizable, scalable, and disseminated, but also culturally sensitive, and assume a personalized and dynamic form. Complying with these requirements was considered highly demanding, especially when developing intervention programs such as internet interventions and web-based or virtual reality rehabilitation programs.

According to some interviewees, developing assessment and intervention programs requires the assembly of a multidisciplinary team. Although mental health professionals need to create the content, designers could be required to work on the graphical presentation, and developers could be needed to create a vehicle to deliver the intervention. Our participants also stated that developing digital mental health programs usually entailed performing comprehensive literature reviews and user research (eg, based on interviews, observations, and usability testing) to identify the best medium for treatment delivery and understanding how to structure the content and exercises to be included in the program under development. As a rule of thumb, participants stated that digital mental health programs should be adaptable and responsive to different formats and devices to reach most clients in ways they find appropriate. However, fulfilling this criterion is not always possible mainly because of financial and technical limitations:

> *In an ideal context we could have developed a web and a mobile app version that complemented each other, but at the time it was not possible. So, we had to decide, and the web version seemed more viable to us, it was...[cheaper] and it allowed us to have the content the way we wanted. An app required...shorter content, a different organization that for us was more difficult to develop in a first rehearsal of the program.* [P8]

Creating intervention content was also considered a challenging process. As identified by P8, it required understanding how the characteristics of a selected technology could affect the therapeutic program being developed. The text length, type of audiovisual content, exercises, and features that can be included in each program vary depending on the selected technology, and the impact that its limitations could have on treatment efficacy should be considered. Furthermore, developing interventions' content implied writing to hypothetical personas [50] and steering development to fit clients' characteristics. However, as the act of typifying clients often collided with the casuistic approach most professionals were trained in and adopted in clinical practice, various participants mentioned feeling uncomfortable with such an approach:

> *I found this adaptation very difficult because we know that the strategies are suitable for each person and what works for one, may not work with another. "But how do we get this into the material?" So, what I tried to emphasize was "these are just suggestions, the most important thing is to follow what makes you feel more comfortable, and you should adapt it according to what makes sense to you," and I underline "don't look at this as laws and rules." Specially because when suggested strategies don't work and everything falls apart, patients who follow all the steps may feel cheated, or question their self-efficacy, their skills...[...] So, my biggest concern was not to cause more damage than people were already experiencing.* [P13]

As discussed by P13, developing digital mental health interventions and tools was considered a major responsibility. This implied not only designing personalized evidence-based empathetic programs but also acknowledging the impact such programs could have on clients beforehand. The different possible intervention outcomes had to be anticipated, and strategies to ensure that possible adverse effects were prevented, monitored, and addressed should be integrated into developed interventions to comply with safety and beneficence requirements. In this regard, iterative testing was considered crucial not only to identify unanticipated characteristics of the program with the potential to negatively affect clients but also to guarantee programs under development were "culturally sensitive and adapted to the target-population" (P9).

To achieve such a high level of technology refinement, participants referred to the different development stakeholders—academia, industry, end users, and funding bodies—that needed to be aligned, and that the multidisciplinary development team should be able to communicate effectively, adapt, and collaborate. However, communication within development teams could be difficult because of different backgrounds within the team, dysrhythmic development processes, and the existence of divergent goal-steering development. This "misalignment" (P7) could significantly affect the quality, usability, and sustainability of developed interventions. As a result, an important gap in what concerns high-quality, evidence-based digital mental health technology was identified by participants.

Intervention Delivery and Follow-up

During the interviews, the "absence of evidence-based ready to use interventions" (P4) and the lack of accessible, secure, and comprehensive assessment and treatment tools were identified as the major factors affecting treatment delivery. According to the participants, if not properly designed, handled, and monitored, technology could be experienced as a "barrier" (P7) or "filter" (P6), especially by clients with limited sensory, cognitive, and physical user capabilities. Various participants recognized the lack of usability of existing tools and programs as an important implementation obstacle. Interventions' "high complexity both in terms of structure and content" (P10), as well as the use of noninclusive design approaches, were considered problematic because of the deleterious impact they could have on treatment adherence, outcome, and rapport.

As perceived by various interviewees, establishing a therapeutic alliance on the web is feasible, and the quality of the established bond may be equivalent to that occurring in face-to-face interactions. However, participants considered that such a process could be affected by poor technology design, adaptation, or failure, and specific strategies should be implemented to facilitate rapport.

> *I did not feel much difference, to be honest, between presential and online interventions in terms of therapeutic alliance [...] you can create the bond in the same way. [...] in the first sessions, I keep assessing if and how the person feels me present, so to speak...If we feel connected and sometimes when I realize that the person is looking at the camera a lot, I give the eye contact suggestion "can you distance yourself from the screen, place the program window in a different way so that we can both be looking at each other in the eye without having to be looking at the camera." [...] It works, and I feel well, I feel in tune with the person, something that I thought I would feel more in person.* [P5]

According to the participants, fostering the therapeutic alliance on the web required close monitoring of both the relational and technological dimensions of the therapeutic process. As mentioned by P5, technical instructions such as adequately distancing and positioning the camera or repositioning tabs and windows on the computer desktop while videoconferencing should be followed to ease eye contact, bring authenticity to digital interactions, and strengthen the working alliance being established. In other intervention formats, such as internet interventions, our participants emphasized the importance of using different communication channels (eg, written, verbal, and visual) to convey warmth and empathy during the intervention and provide timely and personalized feedback to the client regarding homework assignments or intervention strategies being implemented. According to participants, the interventions' materials and therapists' written feedback should be made permanently available to extend the therapeutic setting beyond booked appointments, reinforce the evolving working alliance, and potentially accelerate behavior change. The conduction of close follow-up sessions was also identified as important to "promote relationship continuity" (P1). Various participants suggested that an initial face-to-face appointment was important as well to "give a push to the bond and compromise being established" (P3). Nevertheless, the development of such connection could be influenced by clients' personal characteristics—namely, age, information and communications technology literacy, and cultural aspects. Therefore, close monitoring of the evolution of the working alliance should be performed, and, if necessary, alternative and simpler communication mediums, such as face-to-face appointments or telephone calls, should be used to prevent treatment abandonment.

Client dropout or early abandonment was a recurrent concern captured in the interviews, particularly in the context of crisis situations. Digital mental health was regarded as an unchartered territory in what concerned managing crises, as most participants stated not being prepared to handle such situations remotely and required specific training on how to build contingency plans and how to detect risk situations early:

> *Whoever is on the other side must be aware, know [the signs], and be able to detect the moment when risk arises, right? And despite being at a distance [...] even when in different countries, [the therapist] must be able to properly assess and refer the client. But I don't know how much we can contain on this side...* [P3]

Some of the strategies implemented by participants in this regard included restricting the use of digital mental health to mild or moderate conditions, collecting emergency contacts at the onset of the intervention, and mapping local institutions to be activated under crisis circumstances. Nevertheless, because of the limited action range therapists felt in these situations, various participants were hesitant to work exclusively online, and most refused to consult with anonymous clients.

Delivering digital mental health interventions implied "dealing with unforeseen challenges along the therapeutic process" (P2) without having clear guidelines and training on how to pursue such practice and how to deal with problems such as managing adverse events or crises at a distance. Therefore, a perception of a lack of control over the therapeutic process was experienced by some therapists. This perception was reinforced by the generalized notion that information and communications technology systems are susceptible to security and confidentiality breaches and discouraged therapists' sustained adoption of digital mental health.

Perception of control seemed to be influenced as well by the intervention format and type and frequency of communication established between therapist and client. Ranging from residual in unguided interventions to augmented in blended care interventions, therapists' perception of control seemed to increase when guidance was provided, and synchronous interactions with clients occurred:

> *In unguided interventions, our concern relates to the fact that we don't have control over the evolution of the symptoms and the fact that a person can give up anytime...although, this can happen in presential sessions as well, right? But online we have less*

> *information about what's happening on the other side and this can somehow be a matter of greater concern...I don't think it's an impediment, but it is perhaps the issue that concerns me the most [...] being more frequent [...] half face-to-face sessions and half online sessions, it would allow greater progress monitoring... a greater sense of control in some way, even though this perception might be subjective...* [P8]

According to P8, unguided formats of treatment delivery or guided interventions, including exclusively asynchronous communications with clients, could make a proper case formulation difficult and compromise the assessment of treatment outcomes, hindering therapists' perception of control over the therapeutic process and making them refuse or hesitant to use such formats. Consequently, most participants endorsed blended care interventions.

To be encouraged to implement digital mental health interventions, particularly formats other than blended care, various participants referred to the need for structured training on digital mental health:

> *We must have the necessary knowledge and practice to be comfortable working online [...] otherwise my concern will be "I can't do this, I can't do that" and my attention is no longer on the person, on the questionnaire's results and I believe the usefulness of these tools is lost* [P12]

Training was considered instrumental in providing therapists with the necessary knowledge and practice to implement digital mental health interventions confidently. However, the absence of formal digital mental health training programs was transversally identified as a major gap affecting its adoption by professionals.

Discussion

Principal Findings

This study suggests that mental health professionals deemed important or engaged in the following practices while implementing digital mental health interventions: (1) indication evaluation, (2) therapeutic contract negotiation, (3) digital psychological assessment, (4) technology setup and management, and (5) intervention delivery and follow-up. Although these practices tend to unfold subsequently, they could also co-occur, overlap, be omitted, or assume a recursive nature depending on the purpose of the intervention, the selected treatment modality, and the drivers and barriers encountered along the implementation process.

The implementation of digital mental health started with an evaluation of its indication to a given client and involved the appraisal of individual, technological, and contextual aspects. Similar to previous research, our participants perceived digital mental health as indicated only to a subset of clients [26], restricting it to individuals presenting with mild to moderate symptoms [33,51], limited comorbidity [39], and low risk [41]. However, such recommendations were not consensual among all participants in this study, and in reflection, it may be non–evidence based and unethical [52]. A previous meta-analysis showed that digital mental health interventions could be efficacious for individuals presenting with severe symptoms and suicidal ideation, and there is little evidence that these groups present an increased risk of adverse events [53,54]. Furthermore, a recent publication [55] disclosed that at MindSpot, one of the world's largest publicly funded web-based clinics, users' mean symptom scores were in the moderate to severe range, and a quarter presented with suicidal ideation. This reality suggests that digital mental health might be an important mental health care gateway for clients experiencing severe conditions, and as claimed by various participants, a casuistic indication assessment should be performed to comply with equity and beneficence requirements [56].

Professionals' perceived duty to provide support to clients in need was an important digital mental health adoption driver identified in this study, which has been poorly explored in the literature [32]. Such responsibility often superimposes participants' preferences, concerns, and digital mental health's perceived limitations, which is the triggering point for various participants to start delivering digital interventions. Digital mental health's low-threshold accessibility and convenience [28] reinforced such decision, particularly when treating clients living in geographically underserved areas [51] and patients who were mobility impaired [29], a finding that corroborates previous research [26]. However, due to digital mental health's indication dynamic character [57], such an approach was generally not perceived as a standalone alternative but as part of a continuum where different types and degrees of interactions between client and therapist could be operated to fulfill the clients' best interests. As such, digital mental health interventions were frequently understood as potentially following, intersecting with, or culminating in other treatment approaches (eg, face-to-face interventions and pharmacotherapy), better fitting a hybrid mental health care model [58].

However, hybrid mental health care models have been insufficiently addressed in the literature [26], and a lack of structured intervention frameworks presenting clear guidelines on how to implement digital mental health in an ethical, legal, and secure way was transversally identified by participants as a barrier compromising its implementation. Similar findings have been reported in previous studies [33-36]. To compensate for this lack of structure, professionals independently formulated rules and procedures to organize their digital practice, placing great emphasis on the negotiation of the therapeutic contract.

This practice often involved discussing with clients, in a highly structured manner, digital setting rules, confidentiality and data protection procedures, therapeutic boundaries, and contingency plans to be deployed in potential crisis situations. Despite generalized agreement on the importance of debating the abovementioned aspects with clients, various participants were concerned about the impact such high formality could have on the therapeutic process. To the best of our knowledge, this is the first study to document the digital therapeutic contract negotiation procedure; therefore, further research should be performed to assess its impact.

After framing the therapeutic relationship, professionals typically proceeded with digital psychological assessment. Although the methods they used were similar to the in-person process (eg, observation, testing, and clinical interviews), participants reported that this process was highly dependent on technology availability, characteristics, and performance. During the digital psychological assessment, difficulties in assessing nonverbal communication cues became salient, and the inability to fully control the evaluation setting raised concerns over the possibility of performing an accurate and comprehensive psychological assessment on the web. Such concerns echo the findings of previous research [28,35,59,60]. In a recent study, Mendes-Santos et al [28] reported that approximately 60% of psychologists perceived remote psychological assessment processes as inaccurate, increasing the possibility of misdiagnosis. In another study by Gilmore and Ward-Ciesielski [60], 30% of participants identified digital assessment as risky, particularly when evaluating clients at a high risk of suicide. Nevertheless, previous studies have validated telephone-based behavioral assessments [61], and the equivalence between paper-and-pencil and web-based testing has been consistently documented [62,63]. More importantly, a previous study by Godleski et al [64] reported that suicide risk assessment can be effectively completed via videoconference and in-home messaging devices and is as effective as suicide risk assessment completed in person. This discrepancy between participants' stance toward digital mental health and evidence has been previously identified in other studies [28,34] and suggests that an important knowledge gap in this domain hinders professionals' adoption of such an approach.

Another important obstacle identified in this study, which potentially compromised professionals' performance and, therefore, their sustained adoption of digital mental health [40], was the absence of usable, validated, and affordable digital mental health technology. Although these factors have been singled out as potential barriers compromising digital mental health adoption in previous research [65], their real impact on clinical practice is undetermined. Moreover, the strategies used by professionals to overcome such obstacles have been poorly explored. This aspect may be justified by a greater number of studies focusing on specific research trials [22,29,39,41] or web-based clinics that evolved from research programs [38]. As the technological infrastructure required to deliver interventions in these contexts is assembled beforehand, professionals are possibly spared from the difficulties of acquiring, adapting, and developing digital mental health technology.

Nevertheless, the implementation of digital mental health necessarily entails such procedures. Interestingly, the point at which this technology setup occurred depended on the professionals' work context (eg, research and clinical settings), training, selected treatment approach, and proficiency in the delivery of digital mental health interventions. Professionals developing regular digital practices or working with more structured approaches usually addressed this requirement at the onset of the intervention process, consistently using the preselected technological setup along the process. Conversely, therapists making sporadic use of digital mental health tended to blend in-person and digital approaches more often, frequently electing preferential technology for treatment delivery after a preliminary assessment of the client. The tendency to test and adapt various technologies during the intervention process also characterized the latter group. This practice is possibly justified by a confrontation with technology limitations during the intervention, which were initially unforeseen, or the dynamics of the treatment process requiring different technology affordances to be explored according to clients' progress.

Challenged with the limited availability of affordable evidence-based tools capable of comprehensively supporting treatment delivery, professionals were often forced to narrow the scope of their clinical work or devise alternative ways of pursuing such practice. Mirroring other professionals' procedures [66,67], the adaptation of nonclinical software (eg, Gmail and Zoom videoconferencing) for psychological evaluation and intervention purposes was a strategy frequently adopted by participants in this study. As such practice risked noncompliance with the General Data Protection Regulation, intellectual property rights, and good clinical practices, various participants were hesitant to make sustained use of digital mental health, reserving it for extreme situations such as providing support to migrants. In addition, most professionals underlined the importance of expediting the development of evidence-based digital mental health technology capable of framing therapists' digital practices. This potential of technology to structure the clinical process was also found in previous studies [40,68].

Nonetheless, the development of digital mental health technology was often perceived as long, complex, and expensive. Moreover, a misalignment between development stakeholders (eg, terminology, development priorities, and quality assurance criteria) was identified as a major barrier compromising the effectiveness, usability, and transference of developed programs into clinical practice. Such perceptions align with the current discussion around digital mental health development and implementation processes. Previous publications have discussed the need to turn such processes more agile [69], solution focused [1], and integrated into clinical practice [8,70]. Moreover, a paradigm shift toward the design of digital mental health services instead of products seems to be unfolding [1,55]. According to Mohr et al [1], to be widely adopted and fully integrated into health care systems, digital mental health services need to be designed to fit into the fabric of clients' lives, respect professionals' workflows, and be able to accommodate changes in the care environment and technological ecosystem. If not, digital mental health might be experienced as an added burden rather than as an added value, as became salient in this research. Similar results have been reported by Cerga-Pashoja et al [40].

During intervention delivery and follow-up, professionals were often concerned about the negative impact of nonusable, validated, or defective technology on treatment adherence, outcome, and rapport. Similar to other studies, various participants considered that a positive therapeutic relationship could be established and extended on the web [29,57], potentially accelerating the treatment progress [32]. To be able to foster and monitor the therapeutic alliance, most participants recognized that the development of new relational and technical

skills (eg, the management and development of digital technology and engaging with clients remotely) was necessary, a finding that corroborates previous research [39,55].

However, professionals' lack of training in digital mental health has been transversally identified in this and previous studies [28,34,66], and most participants relied solely on research and trial and error experiences of use to develop such skills. As a result, most professionals questioned their self-efficacy [39] to assess and intervene remotely, and a marked perception of lack of control over the implementation of digital mental health interventions prevented them from fully adopting such an approach. This perception of lack of control has been documented before in relation to technology [39], therapeutic settings [71], therapeutic processes [56], and management of crisis situations [35]. However, no study deeply explored this barrier. Adding to previous research, insights from this study suggest that perceptions of lack of control over case formulation; the assessment of treatment outcomes; and the detection, management, and monitoring of treatment adverse events also discouraged adoption. Moreover, professionals' perception of control seemed to be highly influenced by their experience of use and training. As such, capacitating therapists with the necessary skills to implement digital mental health interventions proficiently seems key to building confidence within the class and expediting adoption.

Unfortunately, there is currently no standard method of training therapists in digital mental health, and structured training and supervision initiatives are limited [72]. Moreover, the paucity of research assessing the impact of such programs is concerning [73]. Considering that the skills and knowledge required for effectively delivering digital mental health interventions are considerably different from those required in traditional models of care [55], not addressing this gap menaces both the quality of interventions delivered by untrained professionals, as well as the future sustained adoption of digital mental health.

Strengths and Limitations

This study had various strengths. It involved a purposeful selection of participants with different sociodemographic characteristics, working within different contexts, presenting different levels of knowledge and use of digital mental health, providing an in-depth understanding of the perspectives and practices of mental health professionals regarding digital mental health. Furthermore, data collection was theory informed and co-occurred with data transcription, helping to reveal areas of the data that required more exploration in subsequent interviews, enriching the data set. Continuous reflection and a consensus approach were also adopted during data collection and analysis. This practice raised awareness of the potential research biases affecting the study. Finally, respondent validation and investigator triangulation were used to increase the validity of the results.

Nevertheless, a few study limitations must be considered when interpreting our findings. Although a stratified purposeful sample was selected to capture variation, as in many interview studies, the representativeness of the sample cannot be established. The results are based on an in-depth analysis of interviews provided by a small sample of Portuguese mental health professionals and, therefore, may not be transferable to other contexts. The fact that digital mental health is still at an embryonic stage in Portugal [25] might have influenced participants' attitudes and opportunities to explore digital mental health—namely in what concerns other digital mental health modalities and technologies (eg, artificial intelligence, serious games, wearable devices); therefore, it is unclear whether the same issues would be identified among professionals practicing, for example, in digital mental health frontrunner countries [74]. Another aspect to consider is that the main interviewer was previously known to most participants from her role as a digital mental health researcher or clinical psychologist. This fact may have introduced a social desirability bias, possibly leading interviewees to be less critical of digital mental health. Finally, this study failed to pursue other forms of triangulation, such as method, theory, and data source triangulation, which would have been advisable to test the validity of the obtained results and gain a more comprehensive understanding of the implementation of digital mental health. However, previous research seems to indicate that the insights from this study have ecological validity [28].

Conclusions and Future Research

This study aimed to characterize in depth the perspectives and practices of mental health professionals regarding the implementation of digital mental health and explore the factors influencing such perspectives and practices. Our findings suggest that mental health professionals deemed important or engaged in the following practices to implement digital mental health interventions: (1) indication evaluation, (2) therapeutic contract negotiation, (3) digital psychological assessment, (4) technology setup and management, and (5) intervention delivery and follow-up. Digital mental health's low-threshold accessibility and professionals' perceived duty to provide support to their clients were identified as the main drivers facilitating implementation. Conversely, the lack of structured intervention frameworks; the unavailability of usable, validated, and affordable technology; and the absence of structured training programs negatively affected implementation and, consequently, professionals' adoption of digital mental health.

To overcome the abovementioned barriers and expedite professionals' adoption of digital mental health, the publication of legal, regulatory, and practice frameworks that can be easily transferred to practice seems necessary. These guidelines could be conjointly elaborated by different digital mental health ecosystem stakeholders (eg, policy makers, regulatory bodies, clinicians, and information technology and data protection specialists) to ensure that they are comprehensive enough to provide the necessary structure professionals require to confidently work remotely. Moreover, the co-development of digital mental health technologies and services must be encouraged. Clients and professionals must participate in the development process to guarantee that such services answer their most pressing needs and integrate smoothly into routine care. In this context, user and implementation research is key to streamlining the development and implementation processes. Finally, to guarantee proper implementation of digital mental health, the design of training programs that are structured according to professionals' most pressing needs and that are

assessed, certified, and made widely available to professionals seems of high importance. To incentivize adoption, professionals must be trained in the implementation of digital mental health interventions and in managing the main barriers affecting it. Research on professionals' current unmet digital mental health training needs is necessary to structure this process. Addressing these research action axes could not only empower professionals in the delivery of digital mental health interventions but also expedite adoption and help close the current mental health care treatment gap affecting health care systems worldwide.

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Disclaimer

The authors alone are responsible for the views expressed in this paper, and they do not necessarily represent the decisions, policies, or views of the International Agency for Research on Cancer/World Health Organization, Linköping University, NOVA National School of Public Health, or Fraunhofer Portugal AICOS.

Authors' Contributions

This study was conceptualized and designed by CMS, FN, EW, RS, and GA. CMS acquired, analyzed, and interpreted the data and wrote the manuscript. FN, EW, RS, and GA revised the manuscript for important intellectual content.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mental health professionals' semistructured interview script.
[DOCX File , 19 KB - formative_v6i4e32558_app1.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

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Original Paper

A Sense of Coherence Approach to Improving Patient Experience Using Information Infrastructure Modeling: Design Science Research

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Abstract

Background: Health care provider organizations are complex and dynamic environments. Consequently, how the physical and social environment of such organizations interact with an individual is a primary driver of an individual's experience. Increasingly, the capabilities required for them to successfully interact with those within their care are critically dependent on the information infrastructure they have in place, which enables people, both patients and staff, to work optimally together to deliver their clinical and operational objectives.

Objective: This study aims to design a framework to address the challenge of how to assemble information systems in health care to support an improved sense of coherence for patients, as well as potentially innovate patients' experiences, by connecting and orchestrating the synergy among people, processes, and systems.

Methods: It is necessary to understand the needs of health care providers and patients to address this challenge at a level relevant to information process design and technology development. This paper describes the design science research method used to combine the sense of coherence, which is a core concept within the Antonosky salutogenic approach to health and well-being, with an established information infrastructure maturity framework, demonstrating the coalescence of 2 distinct conceptual perspectives on care delivery. This paper provides an approach to defining a positive and supportive health care experience and linking this to the capabilities of an information- and technology-enabled environment.

Results: This research delivers a methodology for describing the patient experience in a form relevant to information infrastructure design, articulating a pathway from information infrastructure to patient experience. It proposes that patient experience can be viewed pragmatically in terms of the established sense of coherence concept, with its ability to identify and guide resources to modulate a patient's environmental stressors. This research establishes a framework for determining and optimizing the capability of a facility's information infrastructure to support the sense of coherence defined by the experiences of its patients.

Conclusions: This groundbreaking research provides a framework for health care provider organizations to understand and assess the ability of their information infrastructure to support and improve the patient experience. The tool assists providers in defining their technology-dependent operational goals around patient experience and, consequently, in identifying the information capabilities needed to support these goals. The results demonstrate how a fundamental shift in thinking about the use of information infrastructure can transform the patient experience. This study details an approach to describing information infrastructure within an experience-oriented framework that enables the impact of technology on experience to be designed explicitly. The contribution

to knowledge is a new perspective on modeling how information infrastructure can contribute to supportive health-promoting environments. Furthermore, it may significantly affect the design and deployment of future digital infrastructures in health care.

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KEYWORDS

medical informatics; information infrastructure; digital hospitals; patient experience; implementation; eHealth

Introduction

Background

Information technology (IT) is increasingly playing a pivotal role in forming an individual's experience within a health system. The way processes are initiated and delivered and how we communicate our choices and needs, even the light and climate in the room, are now mostly interfaced and controlled through IT. Although there has been extensive work on defining an organization's ability to deliver such technologies [1], there is a scarcity of information on how technology influences the experiences of staff, patients, and families in the health systems.

The challenge is to construct health care environments that provide enhanced patient experience while enabling high-quality, accessible, and efficient care. To address this, it is necessary to understand more precisely how information and information systems affect patient and staff experiences both now and in the future.

Experience is a complex concept. Its realization is contextual to a person's environment, current emotional state, past experiences, and future expectations. In health care, the question has always been how to define a good experience and identify the elements of that experience that the hospital and its services can contribute. Significant survey-based work has been conducted to isolate the factors that patients believe contribute to a positive experience. Indeed, most care delivery organizations conduct detailed surveys after an episode of care to understand how well patient needs and expectations are met [2].

However, to date, there has been little research on why patients identify these factors. Understanding the forces driving patients' preferences would provide a clearer picture of how to change the hospital environment to improve the perceived experience. Consequently, we need improved models to shape experiences in health care. These models would include health care system–controlled factors that drive experience and describe how these factors come together.

This research aims to design a framework to address the challenge of how to assemble information systems in health care to support an improved sense of coherence (SOC) for patients, as well as potentially innovate patients' experiences, by connecting and orchestrating the synergy among people, processes, and systems. The resulting framework provides a method for shaping the patient experience through the improved use of a hospital's digital infrastructure and for the assessment of the maturity of this use based on an established digital infrastructure assessment methodology [3].

Literature Review

To clarify the relationship between experience and technology in health care, it is important that our definition of a health care experience is appropriate and that a model for generating experience is established. Through this model, the relationship with technology can be detailed. Health care has adopted a specific definition for experience, in which the actions that generate interactions between a patient and their operational environment (people, place, or process) are defined as the experience, and an individual's personal response to those actions is defined as satisfaction [4,5]. Both of these interrelated elements need to be accounted for when considering concepts such as the SOC to account for the generation of experience. In this review, we look at the definition of patient experience and patient satisfaction separately before bringing them together through the lens of SOC and relating them to information infrastructure through the infrastructure assessment methodology.

Patient Experience

Patient experience has been used to identify the weaknesses and strengths of health care delivery, with a view to driving quality health care improvements and promoting patient choice [6]. Such measures can report on communication and, more importantly, the patient's experience related to their involvement in their own care decisions [7]. Hence, it provides both a utilitarian feedback loop on health care delivery processes and the measurement of humanistic characteristics experienced by patients during their episodes of care.

Studies have found positive associations between patient experience and improved health outcomes, often through improved health care delivery processes [6,8-11]. Despite this, there is no consistent agreement about the quality outcomes, despite patient experience being considered a complementary measure for quality [9,12]. Indeed, several systematic reviews have examined patient experience and an elusive search for a specific definition [6,12-14].

Patient Satisfaction

Patient satisfaction can measure three things [15]: sufficiency of treatment and care received to improve health outcomes; fulfillment of requests from patients and families for treatments and diagnostics that are not clinically needed and may be harmful; and person-centered well-being factors such as communication, dignity, and respect and the associated logistical factors such as ease of making appointments, accessible parking, hospital physical environment and location, and hospital gowns. Arguably, the latter aspects relate to well-being and are intrinsically linked to a personal sense of worth [16]. The high variability of patient satisfaction can be confounded by

non–clinically related factors [9,17], over which the health care team has no control [18].

There are many dimensions to health care and, therefore, how a patient experiences an episode of care; consequently, how satisfied they are with the experience is one measure [19]. However, it is a measure that is variable for everyone and means something different for each person. Worryingly, research has shown that patient satisfaction scoring can have a negative and inappropriate impact on clinical care decision-making and behaviors of clinicians because of patient satisfaction score pressures [15,20,21]. At a superficial level, patient satisfaction scores reflect the manipulatable elements of what patients perceive as satisfactory experiences in defined episodes of care, such as hospital stays. In many cases, this indicates environmental factors such as noise levels. Consequently, there is no consistent agreement on whether this is an indicator of the quality of health care delivered or received [8,9,22-24].

The Integrated Design of Patient Experience and Satisfaction

Understanding how to optimize care delivery requires that both experience and satisfaction be addressed simultaneously. Although there will always be a need to separately understand what has been delivered (patient experience–focused measures) alongside how patients experienced that delivery (patient satisfaction–focused measures) when it comes to designing the environment in which a patient would best thrive in; however, both elements need to be considered. The notion of creating an environment for a patient that is supportive of the broader idea of patient health and well-being, balancing both experience and satisfaction, is an important consequence of using a salutogenic approach and its concept of SOC [25]. Indeed, in response to the conclusions of Dietscher et al [26], this research focuses on the impact of a more patient-centric approach, using IT to improve hospital processes and functioning. It is this broader characterization of experience, as viewed through SOC, which forms the ongoing definition of experience in this paper.

Experience and the SOC Concept

An approach to this broader concept of experience (ie, patient interactions and responses) is to look at concepts that consider how individuals respond to their environment and how they affect their well-being. One such concept is that of *SOC*, which is a constituent of the Antonovsky Salutogenic Model of wellness [25]. The Antonovsky model is based on an understanding of how an individual responds to stress and the coping mechanisms that the individual has, which enables them to better cope with this stress [27]. “The sense of coherence reflects a person’s view of life and capacity to respond to stressful situations. It is a global orientation to view life as structured, manageable, and meaningful” [28].

The assumption in using this approach is that a reduction in environmental stressors for an individual patient is core to a favorable personal health care experience. Indeed, research on the application of salutogenic orientation in hospitals identifies that interventions improving the hospital design and processes can have an impact on physical health [26]. This is further supported by evidence from psychoneuroimmunology research linking stress and physical health [29]. Although this may not constitute a complete or perfect definition of the drivers of health care experiences, it has proven to be helpful in the care of older adults and health promotion environments where the Salutogenic Model and its concept of an individual’s *SOC* have guided interventions for several decades [30,31].

The SOC core concept in the Antonovsky Salutogenic Model proposes that an individual’s ability to cope with environmental factors that could lead to stress depends on the individual’s three characteristics: their perception of the manageability, comprehensibility, and meaningfulness of their environment, as described in the following sections [32]. Correspondingly, an environment can be optimized in terms of how it contributes to an individual’s well-being (SOC) by optimizing the environment’s ability to deliver the following:

- Manageability: the experience of managing day-to-day physical realities; staying warm, dry, clean, rested, and nourished—the behavioral or instrumental component
- Comprehensibility: the experience of making sense of a situation and creating a structure from otherwise disordered and unexpected information—the cognitive component
- Meaningfulness: the emotional meaning of life and willingness to resolve setbacks and address potential causes of stress—the motivational component

An individual’s SOC can be assessed using several survey-based tools and is an established method of determining an individual’s well-being [33]. The environment can be characterized in terms of generalized resistance resources (GRRs) and specific resistance resources (SRRs) using the Salutogenic Model [34]. Both GRRs and SRRs assist in managing, reducing, or avoiding stressors [35]:

- GRRs are characteristics of a person, group, or community that facilitate an individual’s ability to cope effectively with stressors (tension) and contribute to the development of an individual’s SOC [36]. The social determinants of health and cultural, social, and environmental conditions, such as education, living conditions, salary, self-esteem, and neighborhood, are examples of GRRs [37]. GRRs are less sensitive to direct influence through the manipulation of local technology and information infrastructure.
- SRRs are situation specific and can be optimized to reduce stress in a particular environment or situation; for instance, the ability to change the temperature of a room, use support services, or provide supportive environments. SRRs are elements of experience that can be highly sensitive to direct influences through local technology and information infrastructure.

There is no literature on SRR manipulation to support patients’ experiences. However, SOC has been studied as an overarching philosophy in areas such as nursing [38]. In addition, no literature describes how to model SRRs across an organization to influence a whole hospital population rather than specific patients or in response to postepisode patient experience survey feedback. However, the concept of SRRs has the potential to provide a useful construct for relating the physical and social artifacts within a hospital’s operating environment to their likely

impact on the reduction of patient stressors and a change in the SOC-defined experience.

The methodology for this characterization of SRRs in health care, particularly the role of IT in SRRs, is a core component of the intended framework. For information infrastructure design, this work is centered on the assessment of the information infrastructure of a facility in terms of capabilities and our ability to characterize them in terms of their technology composition and their contribution to process outcomes, which in turn generate patient experience.

Information Infrastructure and Its Assessment

Previous research by Williams et al [3] investigated how information infrastructure can align with health care operational processes. This study resulted in the Infrastructure Maturity Assessment (IMA) framework that enables digital hospitals to assess the maturity of their information infrastructure against their desired digital transformation. The framework characterizes a hospital's infrastructure maturity to create a road map for digital transformation aligned to operational requirements while simultaneously identifying weaknesses in information and communications technology infrastructure capability. This framework is now an international benchmark of hospital infrastructure performance adopted by Healthcare Information and Management Systems Society Analytics [39]. In this study, we refer to the individual technical capabilities of the IMA process as technology services.

Previous research into the link between patient experience and technology has largely focused on assessing the *soft* or indirect benefits of technology and is primarily concerned with organizational processes [40-42]. Although the IMA framework has, to date, been used to assess the technological competency of a health care facility for supporting their key operational processes, our application here is to use this framework to define an organization's ability to support the collection of specific process sets that generate desired experiences, as defined through the SOC concept. Hence, the research question addressed is how the patient experience can be supported and improved through the better use of information infrastructure using SOC as a lens to understand the critical areas of technology-responsive improvement.

Methods

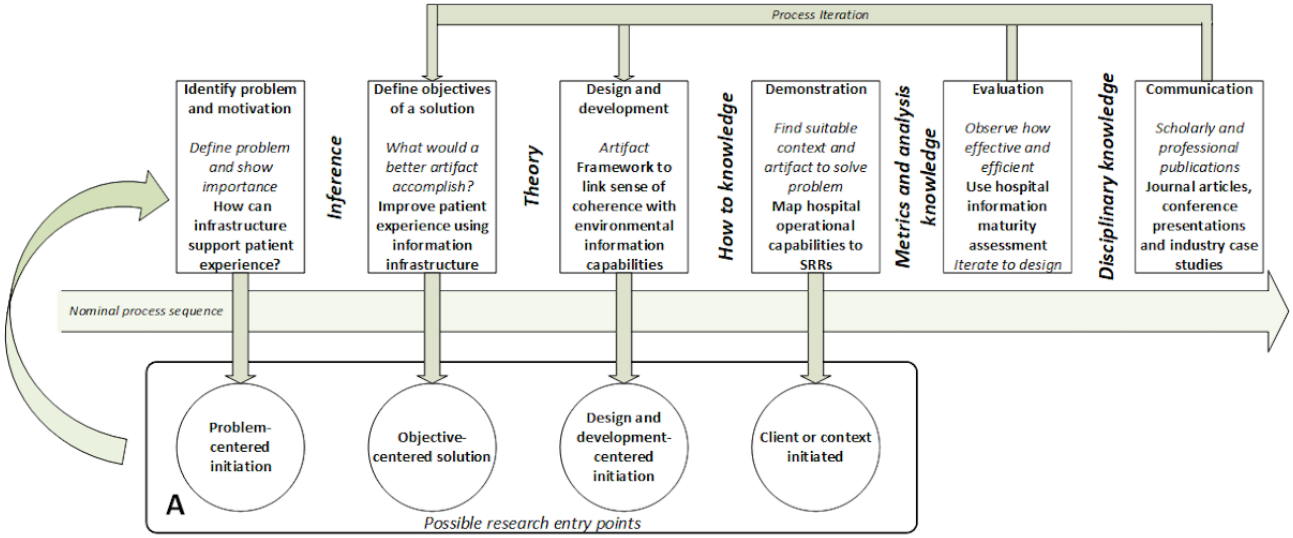
Overview

This research creates a generalizable framework for improving the patient experience through the better use of information infrastructure, which can be implemented in practice. This framework uses existing knowledge to solve the problem of enhancing patient experience underpinned by theoretical learning. This research is positioned in the applied research discipline of information systems (comprising systems, people, and processes). Design science is the chosen research paradigm as it facilitates the construction of problem solving of real-world challenges, applying theory from other disciplines rather than merely exploring, describing, and making sense of the problem [43,44]. This enables the application of multiple theoretical models to be integrated into design science decisions. The resulting framework (artifact) was developed from, and can be applied to, real-world problems in modeling patient experience.

Research Design

The research design defines the contextualization of the methodology for the research question. The application of the Design Science Research Methodology (DSRM) in this research is shown in Figure 1. Each DSRM activity is explained along with its corresponding output in the *Results* section.

Figure 1. Research design based on the Design Science Research Methodology [39]. SRR: specific resistance resource.



Results

The results reflect the steps of each DSRM activity in the research design, as shown in Figure 1.

DSRM Activity 1: Problem Definition

This study had a problem-centered initiation entry point (label A in Figure 1). The underlying problem in many approaches to patient experience is that they hinge on assessing experience using postepisode surveys, targeting only specific processes for

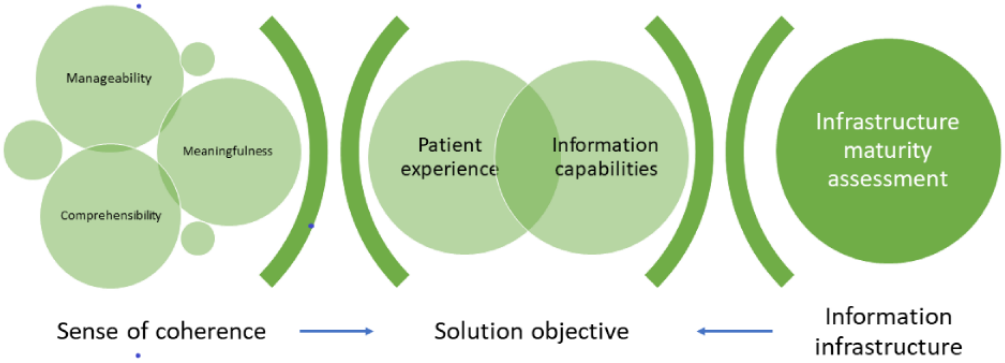
improvement. Postepisode surveys generate little insight into what drives individual patients to form their experiences and what is an optimal experience (a set of interactions and responses) for a patient. The survey approach, although critical in assessment, is insufficient for the purposeful design of patient environments. Experience-based design requires a more holistic model that balances individual patient preferences and benefits. Currently, there is no method for modeling how to improve the patient experience by examining the role of information infrastructure and services in the delivery and support of patient experience. Such a model needs to generate insight into the underlying drivers of such a balanced positive outcome and what influences these drivers. In this study, it was imperative to have those drivers defined in terms relevant to the impact of information infrastructure.

DSRM Activity 2: Solution Objectives

Overview

The solution's objective was to improve the patient experience by reducing environmental stressors for a patient (physical, mental, and social) through the existing hospital information infrastructure. Using the SOC concept as the perspective through which to support care provision in the hospital environment provides a method for defining what a positive and supportive experience looks like and linking this to the information capabilities of the hospital's operational environment. This activity was performed from two sides: defining existing or aspirational patient experiences within the health care environment at one end using SOC and, from the other end, defining how technology comes together to form processes using the IMA framework (Figure 2) that supports those experiences.

Figure 2. Research design: Design Science Research Methodology activity 2—forming the solution objective.



The separate actions in this activity (as shown in Figure 2) were as follows:

1. Mapping the hospital patient experience in terms of the SOC concept, detailing the experience statements that describe the domains of manageability, comprehensibility, and meaningfulness in terms of the operational environments of people, places, and processes
2. Describing how technologies and their combined technological capabilities come together to form information capabilities accessed through the IMA framework
3. Describing how information capabilities combine to form the SRRs that support experience statements.

Mapping the Hospital Patient Experience in Terms of the SOC Concept

The first action involved mapping the hospital patient experience in terms of the SOC concept, detailing the experience statements that describe the domains of manageability, comprehensibility, and meaningfulness in terms of the operational environments of people, places, and processes.

SOC is defined through its three domains: manageability, comprehensibility, and meaningfulness. It is helpful to view these domains in the context of the three environments in which patient experience is often discussed: the operational environments of people, places, and processes. This is the starting point for mapping the experience requirements of a care organization. It is the point at which the organization's vision, mission, and values are distilled into a set of statements that describe the organization, either as it exists at present or as it aspires to be in the future (Table 1).

Each SOC domain can then be articulated relative to these environmental descriptions using a set of experience statements (Textbox 1). These experience statements are not absolute descriptions of the ultimate state of an organization (although, in time, these types of descriptions could evolve); rather, they are distilled from the mission, vision, and values of the organization they describe. In Textbox 1, we articulate a typical set of statements for a modern acute care facility. We have structured the statements to include the condition of the environment (where relevant) and the desired experience, as the condition is an enabler (not a cause) of the subsequent experience. The experience statements are for an individual care organization based on the already defined operational environment descriptions. These statements are defined in collaboration with the facility's clinical and operational staff and their patients and represent either the organization's current state or the future aspirational state of the organization. They are defined for the three operational environments: people, places, and processes.

Table 1. Sample operational environment experience statements for an acute health care organization.

Statements and examples	Place	People	Process
Operational environment experience statements	• "I can individualize my external environment in such a way that best supports my needs." • "The environment is such that there are a minimum number of distractions." • "The environment is responsive to my emotional state and creates a calm and supportive atmosphere." • "The environment can be easily customized to my specific needs, and it reliably stays that way. It produces environmental changes that are traceable, and the logic is transparent."	• "My care team respects my preferences, beliefs, and values, and I have jointly agreed to the goals of care that I can influence in an ongoing way." • "I find working with my carers enriches my life and expands my goals for myself." • "I feel listened to and valued by my carers. There is clear communication between my care team that enables me to feel the I have control." • "There is a close and reliable bond established with the care providers that work with me."	• "I can engage with and appropriately manage the processes and systems to support me in a manner that is optimized to my preferences." • "There is effective coordination between the care team members. There is continuity of care with smooth transitions from one setting to another." • "Processes are responsive to my emotional state and are flexible." • "I feel that the processes are reliable and effective."
Examples	• Temperature, humidity, luminosity, color (hue, saturation, value, and color temperature), noise level, tactile suitability, navigability, cleanliness, enjoyability, comfort, and connectivity	• Friendliness, hospitality, teamwork, cooperation, rapport, transparency, responsiveness, sensitivity, empathy, truthfulness, behavior, professional etiquette, competency (cultural, spiritual, and clinical), accountability, awareness, capability, mastery of the systems (social and technical), respect, and communication	• Interoperability, completeness, reliability, availability, security, resilience, agile, adaptable, simplicity, patient centric, effective, efficient, optimized, empathetic (accommodating to individual circumstance and personalization), well-defined, understandable, engaging (includes user experience), sustainable, acceptable, ethical, legal, fair, equitable, reasonable, coordinated, integrated, safe, and timely

Textbox 1. Sample of typical sense of coherence experience statements.

Environment: place

- "I can individualize my external environment in such a way that best supports my needs."
- "The environment is such that there are a minimum number of distractions."
- "The environment is responsive to my emotional state and creates a calm and supportive atmosphere."
- "The environment can be easily customized to my specific needs, and it reliably stays that way. It produces environmental changes that are traceable, and the logic is transparent."

Manageability

- "I can influence or control the environment."
- "I have sufficient information about the healthcare environment to form reasonable expectations."
- "The environment provides sufficient amenities and facilities to reduce stress and enhance well-being. I feel more able to be in a positive mood due to an environment tailored to my personal preferences."
- "The environment is designed in a way that builds reliability. My environmental needs will be taken seriously. The environment is uniform and consistent with my specified requirements. It is responsive to my needs."

Comprehensibility

- "I understand what I can influence within the environment."
- "The information I have on the healthcare environment is presented in such a way that it is understandable by me (plain language, translated, visual and text)"
- "The absence of excessive environmental demands (noise, crowding, clutter, unclear signage, accessibility) enables a better understanding of the information provided to me."
- "I can direct my attention and focus on what is relevant. The environment reduces the simultaneous demands and minimizes distractions."

Meaningfulness

- "I can exercise my personal preference to build my capacity to make choices about my health now and in the future."
- "Having choices of the environment reinforces my belief in being able to influence my future positively."
- "I feel safe. The environment creates the context for who I am and what I have done. It allows me to interact easily with others creating a greater sense of belonging."
- "The environment supports my exploration of meaning-making by reducing fatigue and stressful demands. It encouraged and supported investigation beyond maintaining daily function. My ability to reliably engage with relevant information sources and share information between key people engenders a high level of trust in the environment."

Describing How Technologies and Their Combined Technological Capabilities Come Together to Form Information Capabilities Using the IMA Framework

A multistage process was used to describe how information capabilities can be formed. The first stage was formed around the IMA, which aggregates technologies into technology services (across the five domains of technical service capabilities of the data center, security, collaboration, mobility, and transport) and structures those services according to a staged maturity matrix [3].

In the second stage, the technical service capabilities of the domain are linked to form *information capabilities* (Textbox 2). Information capabilities are characteristics that information systems require for data actions in end user services. Information capabilities come together to support and create the processes across the three operational environments:

- People (or resources) using the infrastructure (eg, administrators, patients, staff, and equipment)
- Places where the information systems are used (whole hospital, specific hospital units, externally dependent campuses, and car parking)
- Processes that are dependent on information systems (nurse calls, bed management, and task management)

Textbox 2 describes the information capabilities within the operational environments of people, place, and process. Each information capability is defined in terms of the technical capabilities from which it is constructed. The assignment of technical capabilities to an individual's information capability is dependent on the real or aspirational operational objectives of a health care organization. The assignments described in this paper were allocated according to the operational objectives defined for an advanced digital hospital operating at level 8 of the IMA.

Textbox 2. Information capabilities descriptions.

Place

- Accessing: to establish interaction with resources (eg, people, equipment, supplies, information, and systems)
- Controlling: to influence resources (eg, people, equipment, supplies, information, and systems)
- Alarming: to notify the occurrence of a negative (problematic) event
- Alerting: to notify the occurrence of an event
- Measuring: to quantify the characteristics of a resource (eg, people, equipment, supplies, information, and systems)
- Responding: to create an action in response to an event

People

- Sharing: the exchange of data (including textual, image, or graphical information); it can be both synchronous and asynchronous; restricted to permanent and semipermanent file types (retrievable data types)
- Communicating: remote voice and video conversations between individuals or groups; face-to-face gathering of people; the synchronous or asynchronous exchange of textual information in a threaded and persistent form
- Locating: being able to identify how to access resources (eg, people, equipment, supplies, and information) in places
- Recording: the transcription of transient voice and visual information into a permanent record
- Organizing: arranging the schedules of one or a group of people and resources
- Identifying: describing the characteristics of people, places, or things in sufficient detail to uniquely define them
- Analyzing: the processing of information to form insights into decision-making
- Requesting: the identification of a need for a person, place, thing, or process so that it can be supplied at a given time or place
- Interpreting: analysis of current situations or information

Process

- Interoperating: the ability for processes to interact in a way that generates the desired outcome
- Contextualizing: creating information or processes that are relative to an individual's characteristics and the characteristics of the environment around them
- Orchestrating: scheduling, timing, and location of resources to maximize outcomes
- Scheduling: establishing the timing and location of services
- Simplifying: reducing complexity
- Informing: to make people or systems aware of relevant events or information
- Tasking: to assign a specific activity to an individual, group, or process
- Trusting: the creation of secure systems in which information is shared only within the rules established by the organization

Technical capabilities may be considered common (pertaining to all information capabilities within an operational environment) or specific (related to ≥1 but not all information capabilities within an operational environment). In summary, infrastructure-related technologies are used to create technical capabilities, and the aggregation of these technical capabilities forms information capabilities. Using this methodology, we can define an organization in terms of the maturity of its technical capabilities and in terms of the maturity of its information capabilities.

Information capabilities were graded using a modified (4-step) version of the 8-step IMA assessment. The IMA relates to how technology affects processes and is supported by a large volume of data. The 4-step maturity scale in Table 2 reflects a summary of the IMA 8 steps because of the current limited understanding of how hospitals mature in their delivery of the experience. In the future, it may be possible that this scale is expanded as more data are available and more granularity in defining the stages to improve patient experience in hospitals is gained. At this stage, only 4 steps could be assigned with confidence.

The 4-step information capability scale is described in terms of typical outcomes for each level across the operational environments of place, people, and processes (Table 2). This assessment provides organizations with an understanding of the technical strengths and weaknesses of the major operational environments.

Table 2. Information capability maturity—a 4-step maturity scale is used to assess information capability maturity within a health care facility.

Level	Place	People	Process
Level 0: fragmented	Data about the environment, the patient, and the staff may not be accurate or comprehensive because of infrastructure challenges and information capability issues. The format may be understandable but cannot be accessed easily.	It may not be possible for us to share clinical, environmental, and operational information between relevant individuals and groups. Without sharing, we may not be able to add to and refine this knowledge or develop a course of action to achieve our objectives.	An individual or group may not be able to take the plan of action and implement it by delivering physical resources, people, and knowledge to the appropriate places and locations within the organization at the required time. The actions of individuals linked with other individuals and teams coordinated with the assistance of the operational systems within the facility may be compromised.
Level 1: informed	Data about the environment, the patient, and the staff are accurate and comprehensive. It is accessible easily in an understandable format.	One can share clinical, environmental, and operational information between relevant individuals and groups. We can add to and refine this knowledge, developing a course of action to achieve our objectives.	An individual or group can take the plan of action and implement it by delivering physical resources, people, and knowledge to the appropriate places and locations within the organization at the required time. This would encompass the actions of individuals linked with other individuals and teams coordinated with the assistance of the operational systems within the facility.
Level 2: cooperative	Information is in a format and on a system that one feels comfortable using and has sufficient skills to operate effectively. The information is in a language that one is familiar with. One can interpret its content and purpose and gain further insight into the specific situation related to him or her and the course of action that needs to be pursued.	One feels closely connected with their care team, family, and social networks involved with his or her recovery. They understand his or her situation and the ways that they can best support him or her. They feel connected and invested with their situation and action plan. They can seamlessly share information and build collaborative plans to support their objectives.	The operations of relevant systems for delivering one's care are accessible, transparent, and understandable to their care providers and them. They are presented in a way that one can optimize their application for his or her specific outcomes (within the constraints of optimizing the whole of system outputs).
Level 3: systemized	The information is relevant to one's individual needs and future aspirations. The information enables one to cope with his or her daily challenges more effectively, providing a more effective sense of control of his or her outcomes. It allows him or her to craft an understanding of their future that is hopeful yet respectful of challenges that one will face in achieving that future.	Individuals can readily share the information with others to enable them to gain further understanding of their situation and course of action. One can build closer and more supportive relationships with members of his or her team (either patient or clinical) and feel an increased sense of engagement and control because of this.	One feels in control of their care. They understand all the resources at their disposal for optimizing the path to their future objectives. One feels that one has control over those resources, and they coordinate with each other to minimize their intervention in their delivery. They are linked with their care delivery team, and they evolve the services they deliver and how those services are provided, dependent on their progress to recovery.

Describing How the Information Capabilities Combine to Form the SRRs That Support the Experience Statements

The four main classes of information-driven SRRs within a hospital were defined through clinical and operational interviews as follows: teaming and sharing, scheduling and coordinating, monitoring and reporting, and education and training.

Information capabilities are rated according to their relevance to an SRR class. In analyzing an existing facility, the major applications and processes that constitute the SRR classes are defined, and the relevance of the facility's information capabilities is estimated using a 4-step scale (Table 2). This provides a map of SRR classes and their information capability strengths. The relevance of SRRs to the experience statements within the SOC domains (manageability, comprehensibility, and meaningfulness) can then be established using an equivalent relevancy scale. The process of estimating the relevance of both information capabilities to SRRs and SRRs to SOC domains is a critical part of the modeling process that engages a hospital in understanding the information capabilities they have and how they could, or do, affect the patient experience.

DSRM Activity 3: Design and Development

Overview

The design and development activity details the process used and results for each step in the framework creation, leading to the final link between the information infrastructure and patient experience. The solution objective was designed by refining the two ends of the solution (information infrastructure and SOC) into common SRRs that describe both the experiences to be delivered and the technological competency to deliver those experiences.

The experience requirements and technology contributions to the SRRs were described in terms of both their operational environments (people, places, and processes) and the SOC domains (manageability, comprehensibility, and

meaningfulness) using the DSRM 2 outputs of experience (Textbox 1) and IMA-based information capability outputs.

SRR Development

When combined and applied by people in a health care organization, information capabilities result in information-based SRRs and are the aggregation of people with technology to generate processes. The four major classes of information-based SRRs are teaming and sharing, scheduling and coordination, education and training, and monitoring and reporting, as described in Textbox 3. These classes were developed based on an experience study conducted at Fiona Stanley Hospital in Perth on their Enhanced Recovery After Surgery service and were established through extensive discussions with clinicians, technologists, and health care providers.

Through our earlier analysis, we defined the information capabilities that were then quantified through the extension of the IMA process across operational environments (people, places, and processes). In addition, we have experience statements across the operational environments (people, places, and processes) defined at the level of the SOC domains (manageability, comprehensibility, and meaningfulness). It is now possible to link these 2 sets of data together by building specific experience statements for each level of information capability assessment (fragmented to systematized) across each of the SRRs at the operational environment level (Table 3 and Textbox 4). This allows an organization to rank the relevance of its information capabilities to the SRRs they consider most relevant to the type of care they wish to deliver. Table 3 and Textbox 4 show a sample of the process-relevant experience statements for each level of information capability assessment for each of the SRR categories. Equivalent capability level experience statements are created for the information domains of people and place.

An overview of how the technological capabilities and experience requirements were drawn together through the creation of SRRs is depicted in Figure 3. SRRs are described both in terms of their technological components and their inherent experience statements and consequently form a bridge between technology and experience. This forms an overarching *Information Infrastructure to Experience Framework* (presented in the *Discussion* section, together with a discourse on how the framework may be used).

The process flow depicted in Figure 3 can be simplified to the high-level framework description shown in Figure 4. This Information Infrastructure to Experience Framework draws together the three key characteristics of the information infrastructure–driven experience landscape: technology capabilities, experience requirements, and delivery resources. It emphasizes the critical requirement of describing each of these elements within the common operational environments of people, places, and processes. Through this process, it is possible to relate the information infrastructure requirements to support the delivery resources needed to achieve the desired experience.

Textbox 3. Definitions of specific resistance resources.

Teaming and sharing

- Simply and conveniently bringing together clinicians, patients, and carers in the most appropriate format (pairs, groups, teams, and embedded into clinical workflows) to share information and emotion and enable the processes of care delivery and social support, minimizing the barriers of distance and timing

Scheduling and coordinating

- Linking clinical, patient, and carer engagement with scheduling and booking functions within the hospital to enable clear communication and management of activity timing to all participants, staff, and systems in each stage of an individual's patient journey

Monitoring and reporting

- The ability of patients, carers, and clinicians to access, interpret, and add to patient progress data; evaluate patient compliance; and modify the engagement to optimize the clinical and personal outcomes

Education and training

- The provision of education, training, and research materials at the appropriate time and appropriate format, which best supports the patients' clinical and personal needs and the clinician's requirements for decision-making and development

Table 3. An extract of the operational environment characteristics of experience (fragmented to systemized) for each specific resistance resource.

Specific resistance resource	Operational environment information capability maturity level	
	Information capability level 0: fragmented[a]	Information capability level 3: systemization[b]
Teaming and sharing of information contribution	• Task assignment and status are somewhat articulated and are not readily accessible to the individual. • Process structure and status are articulated but may not be readily accessible to the individual. • The skill sets and availability of individuals to accept tasks are articulated but may not be readily available to the individual. • An individual's workload is not readily accessible.	• Individuals have access to technologies that enable them to optimize the allocation of tasks so that they best fit the skill sets, work demands, work environments, and available technologies of the individual to whom the task is assigned. • Individuals have access to the technologies that enable them to define, allocate, and form tasks set into overall processes that sequence around the needs of the individual and the resources that are available within the organization.
Scheduling and coordination of information contribution	• The interactions between component tasks and the overall processes they drive may not be clearly defined and not readily accessible to the individual.	• Individuals and teams can conveniently coordinate tasks, managing those assigned and their sequencing (both in time and with respect to other necessary precursor events).
Education and training of information contribution	• The training and education activities do not articulate the processes that combine to create the required care delivery and how the component activities create the desired outcomes.	• The training and education process enables the individual to understand how to customize their educational resources to their current and predicted future needs, both personal and professional. They enable Individuals to choreograph their education and training programs around an existing potential future commitment.
Monitoring and reporting of information contribution	• How processes deliver upon supporting an individual's culture and values may be monitored and reported on and may not be accessible to all relevant personnel. • How current processes interact to support the quality and reliability of an individual's support services are not regularly monitored and reported on and may not be accessible to all relevant personnel. • How processes deliver upon supporting an individual's culture and values is monitored and reported on to be accessible to all relevant personnel. • How current processes interact to support the quality and reliability of an individual's support services is regularly monitored and reported on so that it is accessible to all relevant personnel.	• The efficiency of processes working in isolation or in more complex systems is monitored and reported, particularly looking to reduce complexity and potential bottlenecks in process execution.

[a]Information capability domain score average: 0.00-0.90; data about the environment, the patient, and the staff may not be accurate or comprehensive because of infrastructure challenges and information capability issues. The format may be understandable but cannot be accessed easily.

[b]Information capability domain score average: 2.41-3.00; an individual or group can take the plan of action and implement it through the delivery of physical resources, people, and knowledge to the appropriate places and locations within the organization at the required time. This would encompass the actions of individuals linked with other individuals and teams coordinated with the assistance of the operational systems within the facility.

Textbox 4. An extract of the operational environment characteristics of experience (experience statements for processes) for each specific resistance resource.

Manageability

- "I can tailor aspects of my care within the larger process of a health organization."
- "The process demands are reasonable and allow for choices and the needs of my life outside the health organization."
- "Tension is reduced because the process is efficient and effective and conforms to my evolving needs."
- "The processes are knowable, reliable, and effective, and I have developed confidence in them."

Comprehensibility

- "I understand my rights and responsibilities within the processes of health."
- "The processes are knowable and predictable."
- "Processes are clearly explained, and I understand my role, and when something is not right, I can voice my concerns and those concerns are heard and responded to"
- "The process is understandable, fair, and equitable for me."

Meaningfulness

- "The choices I make, and the choices offered to me align with my care goals and desired health outcomes."
- "I see the processes as parts that form a whole. They move me closer to my end goal."
- "Despite the volume of processes, I see them culminating in value for my treatment and care goals."
- "I believe that the process aligns with the goals of care and the outcomes I seek."

Figure 3. Process flow for linking experience requirements with technology capabilities to enable the delivery of required SRRs. IMA: Infrastructure Maturity Assessment; SOC: sense of coherence; SRR: specific resistance resource.

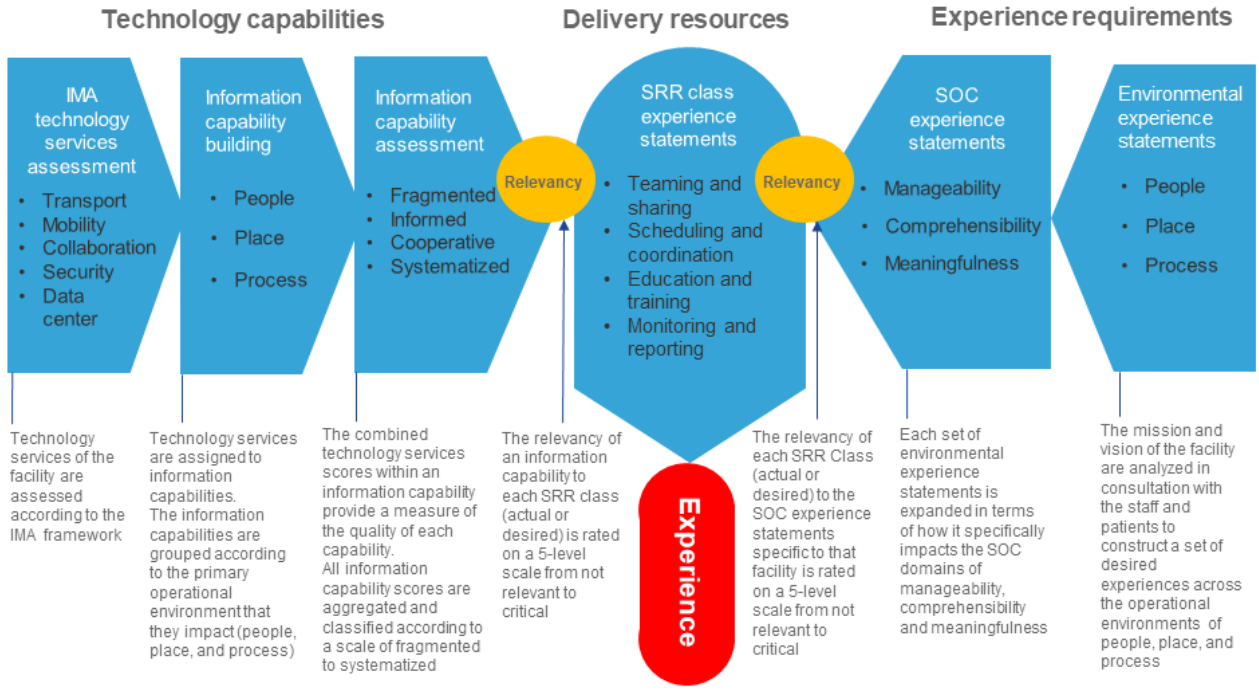
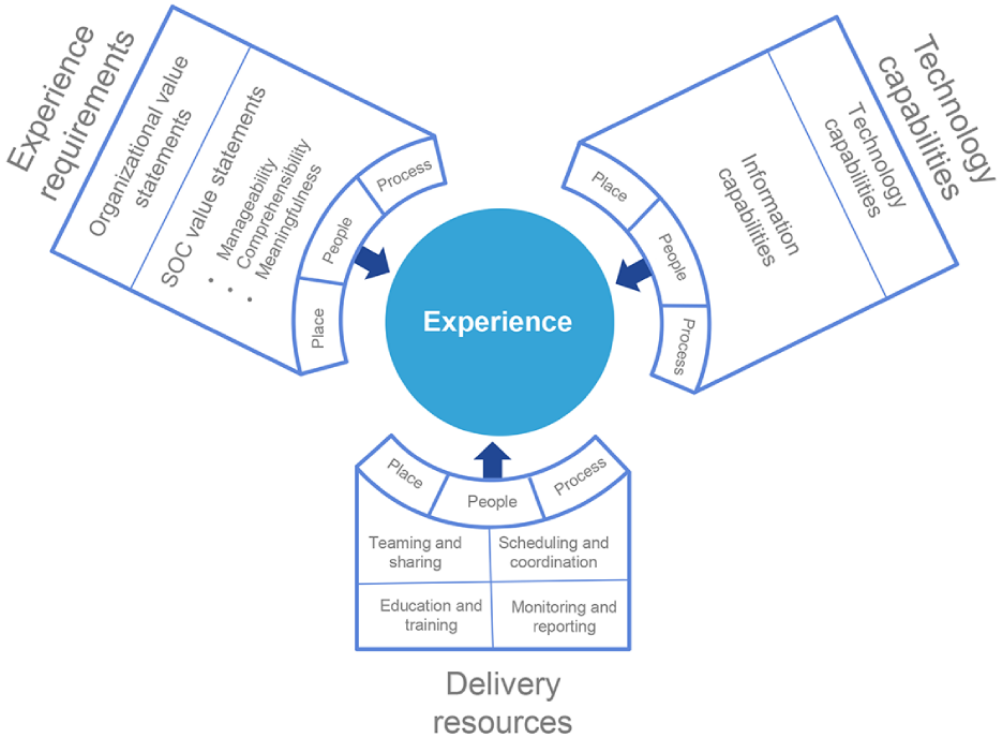


Figure 4. Information infrastructure to experience framework. SOC: sense of coherence.



DSRM Activity 4: Demonstration

Through the combination of information capabilities into applications and processes, grouped together as SRR classes (collectively termed delivery resources), the linkage of technology capabilities with experience requirements was assessed to determine how the framework can be applied using existing IMA data. The assessment provided a proof of concept that demonstrated the use of the framework in practice.

Subsequently, there are 2 ways to demonstrate the Information Infrastructure to Experience Framework (Figure 4). First, it can be used in a descriptive fashion to explore the experience requirements (experience landscape) and possible technological responses to the landscape. This is addressed further in the *Discussion* section, along with the potential impact of this approach.

Second, it can be used in an analytical fashion to directly assess the current digital infrastructure's capability to support the organization's experience goals. In this process, an organization's information capabilities are scored using a modified IMA process. The relevance of these information capabilities to the organization's experience landscape is then rated by defining and analyzing the relevance of the organization's SRRs.

The first step of the analytical process comprises defining the information landscape by establishing sets of experience statements at the following levels:

- Operational environment (people, places, and processes)
- SOC domains (manageability, comprehensibility, and meaningfulness)
- Major SRR classes (teaming and sharing, scheduling and coordinating, monitoring and reporting, and education and training)

This defines the experience requirements of the organization as described in Table 3 and Textbox 4.

The second step is the analysis of the information capabilities. The information capabilities, as established for each of the operational environments (people, places, and processes) in Textbox 2, are assigned applicable technology services. These are the same technology services as described in the IMA research [3]; however, these technology services are assessed on a 4-level maturity scale (Table 2) in contrast to the 8-level IMA maturity scale. This generates an assessment of the technological service contribution to each information capability (see the sample in Table 4). Table 4 shows an extract from a much larger matrix that details the technological service requirements to reach a given experience performance level within the operational environments of people, places, and processes. Table 4 focuses on a selection of the IMA transport domain technological capabilities and how they are accessed in the operational environment of place.

Each information capability was then ranked according to its relevance to each of the 4 sets of SRRs, using the relevancy levels described in Textbox 5. The relevancy scale is used to define the level of importance of an information capability to an SRR, thereby indicating its significance in delivering the SRR. A simple 5-level ranking scale was selected as a smaller scale would be insufficiently definitive, and a larger diversity in rank would potentially create unnecessary differentiation in relevancy and would not add value to the relevancy assignment task.

Table 4. Scoring criteria of the Infrastructure Maturity Assessment technological capabilities on the 4-step experience scale.

Technological capabilities	Level 0	Level 1	Level 2	Level 3
Virtualization	Virtual segmentation of campus infrastructure is based on static configuration.	Macro–virtual segmentation of campus infrastructure is based on VLAN[a] trunking protocol propagation and VRF[b].	Micro–virtual segmentation of campus infrastructure is based on VxLAN[c].	Access controlled, policy-based microsegmentation of campus infrastructure is based on VxLAN.
End of support status	End of support status applies to ≤5% of core and distribution layer technologies and ≤30% of access layer technologies.	End of support status applies to ≤5% of core and distribution layer technologies and ≤20% of access layer technologies.	End of support status applies to ≤3% of core and distribution layer technologies and ≤10% of access layer technologies.	End of support Status applies to ≤3% of core, distribution, and access layer technologies.
Wired device grade	Approximately ≤70% of switches and routers are enterprise grade.	N/A[d]	Approximately 71% to 97% of switches and routers are enterprise grade.	Approximately >98% of switches and routers are enterprise grade.
QoS[e]	Fragmented QoS within the health care entity campus has been implemented. Trust boundaries are well defined.	End-to-end QoS has been implemented within the health care entity campus. Trust boundaries are well defined.	End-to-end QoS has been implemented within the health care entity campus and across the WAN[f]. Trust boundaries are well defined.	SDN[g] controllers have been implemented and are used to provide business applications and dynamic end-to-end QoS within the health care entity campus and across the WAN. Trust boundaries are well defined.

[a]VLAN: virtual local area network.

[b]VRF: virtual routing and forwarding.

[c]VxLAN: virtual extensible local area network.

[d]N/A: not applicable.

[e]QoS: quality of service.

[f]WAN: wide area network.

[g]SDN: software-defined networking.

Textbox 5. Relevance of an information capability relevancy to a specific resistance resource.

Rank 1

- Not relevant or rarely involved; the specific resistance resource is not required or provides information contribution based on safety requirements

Rank 2

- Occasionally involved; the specific resistance resource provides information contribution based on safety and timeliness requirements

Rank 3

- Normally involved; the specific resistance resource provides information contribution based on safety, timeliness, and efficiency requirements

Rank 4

- Should always be involved; the specific resistance resource provides information contribution based on safety, timeliness, efficiency, and effectiveness requirements

Rank 5

- Critical, must always be involved; the specific resistance resource provides information requirements based on safety, timeliness, efficiency, effectiveness, equity, and sustainability requirements

The third step establishes the relevance of the SRR classes to the organization's overall SOC-defined experiences within the domains of manageability, comprehensibility, and meaningfulness. This characterizes an organization's technological capability to deliver on the desired SOC experiences. In this process, each of the SRR classes is rated with respect to their relevance to each of the SOC domains (as defined by their experience statements) using the 5-point scale used in Textbox 5. Rating the SRR's technology capability by its relevance to an SOC domain generates an overall capability score (SOC domain-weighted experience capability) for each of these domains. A sample of this process is presented in the following section, *DSRM Activity 5: Evaluation*.

DSRM Activity 5: Evaluation

Overview

The preliminary evaluation used existing Australian data from past hospital infrastructure maturity assessments to ensure that the framework was robust yet flexible when applied to different health care environments. This research had two major outputs: the Information Infrastructure to Experience Framework and the framework scoring.

The initial evaluation tested the process by observing how the model responded to data inputs from the existing IMA data and taking those outcomes through the SOC experience statements. The next step in the evaluation was to perform detailed assessments using a framework with specific hospitals. For this, the first requirement was to define each of the core components of the experience framework across the operational environments of people, places, and processes.

Experience Requirements

This involves the outcome that the organization seeks to deliver through its experiences, described in terms of the patient experience statements for the SOC domains of manageability, comprehensibility, and meaningfulness.

Technology Capabilities

The information infrastructure maturity of the organization derived from the IMA quantifies the maturity of the technology services that are assembled into the information capabilities of the organization.

Delivery Resources

This involves the information-based processes within an organization that can use the information capabilities to deliver patient experience statements. These information processes form the SRRs defined within the concept of SOC.

The second step is ranking the information capabilities in terms of their relevance to the SRR classes and then ranking the SRR classes in terms of their relevance to the experience statements that define the three SOC domains of manageability, comprehensibility, and meaningfulness.

Framework Scoring

A preliminary evaluation of the information capability scoring and its relevance to the SRR classes is provided as a worked example in Multimedia Appendix 1. This example is based on a previous IMA conducted on an Australian hospital. The framework scoring (Multimedia Appendix 1) demonstrates the competency of a facility's information infrastructure to support the technology requirements of a given set of SRRs for each of the operational environments of people, places, and processes. The framework scoring process considers the relevancy of each SRR to each of the SOC domains, as defined by an individual hospital's experience statements, to generate a final SOC domain-weighted experience capability based on their current technology infrastructure.

With an understanding of the technological strength of an organization's SRRs, the final issue is understanding the relevance of SRRs to achieving the experiences the organizations aspire to deliver. This study provides a link between technology and experience. This could be achieved by taking the experience statements derived through discussion and analysis with the organization's clinical staff, operational staff, and patients and ranking the relevance of the SRR groups. The relevance of each SRR to support the desired experience statements within the SOC domains of manageability, comprehensibility, and meaningfulness was estimated using the relevancy ranking in Textbox 5. The framework score reflects the competency of the information infrastructure to support a given level of experience within each SOC domain of manageability, comprehensibility, and meaningfulness.

Future Evaluation

The next phase of the evaluation process will be undertaken from 2022 to 2023 with specific hospitals to validate the framework using expert reviews and, subsequently, implement the framework with a selection of Australian hospitals.

DSRM Activity 6: Communication

The communication of this research is initially through this paper, detailing the complex research process and the body of work. In addition, an industry case study is in preparation, along with a technical report on the use of the framework for the industry. As the framework is designed for practical use, innovation and usability factors are essential for communication.

Discussion

Principal Findings

The developed framework uses the concept of SOC as a lens through which to view and define patient experience in the context of reducing environmental stressors for patients. Through this approach, the framework demonstrates the links among the critical perspectives of experience, supporting information capabilities, and information infrastructure. In addition, the maturity of these supporting capabilities can be measured using a capability maturity assessment model based on the established digital infrastructure assessment methodology [3], and pathways for improvement can be identified.

The purpose of the framework is to assist hospitals in improving their effectiveness regarding patient experience by connecting and orchestrating the synergy among people, processes, and systems using the organization's infrastructure capability. To this end, the framework can be used in two ways: to contextualize and generate conversation for improvement in patient experience and as an assessment tool to evaluate the current information infrastructure.

Contextualization

The concept of SOC provides a pragmatic structure for establishing the overall experience objectives within a health care organization. These guiding principles can then be reflected in the desired experiences at the operational environment levels of people, places, and processes. These, in turn, can contextualize the experience requirements for the way in which IT-driven operational processes (SRRs) interact with the patient. Such an experience map of an organization enables a clear

definition of the information infrastructure requirements to support these desired experiences.

This approach enables the model to tap into the rich archive of survey-based empirical research to guide the experience statements, which are a critical part of the major stages of this model. This framework can be used as a road map for specific improvements, generating discussions on aspirational experiences and how to reach them. In this way, it assists in the design of patient experience road maps rather than journey maps.

Assessment

There are 2 aspects of this assessment. The first is evaluation, and the second is the scoring methodology.

It is possible to use the framework to assess the current capabilities against the draft experience statements contained in the framework or to distill the organization's vision, mission, and objectives into a revised set of customized experience statements. In doing this translation from organizational goals into organization-specific experience statements, it is possible to assess the organization's ability to meet those experience goals, identify gaps, and establish improvement strategies.

The second aspect is to use a scoring methodology to assess the ability of the current information infrastructure to support the desired experience. To score an organization's existing information infrastructure capability, an SOC was established along the lines of a balanced scorecard, with manageability, comprehensibility, and meaningfulness assessed independently. The organization's culture and objectives define the balance of these components. It is particularly insightful to apply the grading detailed in the framework scoring example in Multimedia Appendix 1 at the individual SOC domain level of manageability, comprehensibility, and meaningfulness and reflect it back to the vision of the hospital.

Summary

The final output of this framework is the capability of an organization's information infrastructure to support the desired SOC for the organization and, in doing so, create an explicit set of experiences supportive of positive patient outcomes. The innovation of this research is that, traditionally, SRRs are used when tensions are perceived to create stress [34]. However, our research challenges this perception to prevent the underlying issues in the first place rather than wait until they are perceived as threatening. In this way, it models the prevention of potential threats across the cohort in a unique hospital situation. This ensures that the right SRRs, using the information infrastructure, are available when needed and are not left to chance.

Significance

This research represents a novel approach, which does not currently exist in the literature, in specifying how SRRs can be explicitly designed to support the patient experience. Perhaps, more uniquely, it defines how the facility's information infrastructure can be designed to best support the role of those SRRs.

This study used the SOC concept to construct a bridge between patient experience process measures and patient satisfaction outcome measures. In doing so, we created an integrated model of how information capabilities using technology can enhance the delivery of care, which has not been done before. The development of the Information Infrastructure to Experience Framework as a process capability framework will assist in the practical application of (service innovation) experience-driven improvement, specifically in supporting capability and collaboration development. This contributes to developing operational capabilities and the assessment or measurement of these operational capabilities.

Finally, regarding the research methodology, using the DSRM with additional embedded theory in the design and development arguably demonstrates a more advanced and complex application of the research paradigm than is typically seen.

Future Research Opportunities

The question of the amount of information infrastructure that affects the activities of experience in practical implementation is still to be fully investigated. The type and definition of information capabilities, as well as the classes of SRRs, will benefit from ongoing exploration, together with further testing of the weighting processes in a wider variety of health care settings.

The next step in this research is the validation of the experience statements and case studies in the use of the framework. In addition, the investigation into the use of the framework methodology to define experience using an SOC in other sectors that are looking to take a novel approach to improve the experience is in progress. These include universities and subsets of specific clinical contexts such as cancer survivorship and complex drug therapies. Furthermore, although this research has focused on patient experience, it should be acknowledged that there would be an analogous process for staff experience.

Conclusions

Given the complex nature of experience in health care and to enable the creation of a coherent and simplified framework, we focused our experience definition on the impact of, as well as our ability to manage, environmental stressors. In doing so, we can use the well-established concept of SOC to describe the processes of stressor reduction. We linked this to the established model of information infrastructure service, the IMA, through the concept of information capabilities and the SRRs they support.

Through this approach, this research has demonstrated information infrastructure to experience mapping, taking the theory and characteristics of salutogenic SOC to inform the articulation of a positive patient experience and how this is supported by the information infrastructure. This is defined in both technological and experience terms at the levels of the operational environment (people, places, and processes) and through the delivery resources (SRR classes: teaming and sharing, scheduling and coordinating, monitoring and reporting, and education and training).

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Worked example of information capability scoring and its relevance to the specific resistance resources.
[DOCX File , 37 KB - formative_v6i4e35418_app1.docx]

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Abbreviations

DSRM: Design Science Research Methodology
GRR: generalized resistance resource
IMA: Infrastructure Maturity Assessment
IT: information technology
RMIT: Royal Melbourne Institute of Technology
SOC: sense of coherence
SRR: specific resistance resource

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Original Paper

Automated Virtual Reality Cognitive Therapy (gameChange) in Inpatient Psychiatric Wards: Qualitative Study of Staff and Patient Views Using an Implementation Framework

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Abstract

Background: Automated virtual reality (VR) therapy could allow a greater number of patients to receive evidence-based psychological therapy. The aim of the gameChange VR therapy is to help patients overcome anxious avoidance of everyday social situations. gameChange has been evaluated with outpatients, but it may also help inpatients prepare for discharge from psychiatric hospital.

Objective: The aim of this study is to explore the views of patients and staff on the provision of VR therapy on psychiatric wards.

Methods: Focus groups or individual interviews were conducted with patients (n=19) and National Health Service staff (n=22) in acute psychiatric wards. Questions were derived from the nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability framework. Expectations of VR therapy were discussed, and participants were then given the opportunity to try out the gameChange VR therapy before they were asked questions that focused on opinions about the therapy and feasibility of adoption.

Results: There was great enthusiasm for the use of gameChange VR therapy on psychiatric wards. It was considered that gameChange could help build confidence, reduce anxiety, and "bridge that gap" between the differences of being in hospital and being discharged to the community. However, it was reflected that the VR therapy may not suit everyone, especially if they are acutely unwell. VR on hospital wards for entertainment and relaxation was also viewed positively. Participants were particularly impressed by the immersive quality of gameChange and the virtual coach. It was considered that a range of staff groups could support VR therapy delivery. The staff thought that implementation would be facilitated by having a lead staff member, having ongoing training accessible, and involving the multidisciplinary team in decision-making for VR therapy use. The most significant barrier to implementation identified by patients and staff was a practical one: access to sufficient, private space to provide the therapy.

Conclusions: Patients and staff were keen for VR to be used on psychiatric wards. In general, patients and staff viewed automated VR therapy as possible to implement within current care provision, with few significant barriers other than constraints of space. Patients and staff thought of many further uses of VR on psychiatric wards. The value of VR therapy on psychiatric wards now requires systematic evaluation.

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KEYWORDS

virtual reality; automated; therapy; inpatient psychiatric care; implementation

Introduction

Potential of Virtual Reality Therapy

Virtual reality (VR) has the potential to be used in the treatment of a range of mental health problems [1]. Aside from the evaluation of clinical effects, there also needs to be consideration of successful implementation in services. A setting where VR therapy may be particularly valuable is psychiatric hospital wards. Pressures on staff time can often lead to limited opportunities for patients to receive psychological interventions or other meaningful activities [2,3]. Clinical symptoms may be reduced upon hospital discharge, but patients are often unprepared for returning to the situations that they had found difficult before admission. VR can provide a safe and controlled setting for patients to practice being in everyday situations. We therefore set out to investigate how VR therapy is viewed by patients and staff in psychiatric hospitals [4].

Objectives

The objectives are 3-fold: first, to obtain initial expectations of patients and staff about using VR headsets and, especially, VR psychological therapy; second, to gain patient and staff views of an automated VR therapy (gameChange). gameChange, which has a user-centered design [5,6], was evaluated in a randomized controlled trial with 346 patients with psychosis [7,8]. Almost all patients were attending outpatient services. The VR therapy led to significant reductions in anxious avoidance and distress, particularly for patients with severe agoraphobic avoidance. In 6 sessions, the aim is to reduce agoraphobic avoidance by presenting graded VR simulations of common everyday situations (eg, getting on a bus and going to a shop) [5,6]. Patients are guided through the program by a virtual coach. The third objective is to consider requirements for implementation. The study design was informed by the nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability (NASSS) implementation framework for health care technologies [9]. Staff and patients were in a position to inform 3 of the framework's 7 domains with regard to implementation of VR therapy: the condition and disorder that the therapy is designed to address, the intended adopters of VR therapy, and the organization where it would be implemented. This is the first implementation study of automated VR therapy in inpatient settings.

Methods

The gameChange Lived Experience Advisory Panel (LEAP), facilitated by the McPin Foundation, contributed to the development of the study. Details of this and other aspects of the study methodology are provided in the full study protocol [4].

Amendment to Protocol

The study was set up before the COVID-19 pandemic. The first focus group was run on March 6, 2020. It had been planned to go on to visit 1-2 inpatient wards at each of 5 National Health Service (NHS) mental health trusts across England, totaling a minimum of 50 participants. However, access to wards and travel across the country became severely restricted. Therefore, we had to reduce the number of sites visited.

Participants

An acute inpatient ward at Nottinghamshire Healthcare NHS Foundation Trust and 2 acute inpatient wards at Oxford Health NHS Foundation Trust took part in the study. Staff working in either the delivery or management of clinical care on the wards were invited to take part. NHS patients staying on the wards were recruited according to the criteria presented in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Participant is willing and able to give informed consent for participation in the study
- Aged ≥18 years
- Willing to consent to being audio recorded
- Sufficient English language skills to participate in the focus group or interview

Exclusion criteria

- High levels of associated risk to self or others through participation in the study; for example, actively suicidal
- Photosensitive epilepsy (use of virtual reality is not recommended for those with photosensitive epilepsy)

Procedure

Focus groups were the primary choice for data collection, but an individual interview was offered where a participant preferred it or was unavailable at the time of the focus groups. Focus groups and interviews initially asked questions relating to expectations before all participants briefly tried gameChange and then discussed their opinions on the therapy and its suitability for the ward. Participants could choose which VR scenario they wanted to try out and what level, although patients were encouraged to try out easier levels first. Each VR scenario lasts several minutes, with higher levels typically being slightly longer and more participative. Where there was enough time,

participants could try more than one level or scenario if they wanted.

Topic Guide

The semistructured topic guide was informed by the NASSS framework. Separate but similar topic guides were created for staff and patients. Study authors, including qualitative research experts, and the LEAP members developed the first drafts of the patient topic guide, and both guides were piloted beforehand. The topic guide was reviewed after conducting the first focus group. No significant changes were made, although 2 questions were slightly rephrased (eg, "Who would you like to deliver VR therapy to you?" was changed to read "If this were to be available on the ward, who would you like to be doing it with you?").

Analysis

Focus groups and individual interviews were audio recorded and transcribed verbatim. Field notes from each focus group and interview were also transcribed. Field notes recorded factors such as group dynamic and nonverbal cues to add context to the transcript of the audio recordings. Transcripts were not returned to participants for comment or correction.

A thematic analysis was performed [10] separately for staff and patient data, although similarities and differences between the analyses were then considered. All data were entered into NVivo (version 12; QSR International) [11] to provide a transparent audit trail. The transcribed data were read and reread to ensure familiarity before developing a preliminary coding framework that was discussed and adapted by the first author (PB) during supervision. A number of transcripts were double coded. An extract of the coding and reflexive log, with examples of adaptations made, can be viewed in Multimedia Appendix 1. Details regarding each code were recorded in memos in NVivo. Themes were derived from the data. Diverse cases and minor themes were considered because breadth was considered as important as frequency.

LEAP Involvement in the Analysis

A summary of the analysis was sent to the LEAP members for consideration to assess the validity of the findings in an additional group. LEAP members showed considerable support for the findings. In particular, they highlighted the need to have treatments beyond medication, the potential for VR to be a helpful route to engaging patients who may otherwise not engage with ward activities, and the potential to have alternative VR scenarios and presentations of Nic, the virtual therapist. The importance of VR increasing access to psychological therapy, rather than being a substitute for any existing therapeutic activity, was also emphasized. A LEAP member additionally underscored that limited private space to use the VR would likely be a significant challenge facing many wards.

Reflexivity

All patient focus groups were led by a doctoral student (PB) and cofacilitated by a clinical psychologist (SL, RD, or JJ). All interviews and staff focus groups were either led solely by PB or jointly by PB and a clinical psychologist. Consideration was given to how professional backgrounds may affect data collection and analysis. For example, existing knowledge, expectations, and hopes regarding VR therapy may have affected how the focus groups were conducted. A reflexive log was kept, and to try to minimize these potential biases, the topic guide was closely adhered to because this was created largely from the NASSS implementation framework rather than from personal experience and expectations. Consideration was given to the gender and class of the facilitators and that visible indicators of socioeconomic status could affect participant engagement. Participants were frequently reminded that the aim of the study is to hear and learn from their views and that the facilitators wanted participants to be as honest and open as possible about any concerns or criticisms they may have.

Ethical Considerations

The study had received ethical approval as part of a substantial amendment to the gameChange trial [7]. The trial received ethical approval from the NHS South Central–Oxford B research ethics committee (19/SC/0075).

Results

Overview

In total, 19 patients (n=12, 63% men and n=7, 37% women) and 22 members of ward staff (n=3, 14% men and n=19, 86% women) took part. Participants were from 3 wards across 2 NHS mental health trusts. There were 7 patient interviews and 4 patient focus groups (each with 3 patients) and 3 staff interviews and 4 staff focus groups (each with 2-7 staff members). The numbers of staff and patients recruited from each ward were approximately equal. Participants were predominantly of White ethnicity, with ages ranging from 18 to 60 years for the patient participant group and from 21 to 60 years for the staff participant group. The staff comprised nurses (including clinical leads), health care assistants, a deputy ward manager, a peer supporter, a ward clerk, activity coordinators, occupational therapists, and assistant psychologists. Although analyzed separately to begin with, all themes were shared across staff and patient responses.

Desire for Treatments Beyond Medication and the Value of Psychological Therapy

Many patients described their dissatisfaction with medication being the primary form of treatment available on their ward and the lack of psychological therapy: "How are we going to get better if we're just on meds?...I would really benefit from therapy at this point." [participant 8]; "We just get filled with pills, there's no talking therapies or anything like that" [participant 3]. This desire for treatment beyond medication led to a sentiment of being "up for trying anything" [participant 1]. Patients typically reported a positive view of psychological therapy and a desire for more to be available: "more one to one therapy" [participant 9]; "I think talking's the way forward" [participant 11]. However, there were some exceptions, with an individual saying, "I don't find talking helps" [participant 18] and another individual describing some negative past experiences with a psychologist and suggesting instead that their priority for recovery was seeking safe housing [participant 17]. Notably, many patients were aware of resource limitations contributing to a lack of therapy provision: "The room and the

money is obviously not enough" [participant 2]; "They're under a lot of pressure, you see" [participant 15]. Staff also reported positive views of psychological therapy, seeing it as an important treatment option for patients: "It's always good to have more therapy" [participant 3]; "the most helpful thing for [patients] to have" [participant 19]. Some staff felt that even if therapy could not lead to large clinical improvements, it would nonetheless help patients to have a purpose while being on the ward and help to reduce boredom. There was acknowledgment from a staff focus group that the psychological perspective differs somewhat from the nursing point of view but both are important.

VR Therapy Sounds Rational and Helpful

Before trying it for themselves, patients and staff members reported positive expectations of gameChange. In particular, they felt that the use of technology, graded levels of difficulty within the program, and the automation of the therapy could all be beneficial. Several staff reported expecting the VR therapy to be popular among patients and felt that it would likely help a lot of patients: "It makes perfect sense...it's definitely something that I think could be really useful...just giving them a bit more confidence" [participant 1]. These views were also shared by patients: "If someone struggles with walking down the street and they can do that in chunks and chunks and chunks and gradually build up, like, that's going to be great" [participant 11]. However, some patients did express concern. After hearing about the rationale of gameChange, a patient stated, "Sometimes I wonder whether highlighting these areas can make the issue a bigger thing" [participant 14].

Surpassing Expectations

After trying the gameChange VR therapy for themselves, many staff and patients reported feeling surprised and impressed. In particular, there was considerable discussion by all participants of how surprisingly real the VR therapy felt and how the experience was enjoyable. For instance, a staff member stated, "That was really amazing...it does absorb you into it" [participant 11]. Several participants said that the VR therapy had surpassed their expectations: "It's better than I thought it would be" [staff member, participant 2]; "I was skeptical before coming in, but I get it now" [patient, participant 3]. Several patients also expressed a desire to try more of it and thought it would be very popular on the wards: "I think there would probably be a big line, a big queue, to use it daily I think, to be honest" [participant 4]. However, a member of the staff reported thinking that the VR therapy actually had a strong "sense of unrealism" and that "nothing much" had surprised them [participant 9].

VR Therapy Could Help

The expectation that the gameChange VR therapy would be helpful was maintained after participants tried it. Patients felt that the gameChange therapy could help in a number of ways, including building confidence and reducing social anxiety ("I think it would be helpful to people with anxiety...I reckon it would help" [participant 19]), providing new perspectives and an escape from the ward on the ward ("I already feel as though I've been out today by just being in that experience, and I actually feel better than when I arrived, so it clearly can help" [participant 1]), and preparing for discharge ("It is going to help you to come out into society, out of the hospital, and back into society" [participant 7]). Staff shared patients' views that gameChange could help build confidence, reduce anxiety, and "bridge that gap" [participant 2] between hospital and discharge and also felt that the VR would be particularly helpful for patients who may typically engage less in therapeutic activities available on the ward, as well as for those who struggle with communication and those who find it difficult to leave their bedrooms. A staff member who had seen some of the patients on the ward trying out the VR therapy also noted: "Seeing them afterwards they seemed really pleased with themselves and it was that kind of sense of accomplishment that was really nice" [participant 17]. However, staff and patients acknowledged that the therapy would not suit everyone. For example, it was discussed that some patients may be too unwell to use the therapy or feel that it is not relevant to their needs: "When [patients are] really unwell it's difficult...it would have to be, you know, picked up at the right time in their recovery for it to benefit them" [staff member, participant 8]; "Initially you might not be at the stage to do any talking therapies" [patient, participant 3]. Some patients also said that the therapy would not be of particular help for themselves, even if it would help others: "Social situations as he said, brilliant, but like for self-harming...I can't see that helping in my situation" [participant 2]; "It's not beneficial to me but it would be a massive help for others that are struggling" [participant 13].

Envisioning Implementation

Where the VR could be physically located on the ward, who would support patients to use it, and which patients it might be offered to and when was discussed. Staff and patients thought that the VR needed to be stored away somewhere safe and secure and that a quiet, private room would be needed for using VR for structured therapy interventions such as gameChange. The wards varied as to whether such a space existed already. A staff member suggested that an option to overcome space challenges on the ward would be to have a "dedicated space off the ward to use the [VR therapy]" [participant 4], although this would require patients to be granted leave from the ward, which would not always be possible.

Regarding who would be present to support the patient to use VR therapy, patients and staff stressed the importance of the member of staff being someone the patient could trust and with whom the patient could form a good therapeutic relationship: "someone you feel comfortable around" [patient, participant 5]; "It should be done with somebody that they've got that therapeutic relationship with" [staff member, participant 22]. Unsurprisingly, staff spent longer considering which specific job roles may be most suited to using the VR therapy with patients. Suggestions included assistant psychologists, health care assistants, and occupational therapists. Of the 4 staff focus groups, 2 (50%) noted that it might be important to have staff members who do not have to respond to personal infrared transmitter (PIT) alarms for ensuring that sessions are not disrupted: "If someone has got a VR headset on and all of a sudden this massive alarm is going off...the person facilitating has to run out of the room...that could be really disorientating"

[participant 5]. Although there was agreement that staff would be "very much willing to be trained in it" [participant 1] and would find it enjoyable to be able to "see the benefits" of the treatment [participant 2], it was considered particularly important to ensure an opt-in system, where staff members could sign up to train in the VR therapy if they wanted to but were not required to if they felt that it was not something they would like to do. It was also suggested that, to begin with, it may be helpful to have staff from outside the ward come and "train the whole ward" [participant 1] or even to deliver the therapy to patients, given that external staff would be "more competent and committed" and could then "get the ward staff involved" [participant 2]. When asked about the possibility of a peer professional, that is, someone with lived experience of a mental health problem who has received training in providing psychological support and confidentiality, being present rather than a member of ward staff, patients saw this as a positive option: "They'd be brilliant" [participant 2]; "They're then speaking from experience, aren't they" [participant 4].

Staff members also felt that if VR therapy were to be implemented on the wards, its use by individual patients would need to be discussed within the clinical team and then prescribed in line with the evidence base: "It would have to form part of a care plan...it wouldn't be something that we just get out and go" [participant 11]. In general, staff mostly felt that the therapy could fit well into existing ward routines: "[Staff] set time aside to sort of have one-to-ones with patients...I think you could incorporate it into that hour" [participant 1]; "I take patients out for, like, community assessments and stuff...so the alternative could be doing this" [participant 12].

Concerns About Having VR Therapy on Wards

Both staff and patients raised concerns regarding how VR therapy could be implemented on wards, although the specific concerns varied. Patients discussed whether VR would be seen as a burden by staff because of the need for constant supervision ("Staff could see it as an imposition because they're too busy taking people out on fag breaks" [participant 3]), the headsets getting broken or forgotten about ("It'd get broken" [participant 16]), the therapy becoming a substitute to enable further cuts to funding of existing psychological therapies ("I think the danger of course is that the technology becomes the substitute for government cuts or lack of funding" [participant 1]), as well as needing to ensure that patient data are kept secure and confidential ("I would want to know that my data was secure" [participant 8]). A patient focus group also voiced concern that it could be embarrassing if one were doing something odd in the VR, which tied into desires for using it in a private space with a trusted member of staff. Staff members shared patients' concern about needing to consider how to look after the equipment and prevent it from getting broken: "I could just see the equipment getting ruined" [participant 21]. Staff also raised concerns around whether the headset might be overwhelming or overstimulating for some patients and difficult for those with less spatial awareness.

Barriers and Facilitators to Implementation Vision

Staff thought that having ongoing access to training, the involvement of a patient's multidisciplinary team, and a mechanism for helping patients to continue to use the VR if discharged to the community in the middle of a set of sessions would all be factors that would make it easier to ensure the successful implementation of VR therapy on psychiatric wards. Having a staff member lead the use of VR on the ward, who would, for example, be someone staff members "can report back to with any concerns" [participant 1] and who would be responsible for maintaining the equipment was also raised as a facilitator. In addition, staff and patients stressed the importance of introducing the VR therapy in the right way. Patients primarily spoke about this with regard to how it would be explained to users, for example, providing reassurance regarding its safety, and "explaining it has been developed with people with psychosis" [participant 11] (the gameChange VR therapy was developed with patients using a user-centered design process). Staff primarily considered how it should be explained to staff: "as much information as you could give...why it's going to benefit, what you hope the outcome will be and basically that it could help create a calmer environment on the ward because that's all we want" [participant 8].

In contrast, current barriers to the implementation of VR therapy on wards included staff shortages and the resultant reliance on agency staff, as well as the lack of appropriate space for using the VR therapy on some of the wards, with existing private spaces either being too small, too noisy, or too infrequently available. There was contrast among members of staff within and between wards regarding whether limits on staff time would be a problem. Some members of staff felt that the VR therapy would not add time pressure to staff roles because it could fit into existing routines or that any additional time it would require would likely only bring about savings in time in the longer term ("I wouldn't say the time is a constraint, no, no...if we're spending more time engaging in therapy with someone that can only be a positive" [participant 1], whereas others felt that pressures on staff time would be a greater challenge, and would, for example, "play a part in how frequently somebody could have a session" [participant 16].

Improvements and Potential

Several ways of improving the VR therapy were discussed. Patients and staff thought it would be beneficial to be able to vary the computer characters and, in particular, the virtual coach, Nic, to suit the preferences of the user. A patient focus group also suggested that Nic could be presented as a peer professional, for example, "a patient with your own characteristics that's out in the community" [participant 1], feeling that "if it's presented as a peer supporter, even though it's not real I think that would make you feel a little bit more relaxed" [participant 3]. A number of additional scenarios were also suggested, including a football stadium, a theater, a courthouse, and a workplace. Having some simulated ward environments such as the communal area and a ward round meeting were also suggested by several members of staff and patients: "[Patients] can get really anxious about ward rounds...so I don't know whether or not that could be something in future" [staff member, participant 20]; "a ward meeting where there's loads of people" [patient, participant 16]. Other improvements suggested were having adaptations for individuals with audio or visual impairments and increasing the level of interactivity in the scenarios. Staff

and patients also discussed a range of ideas for further uses of VR headsets. Relaxation and mindfulness exercises were frequently discussed in particular, with other suggestions including helping autistic individuals to practice eye contact; training in STOP anger management techniques; and staff training on what it is like to have certain psychotic experiences, patient assessment and diagnostics, treating posttraumatic stress disorder, and treating obsessional thinking. As a patient stated, "There's sort of endless possibilities" [participant 1]. Because of the limited resourcing many wards face, it was also suggested that patients could use the VR headsets for gaming when available, which might then also help to reduce boredom on a ward.

Discussion

Principal Findings

We report the first qualitative investigation of staff and patient views on the potential of using automated VR cognitive therapy on inpatient psychiatric wards. It was very clear that patients and staff have considerable enthusiasm for trying something new, especially a potentially effective psychological approach, and that participants were impressed by the potential of the automated VR therapy to help patients, while potentially overcoming some of the resourcing challenges that traditional therapies face. Although caveats were expressed, the enthusiasm bodes well for testing and implementing VR therapy on psychiatric wards.

Separate coding frameworks were initially developed, but there was considerable overlap and consensus between patient and staff views. Particularly striking was that nearly all participants felt positively surprised by certain aspects of gameChange, noting that it surpassed their expectations, in particular with regard to how real it felt. In addition, although staff and patients felt that on a patient's immediate arrival to the ward VR therapy may not be so appropriate, psychological therapy is certainly something that was desired by patients and considered by staff to be important for aiding recovery. Patients staying in hospital may often be thought of as being too unwell to benefit from psychological therapy, but this was not the view of the patients and staff from these wards.

Staff and patient participants both shared the belief that VR therapy could be very helpful, and they were keen to consider practical solutions concerning where and with whom it could be used. There was also variation in the discussion by staff and patients. Within the *envisioning practicalities theme*, staff considered in greater detail which professions might be able to feasibly deliver VR therapy, whereas patients understandably discussed in greater detail who they might feel most comfortable in having to support them. Interestingly, a primary concern of the patients centered on whether staff would be willing and have the time to use the VR therapy with them, whereas many staff members did not raise this as a likely problem.

The topic guide covered three domains of the NASSS framework: the condition or illnesses that the technology is designed to help, the intended adopters of the technology, and the organization where it would be implemented. With regard to the condition, the gameChange automated VR therapy is designed to help anyone who may feel anxious or lack confidence in entering everyday social situations. It is for agoraphobic-type anxious avoidance, which occurs in two-thirds of patients with severe mental health conditions [12]. Patients and staff agreed that this would be a relevant treatment target for many individuals on the ward, but they were of the opinion that factors such as severity of clinical symptoms might complicate successful use. Interestingly, wider applications of VR for patients in psychiatric wards were identified. With regard to the intended adopters, a crucial lesson from this study is the clear enthusiasm and positive feedback displayed by all participants. This is particularly of note, given that studies suggest that acceptance by staff can often be the single most important determinant of whether new technologies succeed at a local level [9,13]. However, it must also be recognized that the staff most likely to volunteer their time to take part in an interview may also be those who judge that they have time available or have the most interest in innovation. Self-selection is likely to bias feedback toward the positive. This potential bias may have been mitigated to a degree by running several focus groups in a regular staff meeting slot. However, it is also the case that most of the staff interviewed were not in senior decision-making roles for ward treatment provision. Regarding the NASSS framework domain of organization, most staff reported that their ward would have the capacity and motivation to take on the kind of change entailed by VR therapy. It was judged that the use of VR therapy could fit into existing ward routines such as one-to-one time that staff have dedicated to spending directly with individual patients, although its use in conjunction with real-life practice in outdoor settings may require careful planning.

A number of potential barriers to implementation were raised. Space to use the equipment may be a barrier in some wards. Staff did think that this barrier could be overcome through adapting current spaces or making use of rooms off the ward. Although staff time was not seen as a barrier when wards are working with usual capacities, times of staff shortages was discussed as a potential problem. This might mean that having staff external to the ward, such as peer professionals dedicated to the delivery of VR therapy in addition to training ward staff, could be the most feasible and popular method of implementing VR therapy. This also fits with recommendations within the NHS Long Term Plan to recruit a workforce of peer support workers in acute settings [14,15].

Our experience is that people need to try VR to understand it fully, and this was the case in this study. For implementation, a VR ward facilitator could ensure that as many staff as possible have the chance to try VR. When introducing the technology to patients, it will be helpful to address explicitly the concerns raised by patients in this study; for example, by providing information on the safety of the equipment and whom it was developed by. Resources such as workbooks and summary sheets of the therapy aim and rationale to help consolidate learning may also be useful. It was also notable that VR was seen as something that could be helpful in many different ways on a ward, including for games or mindfulness exercises.

Limitations

There were several limitations to the study. Most significantly, because of the COVID-19 pandemic, recruitment took place on only 3 acute psychiatric wards across 2 NHS mental health trusts, which may limit the generalizability of the findings. The enthusiasm for VR therapy may have been less on wards where, for example, there are more activities and therefore less boredom or on wards that already have psychological therapy available. It is also likely that participants in implementation studies may represent a more highly motivated group who are less representative of the whole population [16]. Multiple stakeholder involvement is important for implementation research [17,18], and there were too few staff participants (eg, consultants and managers) who are typically involved in strategic decision-making. It is also the case that this study did not consider all domains of the NASSS framework. For instance, it will also be valuable to consult individuals with detailed knowledge of the technology to consider supply, support, and future evolution. However, the results of this study indicate that VR therapy has significant potential to be implemented on psychiatric wards.

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Conflicts of Interest

DF is a founder and nonexecutive board director of Oxford VR, a University of Oxford spin-out company, which is commercializing the gameChange virtual reality therapy. DF holds equity in Oxford VR.

Multimedia Appendix 1
Extract from the coding and reflexive log.
[PDF File (Adobe PDF File), 18 KB - formative_v6i4e34225_app1.pdf]

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Abbreviations

LEAP: Lived Experience Advisory Panel
NASSS: nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability
NHS: National Health Service
PIT: personal infrared transmitter
VR: virtual reality

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Original Paper

Assessment of a Mobile Health iPhone App for Semiautomated Self-management of Chronic Recurrent Medical Conditions Using an N-of-1 Trial Framework: Feasibility Pilot Study

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Abstract

Background: Management of chronic recurrent medical conditions (CRMCs), such as migraine headaches, chronic pain, and anxiety/depression, remains a major challenge for modern providers. Our team has developed an edge-based, semiautomated mobile health (mHealth) technology called iMTracker that employs the N-of-1 trial approach to allow self-management of CRMCs.

Objective: This study examines the patterns of adoption, identifies CRMCs that users selected for self-application, and explores barriers to use of the iMTracker app.

Methods: This is a feasibility pilot study with internet-based recruitment that ran from May 15, 2019, to December 23, 2020. We recruited 180 patients to pilot test the iMTracker app for user-selected CRMCs for a 3-month period. Patients were administered surveys before and after the study.

Results: We found reasonable usage rates: a total of 73/103 (70.9%) patients who were not lost to follow-up reported the full 3-month use of the app. Most users chose to use the iMTracker app to self-manage chronic pain (other than headaches; 80/212, 37.7%), followed by headaches in 36/212 (17.0%) and mental health (anxiety and depression) in 27/212 (12.8%). The recurrence rate of CRMCs was at least weekly in over 93% (169/180) of patients, with 36.1% (65/180) of CRMCs recurring multiple times in a day, 41.7% (75/180) daily, and 16.1% (29/180) weekly. We found that the main barriers to use were the design and technical function of the app, but that use of the app resulted in an improvement in confidence in the efficiency and safety/privacy of this approach.

Conclusions: The iMTracker app provides a feasible platform for the N-of-1 trial approach to self-management of CRMCs, although internet-based recruitment provided limited follow-up, suggesting that in-person evaluation may be needed. The rate of CRMC recurrence was high enough to allow the N-of-1 trial assessment for most traits.

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KEYWORDS

mHealth; patient-specific modeling; chronic disease; smartphone; implementation and deployment; facilitators and barriers

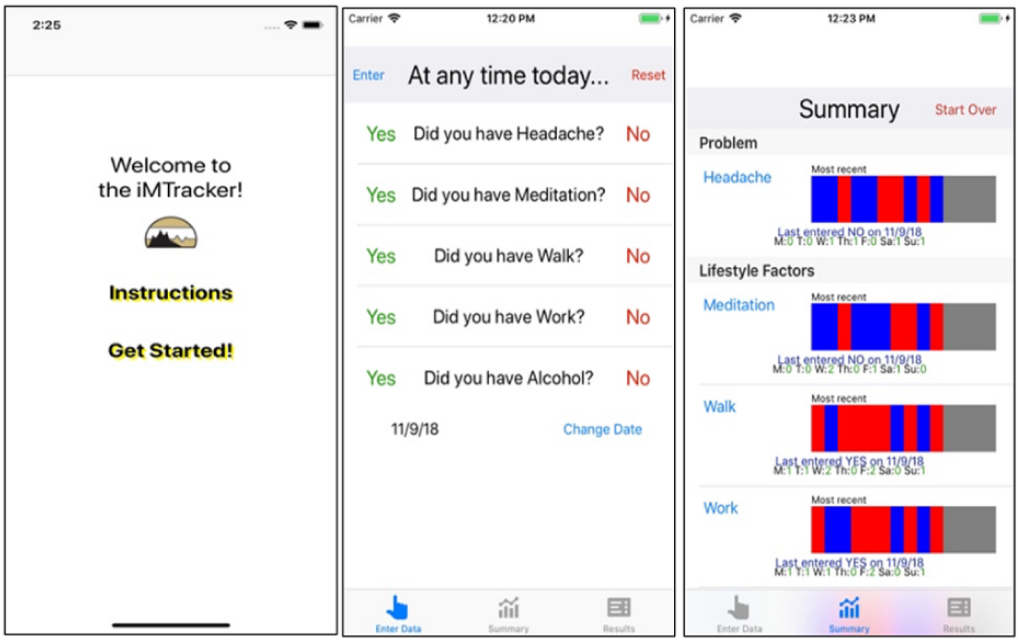
Introduction

Chronic recurrent medical conditions (CRMCs) encompass a major proportion of the modern health care burden, accounting for significant costs in the form of both management and lost productive time [1]. For example, chronic migraine headaches affect about 2% of the global population [2], and in the United States alone, cost more than US $20 billion annually [1] to manage. Chronic low back pain accounts for over 5 hours/week in lost productivity by workers, resulting in over US $10 billion in lost revenue per year [1]. Mental health disorders, including depression and anxiety, accounted for 183.9 million disability-adjusted life years and 175.3 million years lived with disability worldwide [3], with an increase of 37.6% over the years from 1990 to 2010 [3].

On a more granular level, CRMCs create a major challenge for today's busy clinician. Although widely variable across providers and practices, the time available for a face-to-face encounter with patients continues to trend downward, despite an increase in the number of clinical items needing to be addressed [4]. As a result, providers have less time available to focus on the range of triggers and contributing factors for any given CRMC. This trend is unfortunate, as for many CRMCs the number and complexity of environmental and lifestyle triggers can be quite robust. For example, sleep changes have been described in about 50% of patients with migraine headaches, although 75% of patients also chose to sleep due to the migraine headache [5]. In addition, a study of 1207 patients with migraine headache identified no less than 16 possible triggers present in at least 5% of these individuals [6]. A similar scale in triggers has also been noted for depression [7], anxiety [8], and chronic low back pain flares [9]. As such, tailored management of patients with these and other CRMCs often requires the provider to take a detailed, longitudinal history with attention to temporal relationships—an approach that fits poorly with the practical constraints of modern clinical practice.

Despite these limitations, there is evidence that an individualized approach to self-management of CRMCs using mobile health (mHealth) apps has potential to improve clinical outcomes. Specifically, the N-of-1 approach to care has been applied to study various interventions for pain [10-14], depression [15-17], anxiety [18,19], and migraine headaches [20-22], and has been incorporated into mHealth technology [23-25]. In 2017, our team developed a prototype semiautomated iOS mHealth app called the iMTracker (Figure 1), which incorporates the N-of-1 platform for patient-entered data to log recurrences of a given CRMC, as well as the opportunity to log possible triggers or suppressors of the CRMC. The iMTracker provides edge-based analysis of symptom correlations, in which data are stored and analyzed on each user's device, without the need to transfer or store data to a central server. However, it is unknown which specific patients with CRMCs would be most likely to use the iMTracker for self-management, and whether the rate of recurrence is high enough to maintain a sufficient level of engagement to draw meaningful associations with lifestyle triggers and to evaluate the impact of interventions on recurrence rate. In this feasibility pilot investigation, we aimed to apply an internet-based recruitment approach to enroll patients to trial the iMTracker app. Our goal in this study was to examine the 3-month adoption rate of the iMTracker app by patients with CRMCs, to understand the patterns and characteristics of the possible CRMCs and users, and to identify design and functional barriers to the use of iMTracker prior to its use. Additionally, we planned to examine the strengths and limitations of the internet-based recruitment approach to development and testing of mHealth apps, and identify areas to address for future prospective studies aimed at improving outcomes.

Figure 1. Screenshots of iMTracker.



Methods

Patients

From May 15, 2019, to December 23, 2020, we recruited 180 patients to test the iMTracker app for iPhone for self-management of their CRMCs using an internet-based study design. Inclusion criteria were aged 18 or older, presence of a CRMC, and use of an iPhone. There were no official exclusion criteria, although based on study design and app functionality, patients generally needed to be English speaking and familiar with the use of iPhone apps, as well as the use of email and internet. We started with advertising on social media, such as Twitter, campus-based fliers, and provider word-of-mouth, but found limited recruitment, by which only 2 patients were recruited. We then employed the TrialFacts patient-recruitment company [26] (San Diego, CA, USA) to assist with internet-based recruitment. Patients were provided a small financial stipend for participation, which was paid on enrollment only (nothing additional for follow-up). Written informed consent was obtained for all patients.

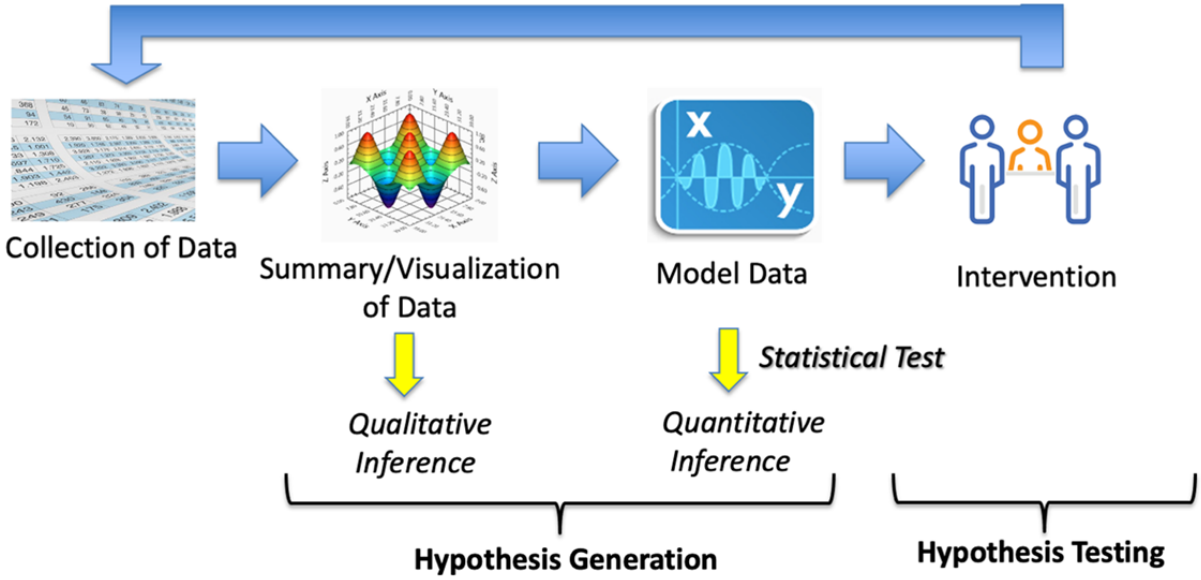
Ethics Approval

The study protocol was approved by the University of Colorado Institutional Review Board (Protocol #18-1000).

mHealth App (iMTracker)

The platform of iMTracker was designed based on an automated N-of-1 trial approach (Figure 2) that includes both hypothesis generation and hypothesis testing, which can be built into the logic of an mHealth app. The iMTracker allows the user to select any problem (outcome) and any potential lifestyle factors (risk factors) or intervention that the user would like to test for an association with the outcome. Through iteration between hypothesis generation (ie, “Is there an association between risk factor A and occurrence of my condition?”) and hypothesis testing (ie, “Does changing risk factor A improve the rate of occurrence of my condition?”), the user is able to self-manage his or her condition toward an overall goal of reducing recurrence. The platform thus provides a semiautomated approach to self-management, in which the analysis provides potential lifestyle/behavioral factors that are associated with the CRMC, but allows users to select which factor to intervene upon to examine impact on CRMC recurrence rate. Importantly, the overarching design of the iMTracker app has been focused on application of edge computing [27,28] strategies that run on the mobile device itself, to allow complete usage of the iMTracker app without the need for transfer or storage of data on a server, which provides patients with a level of privacy and data security [29,30].

Figure 2. The semiautomated N-of-1 approach motivating the iMTracker design.



Data are manually entered by the user, presented in a visual format, and then modeled for correlations between the selected outcome (problem) and potential risk factors (Figure 1). Through built-in notifications, the iMTracker app prompts the user to input data daily, and keeps a running summary of the inputs. This analysis includes correlation between the outcome and risk factors on a daily basis and with 1-day lag to identify risk factors that could potentially cause the outcome on the following day, using the phi statistic for correlation between discrete variables [31]. Although analysis is performed after only 3 days of data collection, users are informed that the accuracy of the correlation is higher with greater amounts of data collection (Multimedia Appendix 1). Once enough data have been collected to form hypotheses about causative associations, users are directed to reset the data collection and select an intervention in the form of a lifestyle modification, from which future data will examine the role of that intervention in reducing recurrences of the outcome.

Survey

Our team designed a brief survey instrument with several goals in mind. First, we wanted to identify which specific CRMCs

users selected for self-management using the iMTracker app. These diagnoses were self-provided, and we did not perform a separate validation with either treating clinicians or chart review. Second, we sought to collect information about the typical pattern of CRMCs—that is, frequency of recurrence—to understand the burden of disease of a possible user of the iMTracker app, and also to guide future work in automating analyses toward sufficient statistical power to detect associated lifestyle conditions and the effect of interventions. Third, we included questions aimed at detecting prior experience with regular data collection (eg, "How often do you weigh yourself?"), information sharing (eg, "How often do you post on social media?"), and electronic engagement with providers using email or secure messaging. Broadly, these questions helped to frame the users' motivation for using this type of technology for self-management of CRMCs. Fourth, we inquired about concerns of using technology for self-management of conditions; specifically, we asked users to rank concerns related to data security, privacy, efficiency (time demand), and efficacy. Finally, we inquired about specific concerns with the iMTracker app, and asked for qualitative input about the design and function. In addition, we collected basic demographic information about categories of age, education, race, and ethnicity.

The follow-up survey was designed to obtain information about the app itself, as well as the process of the N-of-1 approach to self-management of their selected condition, and to assess the 3-month adoption rate to provide a baseline for future clinical trials. Patients were sent a link to the poststudy survey 3 months after the date of enrollment. Patients that provided no answer for the 3-month adoption, but who completed the postsurvey were assumed to have not completed the 3-month adoption. The postsurvey questions are provided in Multimedia Appendix 2.

The study was conducted remotely using email and phone calls with patients. After informed consent was obtained, patients were given a link to the online survey using a REDCap database. Patients were guided through download and use of the iMTracker mHealth app for iPhone (iOS) by a member (AM) of the research team, and given the opportunity to provide qualitative feedback about the app design, outside the survey data. The postuse survey was deployed after 3 months of use (Multimedia Appendix 3).

Analysis

All study data were collected in a REDCap database. Statistical tests of proportions were based on Fisher exact test. The analysis was performed using Stata IC, version 16.1 (StataCorp, Inc.).

Results

Of the 180 patients who completed the preuse survey, 103 also completed the postuse survey (57.2%). Only 2 patients were recruited by the study team outside of use of the TrialFacts company referrals. A total of 172 patients (95.6%) were under the age of 65, with the predominant age range being 31-45 (80 patients, 44.4%; Table 1). Most patients had at least some college (171/180, 95.0%), and most were White (144/180, 80.0%) and non-Hispanic/Latino (161/180, 89.4%).

The most common CRMCs (self-reported) for which patients planned to use the iMTracker app to self-manage were pain (80/212, 37.7%), including low back pain and other musculoskeletal pain syndromes; headaches (36/212, 17.0%), including migraines; gastrointestinal symptoms (17/212, 8.0%), including inflammatory bowel disease flares and irritable bowel disease; and mental health conditions, including anxiety (12/212, 5.7%) and depression (15/212, 7.1%; Table 2). A total of 19/180 patients (10.6%) planned to use the app to monitor more than 1 CRMC. For most CRMCs, frequency was daily (75/180, 41.7%) or multiple times a day (65/180, 36.1%), with few occurring less often than monthly (5/180, 2.8%; Table 3). Patients were allowed to apply the iMTracker app to more than 1 condition, which is why there are 212 listed in Table 2.

To assess overall patterns of self-management and use of media, patients were asked about lifestyle and technology savviness. About one-sixth (28/180, 15.6%) weighed themselves daily, 58/180 (32.2%) weighed themselves at least weekly, 42/180 (23.3%) weighed themselves monthly, and 52/180 (28.9%) weighed themselves rarely or not at all. A total of 49/180 (27.2%) posted on social media multiple times a day, 54/180 (30.0%) posted daily, 49/180 (27.2%) posted weekly, 12/180 (6.7%) posted monthly, 14/180 (7.8%) posted rarely or never, and 2/180 (1.1%) were not on social media; 64/178 (36.0%) communicated with their primary physician regularly using messaging/technology, 66/178 (37.1%) communicated rarely, and 13/178 (7.3%) preferred not to communicate using technology/messaging and only in person. Prior to the study, 74/180 patients (41.1%) said they were very likely to use an mHealth app to self-manage CRMCs, 63/180 (35.0%) were somewhat likely, and 6/180 (3.3%) said they were unlikely to use an mHealth app to self-manage CRMCs. After using the iMTracker app, all patients who said they were unlikely to use an mHealth app changed their answers to neutral (2/6, 33%) or somewhat likely (4/6, 67%).

Patients were asked about concerns for using an mHealth app for self-management of CRMCs both before and after use of the iMTracker. As shown in Table 4, patients were generally more likely to have concerns about effectiveness after using the app, and less likely to have concerns about privacy, data safety/security, or time requirements, after use.

Of the 103 patients who completed the postuse survey, 73 (70.9%; Table 5) said they used the iMTracker app for the planned 3-month period; among those who stopped beforehand, 2/16 (13%) used it for 2 months, 5/16 (31%) used it for 1 month, and 9/16 (56%) used it for less than a month. Among those completing the 3-month use period, only 3/103 (2.9%) failed to enter data on over 50% of days, and 22/103 (21.4%) reported missing less than 5% of days entering data. These patients reported reviewing their data summary weekly or every few weeks in 13/22 (59%) cases, and daily in 3/22 (14%) cases. Finally, 27/103 (26.2%) patients said they were likely or very likely to use the iMTracker app again to self-manage their CRMCs, and 58/103 (56.3%) said they were unlikely to use it without modifications. There was a potential signal for increased levels of education being statistically associated with increased 3-month adoption rate (P=.04; Table 5), although the association did not reach a level of statistical significance after adjustment

for multiple comparisons (Bonferroni *P* for significance [α]=0.05/4=.0125). Among the subjective reasons for not continuing to use the iMTracker app, issues with data sharing and ease of use were most cited, followed by design/display limitations.

Table 1. Demographics of iMTracker users.

Demographics	Value, n (%)
Age (years; n=180)	
Under 30	38 (21.1)
31-45	80 (44.4)
46-55	32 (17.8)
56-65	22 (12.2)
66-75	8 (4.4)
Over 75	0 (0)
Education (n=177)	
Grade school only	1 (0.6)
High-school diploma/general educational development	5 (2.8)
Some college	50 (28.2)
College degree	66 (37.3)
Master's degree	48 (27.1)
Doctorate degree	7 (3.9)
Race (n=180)	
White	144 (80.0)
African American	14 (7.8)
Asian	9 (5.0)
American Indian or Alaskan Native	5 (2.8)
More than 1/unknown	8 (4.4)
Ethnicity (n=180)	
Hispanic/Latino	17 (9.4)
Not Hispanic/Latino	161 (89.4)
Unknown	2 (1.1)

Table 2. Groups of chronic recurrent medical conditions for which patients planned to use the iMTracker app (n=212).

Condition group	Frequency, n (%)
Chronic pain	80 (37.7)
Headaches	36 (17.0)
Gastrointestinal symptoms	17 (8.0)
Depression	15 (7.1)
Anxiety	12 (5.7)
Palpitations	7 (3.3)
Hypertension	7 (3.3)
Dizziness	5 (2.4)
Other	33 (15.6)

Table 3. Frequency of recurrence (n=180).

Recurrence rate	Frequency, n (%)
Multiple times/day	65 (36.1)
Daily	75 (41.7)
Weekly	29 (16.1)
Monthly	6 (3.3)
Every few months	3 (1.7)
Less than every few months	2 (1.1)

Table 4. Change in concerns about mHealth apps for self-management of chronic recurrent medical conditions (n=103).

Concern	More likely, n (%)	Less likely, n (%)	Significance (*P* value)
Effectiveness	28 (27.2)	10 (9.7)	.001
Privacy	8 (7.8)	11 (10.7)	<.001
Data safety/security	5 (4.9)	18 (17.5)	.001
Time demands	11 (10.7)	29 (28.2)	.005

Table 5. Poststudy survey.

Characteristics[a]	Completed follow-up, n/N (%)	3-month adoption, n/N (%)[b]
Age category (n=103/180)		
Under 30	19/38 (50)	13/19 (68)
31-45	46/80 (58)	29/46 (63)
46-55	20/32 (63)	15/20 (75)
56-65	13/22 (59)	11/13 (85)
66-75	5/8 (63)	5/7 (71)
P value	.87	.37
Education (n=101/180)		
Grade school only	0/4 (0)	N/A[c]
High school diploma/general educational development	1/5 (20)	1/1 (100)
Some college	22/50 (44)	17/22 (77)
College degree	39/66 (59)	28/39 (72)
Master's degree	34/48 (71)	22/34 (65)
Doctorate degree	5/7 (71)	3/5 (60)
P value	.04	.83
Race (n=103/180)		
Caucasian	84/144 (58)	60/84 (71)
African American	9/14 (64)	8/9 (89)
Asian	2/9 (22)	2/2 (100)
American Indian or Alaskan Native	3/5 (60)	3/3 (100)
More than 1/unknown	5/8 (63)	3/5 (60)
P value	.37	.05
Ethnicity (n=103/180)	N=103	
Hispanic/Latino	10/17 (59)	7/10 (70)
Not Hispanic/Latino	92/161 (57)	65/92 (71)
Unknown	1/2 (50)	1/1 (100)
P value	>.99	>.99

[a]N=103 for age category, race, and ethnicity, and 101 for education.

[b]N=73 for age category and ethnicity, 71 for education, and 76 for race.

[c]N/A: not applicable.

Discussion

Principal Findings

In this internet-based, pilot study of predominantly young and middle-age, educated, White patients, using a semiautomated, edge-based, mHealth app that uses individualized data for tailored management of CRMCs, we made several key observations with regard to both the internet-based recruitment approach to the study of mHealth apps, as well as the specific usage rates and patterns of use by participants. First, we found that while an internet-based recruitment approach was superior to "grass-roots" local methods of recruiting participants on our campus using fliers and word-of-mouth, the 3-month follow-up rates were only slightly above 50% (103/180), indicating that future studies using this type of methodology targeted to achieve a prespecified degree of statistical power will need to account for a high number of dropouts. Second, we found that among those with complete follow-up, the 3-month adoption rate of the iMTracker app was about 70.9% (73/103), with the most common CRMCs that users chose to self-apply the app being chronic pain, headaches, and mental health conditions. This information not only provides conditions and clinical settings in which to target future clinical trials, but also indicates that there may be a need for better tools to manage these conditions beyond what is presently available in clinical practice. Importantly, we found that on completion of this study, more patients had increased perceptions of the safety, privacy, and time demands with the use of an mHealth app for self-management of CRMCs. Finally, we found that the main barrier to use, based on both subjective and quantitative

feedback, was related to the design and workflow of iMTracker itself, which was reflected in the decrease in perception of efficacy noted on completion, and has important implications for future development and testing of this app as well as other mHealth technologies. In other words, this finding indicates that patients are likely to be receptive to the semiautomated N-of-1 trial methodology employed by the iMTracker app, but that greater attention to design and function is needed before moving forward with clinical testing targeted toward improvement in outcomes.

mHealth apps have increased significantly in frequency over the years, with iOS apps including health and fitness groups increasing from 43,000 in 2013 to 98,000 in 2015 [32]. Unfortunately, these tools do not consistently employ best practices for self-management [33], and many of these approaches have failed to reach any meaningful level of adoption across the medical community [32,34], likely due to a lack of formal clinical testing. Our finding that there was an increased concern among patients about the effectiveness of iMTracker is consistent with prior studies of mHealth app for self-management of CRMCs. In a previous investigation, it was found that only 3.4% of apps on the iTunes and Google Play stores promoted for management of depression and anxiety had research to justify their claims of effectiveness, with only 30.4% having expert input in development [35]. A study by Devan et al [36] of 19 apps available commercially for self-management of pain found that only 2 had been validated to improve health outcomes. A similar lack of scientific support for commercially available mental health–targeted [37-39] and pain [25,40] apps has been reported by other investigators. Although we did not inquire about prior use of mHealth apps for self-management, one can infer that most participants in this study had tried prior apps without success. Clinical validation of any mHealth app should be required before integration into the clinical care process, and our study further suggests that while users are optimistic that self-management using an app is possible, follow-up clinical studies will be needed.

Among the characteristics of the specific CRMCs that patients identified for use of an mHealth app, recurrent pain, headaches, and mental health were highly represented. While these diagnoses were self-identified by users, and not validated with clinicians or clinical data (ie, chart review), it does help to identify potential clinics and providers for testing mHealth apps, as would be needed before an app such as the iMTracker could be incorporated into routine clinical care. In addition, the majority of patients noted a high frequency of recurrence of their condition, which is key in determining the number of patients needed for a prospective study to demonstrate efficacy, as a condition that occurred less frequently, for example, once or twice a year, would require an extended amount of time to identify correlation of episodes with other lifestyle and behaviors, or assess the impact of an intervention.

Although our study did not specifically examine clinical efficacy of the iMTracker app in terms of a reduction in the primary CRMC, we did note that there was enthusiasm about future uses, particularly if barriers related to design and function could be addressed. This finding is in line with prior work, such as that by Neuhauser et al [41,42], who noted that participatory methods linked with traditional health communication theory and methods can create effective health communication using artificial intelligence, highlighting the role of design science theory in the development and refinement of mHealth apps. Such insights highlight the challenge that is unique to mHealth, and other health IT apps, in which consideration of user-based preferences and desires must be merged with information and guidance grounded in biology and evidence-based medicine principles. In terms of design life cycles, this requires an integrated design approach with features of both top-down (ie, waterfall) strategies and bottom-up, user-driven design (eg, agile) strategies. Our team has already begun efforts to improve the design and function of the iMTracker app, and future studies will examine the improvement in these changes to make the app more in line with the level of commercial design that many patients have come to expect from all mobile apps, in addition to mHealth.

Despite results to suggest a high degree of potential for clinical application of the iMTracker app, there were several key limitations in our study. First, we generally had a limited amount of follow-up of patients, with roughly half of the patients who enrolled being lost to follow-up. We suspect that this limitation highlighted the challenges of using the internet for recruitment, and the trade-off between use of network-based recruitment methods (ie, online) and in-person clinic recruitment. As an extreme example of the potential of the former, the Apple Watch study recruited over 400,000 participants in an 8-month period using online methods, although only 450 actually returned the confirmatory patches in follow-up [43]. As such, future studies of mHealth technology should consider that the potential benefit in terms of recruitment numbers using internet-based recruitment may accompany a relatively high degree of dropouts. A second limitation was that the population we studied were primarily White, educated, and young/middle age adults; these were individuals who engage regularly with providers using technology, post to social media, and perform self-management with regular weight checks. Missing from our population are older patients, those with less education, and those from underrepresented populations—the type of populations that have also been shown to have less close clinical follow-up for their conditions [44-46], and who might stand to benefit the most from an app that allows self-management. This population bias is critical in considerations of further app development as the design and functionality changes that would typically guide app development would be needed for successful integration with clinical care. Further work is needed on methods to include less represented populations in mHealth studies. Among the issues with biased recruitment was the omission of sex from the baseline variables we collected. Qualitatively (based on the first names of the participants), we suspect recruitment was not heavily imbalanced toward 1 specific sex, although formal assessment would have been beneficial in terms of statistical analysis. In future studies, we plan to examine sex along with other user characteristics in terms of both usage patterns and study participation. Finally, a key limitation of the study was the inability to confirm diagnoses or response to therapy among users of iMTracker. While we have ongoing studies to examine the app prospectively toward clinical outcomes, the findings from this investigation provided important information about

which specific conditions, and which types of clinics, to target for recruitment. This finding was critical as the iMTracker was originally developed toward treatment of recurrent cardiac symptoms (ie, palpitations), and yet we identified other conditions that included chronic pain, headaches, and mental health as being more heavily favored by patients in this investigation.

In future studies we plan to examine the impact of specific design and function improvements on iMTracker, including an examination of the use of industry-standard Agile development life cycles to make iterative improvements to the user interface within the Scrum methodology [47]. Our team has already employed a newer user interface and data entry design based on emojis, although additional work is needed to ensure all users of all levels of education and medical literacy can use the app comfortably. Following this step, we plan to target clinical trials of iMTracker to primary care, neurology, and psychiatry clinics to assess the impact of N-of-1 management on recurrence of chronic pain, headaches, and mental health conditions. Finally, our team has continued work on integration of more sophisticated data management approaches using federated and distributive learning, as well as Bayesian-based analytical frameworks, and we plan to examine the improvement in accuracy with these innovations. Ultimately, much work is needed before the iMTracker app can be used routinely in clinics to manage CRMCs, although feedback from this study has helped target efforts toward high-yield conditions and modifications to improve the chances of success.

Conclusions

In conclusion, in this feasibility pilot study using internet-based recruitment, we found that the primary barrier to investigation was study follow-up, but that among those who were not lost to follow-up, there was generally good adherence to use of the iMTracker app. We identified design and function barriers as being of foremost concern among users, but also noted that the frequency of recurrence of the selected CRMCs should provide ample opportunity to identify a clinical benefit for future studies. We also identified population bias in the patients enrolled using internet-based recruitment alone, and note that additional efforts will be needed to ensure that future studies enroll sufficient numbers of underrepresented populations, specifically older, non-White, and less education populations.

Acknowledgments

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Conflicts of Interest

The iMTracker app is a licensed intellectual property of the University of Colorado. The authors have no other conflicts of interest to disclose.

Multimedia Appendix 1
Screenshot from Results presentation of iMTracker.
[PNG File , 414 KB - formative_v6i4e34827_app1.png]

Multimedia Appendix 2
Postuse survey questions.
[DOCX File , 14 KB - formative_v6i4e34827_app2.docx]

Multimedia Appendix 3
Sample of feedback about iMTracker from users on postsurvey.
[DOCX File , 14 KB - formative_v6i4e34827_app3.docx]

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Abbreviations

CRMC: chronic recurrent medical condition
mHealth: mobile health

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Original Paper

Discussions and Misinformation About Electronic Nicotine Delivery Systems and COVID-19: Qualitative Analysis of Twitter Content

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Abstract

Background: Misinformation and conspiracy theories related to COVID-19 and electronic nicotine delivery systems (ENDS) are increasing. Some of this may stem from early reports suggesting a lower risk of severe COVID-19 in nicotine users. Additionally, a common conspiracy is that the e-cigarette or vaping product use–associated lung injury (EVALI) outbreak of 2019 was actually an early presentation of COVID-19. This may have important public health ramifications for both COVID-19 control and ENDS use.

Objective: Twitter is an ideal tool for analyzing real-time public discussions related to both ENDS and COVID-19. This study seeks to collect and classify Twitter messages (“tweets”) related to ENDS and COVID-19 to inform public health messaging.

Methods: Approximately 2.1 million tweets matching ENDS-related keywords were collected from March 1, 2020, through June 30, 2020, and were then filtered for COVID-19–related keywords, resulting in 67,321 original tweets. A 5% (n=3366) subsample was obtained for human coding using a systematically developed codebook. Tweets were coded for relevance to the topic and four overarching categories.

Results: A total of 1930 (57.3%) tweets were coded as relevant to the research topic. Half (n=1008, 52.2%) of these discussed a perceived association between ENDS use and COVID-19 susceptibility or severity, with 42.4% (n=818) suggesting that ENDS use is associated with worse COVID-19 symptoms. One-quarter (n=479, 24.8%) of tweets discussed the perceived similarity/dissimilarity of COVID-19 and EVALI, and 13.8% (n=266) discussed ENDS use behavior. Misinformation and conspiracy theories were present throughout all coding categories.

Conclusions: Discussions about ENDS use and COVID-19 on Twitter frequently highlight concerns about the susceptibility and severity of COVID-19 for ENDS users; however, many contain misinformation and conspiracy theories. Public health messaging should capitalize on these concerns and amplify accurate Twitter messaging.

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KEYWORDS

COVID-19; coronavirus; e-cigarette; electronic nicotine delivery systems; Twitter; social media; misinformation; discussion; public health; communication; concern; severity; conspiracy

Introduction

The COVID-19 pandemic has spread rapidly, with over 490 million confirmed cases and over 6.1 million confirmed deaths worldwide at the time of this writing [1]. COVID-19, which can lead to acute respiratory distress syndrome, may be particularly dangerous for nicotine and tobacco users [2]. Emerging evidence suggests an association between the use of electronic nicotine delivery systems (ENDS) and greater incidence of COVID-19 susceptibility and severity, testing, and diagnosis—particularly among US adolescents and young adults [3]. This is concerning considering the increase in the use of these products. Worldwide, approximately 35 million individuals reported ENDS use in 2015, and this number is expected to increase as refillable and disposable ENDS become more popular [4].

The research on the potential associations between tobacco and nicotine use and COVID-19 risk has been mixed. Some published research has indicated that self-reported COVID-19 infection is greater among current cigarette smokers and former smokers compared to nonsmokers [5], that cigarette smoking is associated with higher odds of COVID-19 progression [6], and that ENDS use is associated with increased risk of COVID-19 infection [3]. However, a series of preprints suggesting an inverse relationship between tobacco and nicotine use and COVID-19 risk have also been released, some with substantial reach. For example, a preprint suggesting that cigarette smoking decreases the risk of COVID-19 infection by half was viewed over 56,000 times and has been tweeted 200 times at the time of this writing [7]. Likewise, a preprint suggesting that current cigarette smoking was inversely correlated with COVID-19 mortality has been viewed over 14,000 times [8]. A study using Twitter data found that sentiment toward cigarette smoking and ENDS use became more positive after the release of these preprints and non–peer-reviewed publications, suggesting that tobacco and nicotine users may be at less risk from COVID-19 infection and progression [9].

Likewise, research on the impact of COVID-19 on ENDS use has been mixed. A survey of a small convenience sample of US adult dual cigarette and ENDS users found that approximately one-quarter of participants attempted to reduce their tobacco and nicotine use during the pandemic [10]. Results from a five-country survey, which included the United States, also found an increase in quit attempts due to the pandemic; however, this study also showed little change in actual consumption of tobacco and nicotine products during COVID-19 lockdowns [11]. A qualitative study of ENDS users found that limited availability of ENDS products during lockdowns prompted them to turn to readily available cigarettes [12].

The COVID-19 pandemic has been accompanied by an "infodemic" in which a substantial amount of information has been spreading both online and offline [13]. In particular, misinformation about COVID-19 has been spreading on social media throughout the duration of the pandemic [14,15]. Misinformation about COVID-19 on Twitter has been found to spread virally within a matter of days, often fueling conspiracy theories [14]. Twitter is an ideal platform with which to conduct research on public opinion, conversations, and misinformation related to current health topics, including COVID-19 and ENDS. Most Twitter users maintain public profiles from which data can be obtained using Twitter's Public Streams Application Programming Interface in real time, advancing itself as a tool for "infoveillance" [16,17]. Recently, Twitter data has been used to conduct preliminary work related to discussions around COVID-19 and ENDS, with the authors calling for a more systematic, in-depth qualitative examination of Twitter messages (ie, tweets) related to ENDS use and COVID-19 [18]. Another study examining Twitter data found that individuals who tweeted about ENDS during the pandemic expressed more concern about COVID-19 deaths compared to those who did not tweet about ENDS [19], but an in-depth qualitative analysis into the content of these tweets was not conducted.

Therefore, the purpose of this study was to systematically collect tweets related to COVID-19 and ENDS during the height of the pandemic in the United States and qualitatively analyze them to classify user discussions related to perceived associations between ENDS use and COVID-19. Using a "social listening" approach on Twitter can lead to a better understanding of tobacco-related topics of current importance [20]. Additionally, a qualitative approach allows for an in-depth exploration of discussions and often results in rich data that can be triangulated with quantitative results for a more complete understanding of a phenomenon. This could inform public health messaging and interventions related to ENDS use and COVID-19 misinformation throughout the remainder of the pandemic as well as future investigations of other misinformation related to ENDS and other tobacco products.

Methods

Data Collection and Sampling

We used the open source real-time infoveillance of Twitter health messages (RITHM) framework [17] to collect approximately 2.1 million tweets matching ENDS-related keywords and hashtags (vape, vapes, vaper, vapers, vaping, vaped, e-cigarette, e-cigarettes, e-cig, e-cigs, ecig, ecigs, juul, juuls, juuling) over multiple time points from March 1, 2020, through June 30, 2020, as recommended by Lienemann et al [21]. Of these, approximately half (1 million) were original tweets and the other half (1.1 million) were "retweets" (ie, rebroadcasts of others' content). We then identified tweets containing keywords and hashtags related to the virus SARS-CoV-2 and the disease it causes, COVID-19 (sarscov2, sars-cov-2, covid, covid-19, covid19, corona, coronavirus, the rona, miss rona), which included 67,321 original tweets and 204,603 retweets. We next obtained a random 5% (n=3366)

subsample of original COVID-19–related tweets for human annotation. Previous research has demonstrated that this approach maintains generalizability of the subsample within the context of the full data set [17,22]. This study was approved by the University of Pittsburgh Human Subjects Protection Office.

Codebook Development and Coding Procedures

Initial codebook development involved a separate pool of random tweets (ie, not from the 3366 primary tweets). Individual codes were developed through a hybrid process, using both the themes identified by previous research and an examination by two independent coders of the pool of random tweets [18]. Coders reviewed and annotated these tweets and discussed potential codes with the lead author. After two rounds of this process, an initial codebook containing code and subcode names, definitions, and examples was developed (Table 1).

After initial codebook development, the two coders were provided with a spreadsheet containing the tweet text and a link to each tweet online. The tweet text was initially coded for relevance, defined as discussing a perceived association between COVID-19 and ENDS (eg, "almost 40% of ppl in the U.S. hospitalized for # COVID19 are between 20 and 54. #Vaping may be driving the rise in this" and "I'm going to juul the rona away"). Tweets that discussed ENDS or COVID-19 but not a perceived association between the two were excluded (eg, "coronavirus fears lessening in China as vape production goes back up there"). Coders viewed all relevant tweets that remained publicly available at the time of coding on Twitter so that links to external content could be assessed. However, coders included the text from unavailable tweets to preserve the comprehensiveness of the original data.

Relevant tweets were then coded as to whether they referenced four overarching categories: discussions about associations between COVID-19 severity and ENDS use; discussions about COVID-19 and e-cigarette or vaping product use–associated lung injury (EVALI) symptom similarity; discussions about COVID-19 affecting ENDS use; and discussions about personal or proximate experiences (eg, referencing something the tweeter saw themself or something that happened to someone the tweeter knows). Additionally, substantial misinformation related to COVID-19 and ENDS was found during coding and tweets containing potential misinformation—defined as statements not supported by the current peer-reviewed literature or exaggerations of research findings or public health findings—were identified and tagged by coders. Tweets containing potential misinformation were analyzed by an experienced graduate-level coder and the first author as themes within the major coding categories. All codes and subcodes are described in Table 1.

Codes were not mutually exclusive. For example, a tweet that stated, "Coronavirus attacks the lungs so one of the most important things you can do is to quit smoking and vaping. I'm in day 5 – join me!" would be coded as discussions about the association between COVID-19 severity and ENDS use (subcode: perception that ENDS use is associated with worse COVID-19 symptoms), discussions about COVID-19 affecting ENDS use (subcode: quitting ENDS because of COVID-19), and discussions about personal or proximate experience. We coded both textual and visual (eg, pictures, videos, and emojis) content [17].

The iterative coding process involved double-coding 100 tweets by two independent, experienced Twitter coders that were guided by a senior-level coder. All disagreements were discussed with the senior-level coder and adjudicated with the lead author, after which the codebook was modified accordingly. Interrater reliability was assessed using Cohen κ [23], and it was decided a priori that values above 0.70 would be acceptable. After four rounds of this process, Cohen κ reached acceptable levels of reliability (ranged 0.70-1.00) [24]. The two coders then independently coded the remaining tweets in the data set.

Table 1. Definitions for categorical codes and example tweets.

Code and subcode[a]	Definition	Examples[b]
Discussions about the association between ENDS[c] use and COVID-19 susceptibility or severity	Tweet mentions that ENDS use is associated with contracting COVID-19 or severity of symptoms	
Perception that ENDS use causes COVID-19	Tweet mentions that ENDS use may be a cause of developing COVID-19	• "Vaping may be a cause of coronavirus cases in young people, experts say." • "PSA: vaping is an effective way to spread Covid 19! The viral aerosol mist stays in the air, so lots of your friends can catch the virus."
Perception that ENDS use is associated with worse COVID-19 symptoms	Tweet mentions that ENDS use may be linked to worse COVID-19 symptoms/outcomes	• "People who vape are more likely to experience negative effects from COVID-19." • "That vaping nic eliquid makes the Covid worse! Why do you continue with this?? Until there is data to confirm, just STOP IT! So tired of this!"
Perception that ENDS use protects against COVID-19	Tweet mentions that ENDS use can protect users from COVID-19 or make COVID-19 symptoms less severe	• "If you've ever had vape juice get in your mouth after you take a hit you're immune to the corona virus. I said what I said." • "Juuling and vaping makes you immune to COVID."
Discussions about COVID-19 and EVALI[d] symptom similarity	The tweet discusses both EVALI and COVID-19	
Perception that EVALI is COVID-19	Tweet mentions thinking that EVALI was actually COVID-19	• "Or, we already had the virus and they called it EVALI. CTs of COVID pts and EVALI patients look very similar." • "No ENDS was ever linked to EVALI. EVALI was just COVID a year early."
Perception that EVALI is not COVID-19	Tweet mentions that EVALI and COVID-19 are distinct diseases	• "The first cases of EVALI were reported in April 2019, way before covid. I don't think they are related, but I could see how vaping makes it worse."
Quitting ENDS because of COVID-19	Tweet mentions quitting ENDS use because of COVID-19	• "In the middle of the COVID pandemic of a respiratory disease, smokers and vapers, now is a great time to think abt quitting before the habit kills you." • "Vaping nicotine makes coronavirus worse! Why do you all keep vaping? Until there is more data, just STOP vaping! So exhausted by this!"
Switching from combustible cigarettes to ENDS because of COVID-19	Tweet mentions switching from smoking cigarettes to using ENDS because of COVID-19	• "I have converted so many people from smoking to nicotine vaping during this time of COVID-19!! 18 people have now made a healthier decision to use a harm reduction tool that really works!" • "There are so many people switching to e-cigs and ditching traditional cigarettes. Vaping could help lower the number of people admitted to hospital if they get affected by the coronavirus."
Starting or continuing ENDS use because of COVID-19	Tweet mentions starting or continuing using ENDS because of COVID-19	• "I've just started vaping again as a way to manage stress. I'd quit nicotine for six months up until today...I'm blaming it on the Covid effect." • "COVID really has me back on my high-school diet of juul pods and iced lattes."

Code and subcode[a]	Definition	Examples[b]
Discussions about personal or proximate experiences	Tweet contains reference to something the tweeter saw themself or something that happened to someone the tweeter knows	
Respiratory symptoms	The tweet mentions symptoms that could be from COVID-19 or ENDS use, and the tweeter is not sure which is the cause	• "About once or twice a week I'll wake up with congestion, and I'm like well, I've got covid. And then I'll remember that I burn through like 2 juul pods a day easy." • "He and my friends thought we had something before covid but we're all smokers and thought it was from vaping – who knows?"

[a]Code derived from original codebook; subcode derived from content analysis discussions and adjudications.

[b]Examples are provided for subcodes. Proper names and expletives have been censored. Minor details of tweet content were changed to prevent reidentification of individual Twitter users via direct quotes.

[c]ENDS: electronic nicotine delivery system.

[d]EVALI: e-cigarette or vaping product use–associated lung injury.

Content Analysis

Frequencies and percentages were calculated for each code. A thematic qualitative content analysis approach was used to inductively assess the tweets and refine thematic units within codes [25]. The thematic analysis approach is recognized as a highly flexible qualitative approach that provides a rich and detailed account of data, especially within large data sets [26]. Qualitative themes and quotes around quantitative findings were organized to contextualize associations between COVID-19 and ENDS. Quotes were deidentified, and unique quotes were slightly rephrased while preserving the original meaning of the statement to prevent identification of individual Twitter users [17].

Results

Of 3366 human-coded tweets, 1930 (57.3%) were coded as relevant (ie, discussed a perceived association between COVID-19 and ENDS) and were included in the analysis (Table 2). A total of 1008 (52.2%) tweets discussed the perceived association between COVID-19 susceptibility or severity and ENDS use, with a plurality (n=818, 42.4%) suggesting that ENDS use is associated with worse COVID-19 symptoms. Overarching themes focused on how young people should be concerned about this association because they are more likely to use ENDS than older people and how ENDS use damages the lungs and weakens the immune system. Tweets containing these themes were a mixture of news headlines and personal opinions.

Some tweets (n=120, 6.2%) suggested that ENDS use protects individuals from COVID-19 infection and progression. One theme focused on the potential curative effect of ENDS, with references to early research suggesting the protective effect of nicotine (eg, "Doctors in France recognize the power of nicotine to fight COVID-19 virus. Nicotine & vaping may become a preventive treatment & cure for COVID-19") and the components of ENDS that may cure those with COVID-19 (eg, "Vaping most likely kills COVID because of the propylene glycol content in it"). Other themes suggested that ENDS use protects users from infection and that there was no link between COVID-19 and ENDS (ie, neither protective nor harmful).

Fewer tweets (n=80, 4.2%) suggested that ENDS use actually is the cause of COVID-19, with themes focused on the possibility that the COVID-19 virus was in ENDS liquid (eg, "Remember that mysterious illness caused by vapes in January? A severe respiratory illness. Well the first e cigs came from Wuhan China. What if they put Covid in vape juice, causing the illness and the spread?") and that secondhand vapor might be contributing to the spread of COVID-19 (eg, "Public Service Announcement: Vaping is an effective way to spread COVID-19! The viral aerosol mist stays in the air, and your friends and family can catch the virus. DON'T VAPE").

A total of 479 (24.8%) tweets discussed the perceived similarity (or dissimilarity) of the symptoms of COVID-19 and EVALI. Of these, a greater number of tweets (n=424, 22%) suggested that COVID-19 and EVALI are actually the same disease, with overarching themes focused on government deception (eg, "America is the epicenter and origin of coronavirus, But Trump and American Government have cheated the world since vaping-pneumonia erupted in August 2019. The Covid-19 patient 0 is from Fort Detrick. #TrumpLiedPeopleDied") and similarities of symptoms and medical imaging. A smaller number of tweets (n=57, 3%) focused on distinctions between COVID-19 and EVALI, with overarching themes mentioning how EVALI was not infectious (eg, "If it was true that the vaping deaths were coronavirus, you would see patient-to-healthcare-worker infections") and differences in age groups affected (eg, "Why didn't any old people get EVALI then? It was all young people who vape").

Table 2. Frequencies of coding categories for relevant tweets (n=1930).

Code and subcode	Frequency, n (%[a])
Discussions about the association between ENDS[b] use and COVID-19 susceptibility or severity	1008 (52.2)
Perception that ENDS use causes COVID-19	80 (4.2)
Perception that ENDS use is associated with worse COVID-19 symptoms	818 (42.4)
Perception that ENDS use protects against COVID-19	120 (6.2)
Discussions about COVID-19 and EVALI[c] symptom similarity	479 (24.8)
Perception that EVALI is COVID-19	424 (22.0)
Perception that EVALI is not COVID-19	57 (3.0)
Discussions about COVID-19 affecting ENDS product use	266 (13.8)
Quitting ENDS because of COVID-19	180 (9.3)
Switching from combustible cigarettes to ENDS because of COVID-19	33 (1.7)
Starting or continuing ENDS use because of COVID-19	59 (3.1)
Discussions about personal or proximate experiences	231 (12.0)
Respiratory symptoms	40 (2.1)

[a]Row percentages may not equal 100 due to rounding.

[b]ENDS: electronic nicotine delivery system.

[c]EVALI: e-cigarette or vaping product use–associated lung injury.

Approximately 13.8% (n=266) of tweets discussed a potential relationship between ENDS use behavior and the pandemic. Of these, most mentioned quitting ENDS in response to the pandemic (n=180, 9.3%). The most prominent theme in this category was quitting ENDS because of its effects on respiratory health (eg, “This is an excellent reason to quit smoking and vaping...those habits decrease your lungs' ability to keep clean and fight off coronavirus infection. Do not make it easier to get sick or sicker”). Fewer (n=59, 3.1%) mentioned starting or continuing ENDS because of the pandemic (eg, “corona got me thinkin bout my health so i got a juul for in b/w cigs”) and the perceived health benefits of nicotine (eg, “YOU NEED TO VAPE. Nicotine users are at a lower risk of developing COVID-19 symptoms...”). Finally, 33 (1.7%) tweets mentioned switching from traditional cigarettes to ENDS, with all tweets in this coding category containing the theme of ENDS being a safer alternative to cigarette smoking.

Approximately 12% (n = 231) discussed a personal or proximate experience. Among users who mentioned ENDS use themselves, one theme focused on limiting the sharing of their ENDS because of COVID-19 (eg, “Because of COVID, no you cannot hit my vape”). A total of 40 (2.1%) tweets discussed respiratory symptoms that users believed could be due to either COVID-19 or ENDS use (eg, “Was it it the constant vaping that gave me a sinus infection or do I have the rona”). Another theme focused on possibly having COVID-19 in the past but attributed symptoms to ENDS use at the time. Additionally, some users expressed concern about COVID-19 for friends/family who use ENDS (eg, “I think there's something very serious we need to address regarding Covid-19 and young people, considering 90% of the people I know use e-cigarettes and vapes perpetually”) and relief about not using ENDS themselves in light of COVID-19.

Discussion

In this study, approximately half of the tweets that discussed perceived associations between ENDS use and COVID-19 contained language suggesting the perception that ENDS may worsen COVID-19—specifically that the use of ENDS by predominantly younger individuals may increase risk of severe COVID-19 symptoms. This is consistent with recent research finding that, among those aged 13 to 24 years, current ENDS users and current ENDS/cigarette dual users are 5 and 6.8 times more likely to be diagnosed with COVID-19 compared to nonusers, respectively [3]. This is also consistent with research finding that ENDS may have adverse effects on the cardiovascular and respiratory systems, and increase risk for infections, especially when combined with traditional cigarettes [27]. Likewise, tweets from users indicating a desire to quit ENDS were consistent with research suggesting that approximately one-quarter of US adult tobacco users sought to reduce their use during the pandemic [10].

The themes emerging from this study, combined with previous research, suggest that focusing public health messaging on the potential for worse COVID-19–related health outcomes among ENDS users may resonate with those discussing this topic on social media. Specific strategies, such as magnifying accurate Twitter messages linking ENDS use with COVID-19 and disseminating messages via social media with clear actionable public health advice linked to credible sources may be important health communication tools moving forward [28].

Our findings were also consistent with others who have reported rapid spread of misinformation related to COVID-19 in general [29,30]. In our study, one apparent source of misinformation was the preponderance of preprints of COVID-19–related research that had not yet undergone peer review and were later

contradicted [9,31]. For example, we found that unsubstantiated reports that tobacco and nicotine users were at less risk for COVID-19 complications were being cited by Twitter users as justification to begin or maintain ENDS use [7,8]. Development and dissemination of counter-messaging clarifying the evidence related to ENDS use and COVID-19 may be useful at curtailing this spread of misinformation [32].

Additionally, our analysis uncovered conspiracy theories related to the origins of the virus, its transmissibility, and potential treatments [29,33]. For example, multiple tweets suggested that COVID-19 and EVALI were in fact the same condition. Several other tweets suggested that China engineered the virus and transmitted it to the United States via ENDS. Prior to COVID-19, concerns about EVALI appeared to have contributed to declines in ENDS use among youth [34]. If youth begin to equate EVALI with COVID-19 but do not believe in the dangers of COVID-19 or are no longer concerned about a uniquely vaping-related condition, this trend may reverse. Because the symptoms of EVALI and COVID-19 are similar, it is suggested that clinicians assess ENDS use during all clinical encounters in which COVID-19 is suspected [35].

Several tweets suggested that propylene glycol may kill the virus, thus protecting ENDS users from infection, which relates to a popular misperception of the antiviral and antibacterial properties of propylene glycol gas [32]. Some of these individuals also suggested that regulations around ENDS, including flavor bans, were initiated by the US government in an attempt to hoard propylene glycol for use with COVID-19 treatment. While more research is needed to better understand the relationship between the online spread of conspiracy theories and ENDS use behavior, these findings emphasize the value of using social media to monitor current discourse about various public health crises [13]. The real-time nature of Twitter allows for the capture and analysis of health-related information, misinformation, and disinformation more quickly than traditional methods such as surveys. Additionally, the use of techniques such as social network analysis can help assess the reach and spread of these messages, which can allow for the development of targeted interventions to mitigate the sharing of mis- and disinformation.

Our study was limited in that these results are neither generalizable to non-Twitter users nor the general population. Twitter users tend to be younger and more educated than the general population [36], and the content in the analyzed tweets may reflect that. Moreover, while we endeavored to collect a random sample of tweets, collected tweets are not necessarily representative of all Twitter content on this topic. It is also a necessary limitation that the tweets in this study were coded and analyzed by human coders. However, a series of steps were taken to mitigate this concern. First, we used highly trained and experienced Twitter coders that were guided by a senior-level coder. Second, our codebook was systematically developed and contained specific definitions and examples to guide coders in their interpretations. Third, we conducted four rounds of double-coding until sufficient interrater reliability was reached. At each round, coders discussed inconsistent results with the senior-level coder. A final limitation is that no conclusions about an association between ENDS and COVID-19 can be made from this study. Instead, this study consisted of qualitative analyses of discussions about ENDS and COVID-19.

In conclusion, discussions about the perceived associations between ENDS and COVID-19 on Twitter are often conflicting. These conflicts reflect the lack of consistent health communication messaging, which may have facilitated the spread of speculation and misinformation. The results suggest the need for further research to investigate the spread of information and misinformation about ENDS use and COVID-19, especially on social media platforms. They also suggest potential targets for evidence-based clarifications public health providers can implement.

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Conflicts of Interest

Unrelated to ENDS use, author JJR is a coinventor on patents directed at antidotal therapies for carbon monoxide poisoning that are licensed to Globin Solutions, Inc. Author JJR is a cofounder, shareholder, President and Chief Executive Officer of Globin Solutions, Inc. Author JJR is a cofounder of Omnibus Medical Devices.

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Abbreviations

ENDS: electronic nicotine delivery system
EVALI: e-cigarette or vaping product use–associated lung injury
RITHM: real-time infoveillance of Twitter health messages

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Original Paper

Online Support and Intervention for Child Anxiety (OSI): Development and Usability Testing

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Abstract

Background: Internet-based treatments for child anxiety may help to increase access to evidence-based therapies; however, user engagement, uptake, and adherence within routine clinical practice remain as challenges. Involving the intended end users in the development process through user-centered design and usability testing is crucial for maximizing user engagement and adoption of internet-based treatments, but so far this has been lacking for internet-based treatments for child anxiety.

Objective: The aim of this study is to develop an internet-based treatment for child anxiety through a process of user-centered design (phase 1) and usability testing (phase 2), based on an existing evidence-based, face-to-face, therapist-supported, parent-led cognitive behavioral therapy intervention. It is intended that the internet-based version of this treatment would consist of a parent website, case management system for clinicians, and mobile game app for children.

Methods: Parents, children, and clinicians who were familiar with the face-to-face version of the treatment were recruited from 2 National Health Service clinics. In phase 1, participants participated in 3 workshops to gain feedback on the overall concept, explore their wants and needs for the websites and game, generate ideas on how the treatment may look, and gain feedback on initial mock-ups of the websites and game. In phase 2, participants attended 3 individual usability testing sessions where they were presented with working prototypes of the website or game and asked to perform a series of tasks on the website (parents and clinicians) or play the game (children). The frequency and details on usability errors were recorded. Participants were asked for their feedback on the website and game using a standardized usability questionnaire and semistructured interviews. The websites and game were iterated after each round of usability testing in response to this feedback.

Results: In phase 1, participants approved the general concept and rated the initial mock-ups of the website and game positively. In phase 2, working prototypes were rated positively and usability errors declined across the iterations and were mainly cosmetic or minor issues relating to esthetic preference, with few issues regarding ability to navigate the website or technical issues affecting functionality. Feedback from the semistructured interviews further supported the positive response of participants to the website and game, and helped identify areas for improvement during the iteration process. The final iteration of the website and game are presented.

Conclusions: Taking an iterative approach to development through user-centered design and usability testing has resulted in an internet-based treatment for child anxiety (Online Support and Intervention for child anxiety) that appears to meet the needs and expectations of the intended users (parents, children, and clinicians) and is easy and enjoyable to use.

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KEYWORDS

user-centered design; co-design; usability testing; internet-based treatment; app; CBT; anxiety; children; mobile phone

Introduction

Background

There is growing interest in providing psychological treatments via the internet to increase access to evidence-based therapies. This is particularly salient for child anxiety disorders as most children who would benefit do not access treatment [1-4]. Internet-based cognitive behavioral therapy (iCBT) for child anxiety is effective and acceptable within research settings [5,6]; however, user engagement, uptake, and adherence remain as challenges within routine clinical practice [7-9].

Involving the intended users in the development process and following a user-centered approach is crucial to maximize service user engagement and adoption of internet-based interventions within routine clinical practice [10,11]. User-centered design is different from the traditional approach of expert-led intervention development *for* users and embraces *active* collaboration *with* users to ensure that the digital solution is usable and meets their needs and preferences [11,12]. Key elements of user-centered design include (1) identifying user needs, preferences, and expectations for the digital solution; (2) actively involving users in the design and prototyping; and (3) conducting usability testing on a working prototype to provide feedback and identify technical and esthetic issues that may affect user satisfaction [10]. User-centered design can improve (1) design quality [13], (2) user adherence [14], (3) usability [15], (4) efficacy and sustainability [16], and (5) stakeholder acceptance and adoption at the system and organizational levels [17]. Recent iCBT development guidelines advocate active collaboration with users [10,18,19], and funding agencies increasingly demand stakeholder involvement.

Despite a clear rationale for user-centered design, few existing mental health digital interventions for young people have incorporated these principles within their development process. However, the number of digital interventions designed with young people is growing, with recent examples for depression [20,21], positive mental health [22], and recovery from mild traumatic brain injury [23]. Others have conducted usability testing of digital interventions for self-harm [24,25], depression [26], positive mental health [27], and recovery from pediatric cancer [28]. To the best of our knowledge, no existing iCBT interventions for child anxiety disorders actively involved users in the design process and only one intervention (*Breathe*, which is focused on adolescent anxiety) conducted usability testing [29]. This study highlighted the importance of involving both young people and clinicians in providing feedback in the iterative usability testing process, and the final iteration of *Breathe* showed improved usability and acceptance following this process.

Aims

The aims of this study are to (1) collaborate with users to design an internet-based treatment for child anxiety disorders (phase 1) and (2) test the usability of this internet-based treatment (phase 2). Existing iCBT interventions for child anxiety disorders involve providing direct support to children or adolescents, via internet-based sessions or modules [5]. However, face-to-face CBT for child anxiety disorders can be delivered in a brief format directly to parents alone [30,31]. Therefore, we set out to design an internet-based treatment based upon a face-to-face parent-led CBT for child anxiety disorders that is effective compared with waitlist [30], is cost-effective compared with another brief psychological intervention (Solution-Focused Therapy [31]), is acceptable and feasible for use within routine clinical practice [32], and is now widely used in early intervention services in the United Kingdom [33]. This brief face-to-face treatment for child anxiety disorders involves the parent reading chapters of the accompanying treatment book [34] and meeting with a therapist for approximately 5 hours of support over approximately 8 weeks, to help apply the CBT strategies with their child and problem solve any difficulties [35]. Although the child is not seen by the therapist during treatment, the parent is encouraged to work through the CBT techniques collaboratively with their child and involve them throughout the process.

Before the design phase, we developed an initial overview plan for the internet-based version of this treatment, in consultation with stakeholders via our research clinic patient and public involvement group. This initial plan specifies that the internet-based version of the treatment would involve a parent website, case management system for clinicians, and a mobile game app for children that could be downloaded onto a smartphone or tablet. The intention is that parents would work through modules containing treatment material adapted from the book, with videos and animations to help demonstrate the CBT strategies. Clinicians would use the case management system to view the parents' responses provided on the parent website and to release the next treatment module after a 20-minute telephone review therapist session. The plan to include a mobile game app for children was developed in response to feedback from our patient and public involvement group that it is important to incorporate opportunities to involve and motivate children in the treatment process. The intention of the game app for children is to help motivate the child in engaging in the treatment strategies such as facing their fears (graded exposure).

Phase 1: User-Centered Design

Methods

Participants

A total of 7 parents (n=6, 86% mothers and n=1, 14% father) and 4 children (n=2, 50% boys and n=2, 50% girls) aged 9-12 years were recruited. Of the 7 parents and 4 children, 5 (71%) parents and 4 (100%) children had recently received the brief face-to-face, parent-led CBT treatment and were recruited from a local child and adolescent mental health service, and 2 (29%) parents had received the face-to-face treatment several years ago as part of a research trial [30]. A total of 11 clinicians (n=7, 64% women and n=4, 36% men) who had experience of delivering the face-to-face treatment were recruited from 2 local child and adolescent mental health services. Sample characteristics are provided in Table 1.

Table 1. Demographic characteristics of phase 1 and phase 2 participants.

Participant group and characteristic	Phase 1	Phase 2
Parents, n	7	7[a]
Age (years), mean (SD)	42.43 (5.68)	45.86 (9.84)
Sex (women), n (%)	6 (86)	6 (86)
Relationship with child, n (%)		
Mother	6 (86)	6 (86)
Father	1 (14)	1 (14)
Ethnicity, n (%)		
White British	6 (86)	5 (71)
White Irish	0 (0)	1 (14)
Other White background	1 (14)	1 (14)
Highest level of education, n (%)		
School completion	0 (0)	1 (14)
Further education (eg, college and vocational course)	4 (57)	3 (43)
Higher education (undergraduate degree)	2 (29)	1 (14)
Postgraduate qualification	1 (14)	2 (29)
Employment status, n (%)		
Unemployed	1 (14)	0 (0)
Part-time work	2 (29)	2 (29)
Full-time work	4 (57)	3 (43)
Retired	0 (0)	2 (29)
Children, n	4	4[b]
Age (years), mean (SD)	10.25 (1.26)	9.50 (0.58)
Sex (women), n (%)	2 (50)	2 (50)
Ethnicity, n (%)		
White British	3 (75)	3 (75)
Mixed: White and Black African	1 (25)	1 (25)
Clinicians, n	11	8[c]
Age (years), mean (SD)	40.36 (9.28)	41.88 (9.42)
Sex (women), n (%)	7 (64)	4 (50)
Ethnicity, n (%)		
White British	10 (91)	6 (75)
Other White background	1 (9)	2 (25)
Professional background, n (%)		
Clinical psychologist	7 (64)	6 (75)
CBT[d] therapist	1 (9)	1 (13)
Assistant psychologist	1 (9)	0 (0)
Social worker	1 (9)	1 (13)
Child and adolescent psychiatrist	1 (9)	0 (0)

[a]A total of 5 parents participated in both phase 1 and phase 2.

[b]A total of 3 children participated in both phase 1 and phase 2.

[c]A total of 6 clinicians participated in both phase 1 and phase 2.

[d]CBT: cognitive behavioral therapy.

Measures

Participants reported on their technology use using a customized questionnaire. We collected feedback from parents and clinicians on each screen of initial mock-ups of the parent treatment website and clinician case management website, respectively, using an adapted version of the Program Content and Usability Questionnaire (PCUQ). Shortened versions of the PCUQ were administered to children to obtain feedback on various game visuals (character type, environment, and style), existing mobile game app types (story-led games, minigames, and virtual toys), and pen-and-paper mock-ups of the game (see Multimedia Appendix 1 [29,36,37] for full measure details).

Procedure

In all, 3 workshops were conducted separately for each user group (parents, children, and clinicians) approximately 1 month apart. Participants were financially compensated for their time and any travel expenses. Members of the university research team and the website development company conducted the workshops at varied times to facilitate participation.

A breakdown of the content for each of the 9 workshops is presented in Table 2. The workshops for each user group followed an iterative process, whereby feedback from workshop 1 fed into workshop 2 and so forth. In workshop 1, participants provided written consent and completed the demographic (parents and clinicians only) and technology use questionnaire.

Table 2. Phase 1 workshop content.

Participant group	Workshop 1	Workshop 2	Workshop 3
Parents	• Introductions and aim for the workshop • Warm-up exercise • Explanation of the project • Discussion on (1) the treatment itself, (2) how they would use internet-based version, and (3) therapist support: what and how • MoSCoW[a] card-sorting task for functions • Rapid visual prototyping of top 1 or 2 functions	• Introductions and aim for the workshop • Warm-up exercise • Talk through user journey using initial prototype • Feedback (PCUQ[b]) on initial prototype • Group discussion on initial prototype • Rapid visual prototyping of areas identified for improvement	• Introductions and aim for the workshop • Warm-up exercise • Talk through user journey using revised prototype • Feedback (PCUQ) on revised prototype • Group discussion on revised prototype • Read through and discussion of excerpt of treatment content • Feedback on plans for child app
Children	• Introductions and design own name badge • Explanation of the project • Warm-up game • Draw favorite superhero or character • Discussion of (1) what the character would be scared of, (2) how they would face fears, (3) where they would live, and (4) rewards for facing fears	• Introductions and design own name badge • Recap of the project • Warm-up game • Feedback (PCUQ) on game visuals: (1) character type, (2) environment, and (3) style • Feedback (PCUQ) on existing game types: (1) story-led games, (2) minigames, and (3) virtual toy	• Introductions and design own name badge • Recap of the project • Talk through concept of the game and initial designs • Feedback (PCUQ) on mock-up game: (1) character, (2) home screen, (3) dress-up game, (4) challenges, and (5) minigames
Clinicians	• Introductions and aim for the workshop • Warm-up exercise • Explanation of the project • Discussion on (1) concerns and positive aspects about providing the treatment via the internet, (2) issues in the face-to-face treatment, (3) clinician involvement in the internet-based treatment, and (4) digital tools currently used • MoSCoW card-sorting task for functions • Rapid visual prototyping of top 1 or 2 functions	• Introductions and aim for the workshop • Warm-up exercise • Talk through user journey using initial prototype • Feedback (PCUQ) on initial prototype • Group discussion on initial prototype • Rapid visual prototyping of areas identified for improvement	• Introductions and aim for the workshop • Warm-up exercise • Talk through user journey using revised prototype • Feedback (PCUQ) on revised prototype • Group discussion on revised prototype • Read through and discussion of excerpt of treatment content • Feedback on plans for child app

[a]MoSCoW: Must have, Should Have, Could Have, Won't Have.

[b]PCUQ: Program Content and Usability Questionnaire.

The aims of workshop 1 for parents and clinicians were to (1) present the overall concept of the internet-based intervention, (2) explore participants' wants and needs, and (3) generate ideas about what the internet-based intervention might look like and the functionality it may have. Parents focused on the parent treatment website and clinicians focused on the clinician website. The MoSCoW approach (Must have, Should have, Could have, Won't have) [38] was used to gain insight into what the priority of functions should be and what functions were not wanted by users. Participants quickly sketched their ideas for what key functions would look like using rapid visual prototyping [39]. Early prototypes of the websites were created from the learnings from workshop 1 and presented to the participants in workshop 2 to gain their feedback through

discussion and the PCUQ. These early prototypes were interactive screens that could be navigated to represent the intended user experience. This purported to evaluate what the participants liked and what refinements were needed at a very early stage of development. Refined prototypes were presented in workshop 3 and participant feedback was collected through discussion and the PCUQ. The learnings from workshop 3 subsequently informed the development of the working prototype that was used in the usability testing (phase 2).

The aim of workshop 1 for children was to gain an understanding of the kind of character the game should have and how the game could help them face their fears. In workshop 2, children were presented with various game visuals in a colorful booklet and they played different types of existing games on a tablet. Children completed the PCUQ to obtain feedback on what children wanted the game to look like and the type of game they preferred. Pen-and-paper mock-ups of the game were created based on this information and presented to children in workshop 3. Children provided their feedback on the mock-ups through discussion and the PCUQ. This informed the development of a working prototype of the game that was used in the usability testing (phase 2).

During the workshops, detailed field notes were taken to capture the discussion, and visual activities were photographed. Following each workshop, members of the research team and website development company met to collate and summarize feedback from the discussion, activities, and the PCUQ.

Data Analysis

Phase 1 involved gathering information to inform the subsequent development of the intervention, and therefore, no formal statistical analysis was conducted. Key learnings and descriptive statistics for the PCUQ are presented below. The outcomes of phase 1 were a description of the needs and wants of the intended user groups for Online Support and Intervention for child anxiety (OSI) and confirmation that these have been met in the early prototypes.

Ethics Approval

The study was approved by the University of Reading Research Ethics Committee (16/48) and the National Health Service South East Coast–Surrey Research Ethics Committee (16/LO/1598).

Results

Technology Use

As shown in Table 3, all the parents and clinicians had regular access to the internet and a PC or laptop, and most of them had regular access to a smartphone. Parents and clinicians reported feeling confident in using these technologies and endorsed that they liked using them. Most of the clinicians had no experience with delivering internet-based psychological therapies. Children reported regular use of the internet and tablets, with some use of PCs or laptops and smartphones. All children rated themselves as confident in using and liking these technologies.

Table 3. Technology use of participants in phase 1 and phase 2.

Participant group and variables	Phase 1	Phase 2
Parents, n	7	7
Regular access to the device, n (%)		
PC or laptop	7 (100)	7 (100)
Internet	7 (100)	7 (100)
Smartphone	6 (86)	6 (86)
Tablet	5 (71)	5 (71)
None of the above	0 (0)	0 (0)
Confidence[a] in using the device, mean (SD)		
PC or laptop	4.14 (0.69)	4.29 (0.76)
Internet	4.14 (0.69)	4.29 (0.76)
Smartphone	4.33 (0.52)	3.86 (1.35)
Tablet	4.33 (0.52)	4 (1.41)
Liking[b] for using these technologies, mean (SD)	4.14 (0.69)	4.29 (0.76)
Children, n	3[c]	4
Frequency[d] of using the device, mean (SD)		
PC or laptop	3.33 (0.58)	3.25 (0.50)
Internet	4 (0)	4 (0)
Smartphone	3 (1)	2.75 (0.96)
Tablet	4 (1)	4 (0.82)
Confidence[a] in using the device, mean (SD)		
PC or laptop	4.33 (0.58)	4.50 (0.58)
Internet	4.67 (0.58)	4.75 (0.50)
Smartphone	4.67 (0.58)	4.75 (0.50)
Tablet	4.67 (0.58)	4.75 (0.50)
Liking[b] for using these technologies, mean (SD)	5 (0)	4.75 (0.50)
Clinicians, n	11	8
Regular access to the device, n (%)		
PC or laptop	11 (100)	8 (100)
Internet	11 (100)	8 (100)
Smartphone	9 (82)	7 (88)
Tablet	6 (55)	4 (50)
None of the above	0 (0)	0 (0)
Confidence[a] in using the device, mean (SD)		
PC or laptop	4.45 (0.52)	4.25 (0.46)
Internet	4.45 (0.52)	4.25 (0.46)
Smartphone	3.91 (1.04)	3.88 (0.99)
Tablet	3.73 (1.10)	3.57 (0.98)
Liking[b] for using these technologies, mean (SD)	4 (0.63)	4.13 (0.64)
Experience of delivering web-based psychological therapies, n (%)		
No experience	7 (64)	6 (75)

Participant group and variables	Phase 1	Phase 2
A little experience	3 (27)	2 (25)
Some experience	0 (0)	0 (0)
Quite a lot of experience	0 (0)	0 (0)
Lots of experience	1 (9)	0 (0)

[a]Rated on a 5-point Likert scale, with higher scores indicating greater confidence.

[b]Rated on a 5-point Likert scale, with higher scores indicating greater liking.

[c]Data missing for 1 participant.

[d]Rated on a 5-point Likert scale, with higher scores indicating more frequent use.

Workshops

The key learnings from workshop 1 are presented in Textbox 1. Overall, parents and clinicians were positive about the idea of creating an internet-based version of the face-to-face treatment, and children were excited about a game that could help them face their fears.

The functionality proposed for the parent and clinician OSI websites was largely welcomed, with the exception of secure videoconferencing for the therapy sessions. Although clinicians considered this as a *must have*, they had concerns about the technology failing and the implications this could have partway through a therapy session. In contrast, parents did not want the therapy session to be held over a secure videoconferencing system and preferred telephone contact. In response to this feedback from parents, secure videoconferencing was not included in the prototypes presented in subsequent workshops.

Both parents and clinicians suggested additional functionality that they wanted for OSI. For parents, this included a *favorites* section where parents could bookmark key parts of the treatment modules and a written summary of the therapy session. Clinicians suggested that a *welcome* module would be helpful to orientate parents to the treatment approach.

The children wanted to be able to personalize the character in the game through customizable elements such as hair, clothes, and color. They thought the game could help them face their fears if they could earn rewards through it for facing their fears on their *step plan* (exposure ladder).

Initial prototypes of the parent and clinician OSI websites were presented to parents and clinicians, respectively, in the subsequent design workshops (workshop 2 and workshop 3). Overall, the PCUQ results showed that parents and clinicians were positive about the proposed design and functionality (Table 4). Feedback provided during workshop 2 helped to further improve the intervention, as shown by the higher PCUQ ratings during workshop 3.

The main finding from the children's design workshop 2 was that they were largely positive about the game visual options, with a slight preference for a mountain setting and cartoon style for the game app over alternative designs (Multimedia Appendix 2). They liked the concept of having more than one game type to choose from, and their favorite minigame type was *bottle-flipping* [40]. In workshop 3, children were presented with pen-and-paper mock-ups of the game. Children rated all aspects of the game dynamics specified in the PCUQ (game character, home screen, dress-up game, game selection screen, and challenges) as highly liked and easy to use (Multimedia Appendix 3). All the game play options presented were also rated as highly liked and easy to use. Overall, the children agreed that the game developer had understood what they wanted and few changes were needed. On combining feedback from workshops 1 and 2, game option 1 (monster flipping) was selected as the primary game.

Textbox 1. Key learnings from workshop 1.

Key learnings from parents:

- Therapy session to be conducted via telephone and not via secure videoconferencing.
- Include a *favorites* section.
- Clinician should provide a written summary of the therapy session.

Key learnings from children:

- Ability to personalize the character in the game.
- Earn rewards through the game and step plan.

Key learnings from clinicians:

- Not include an instant messaging service with the parent.
- Conduct the therapy session over secure videoconferencing built into system but concerned about technical issues.
- Not include one-way messages of encouragement to the child app.
- Include a *welcome* module to orientate parents to the website and clarify expectations of the treatment approach.

Table 4. Phase 1 parent and clinician feedback on initial mock-ups of Online Support and Intervention for child anxiety.

PCUQ[a] item[b]	Parents, mean (SD)		Clinicians, mean (SD)	
	Iteration 1	Iteration 2	Iteration 1	Iteration 2
It looks easy to use	4.78 (0.32)	4.86 (0.19)	4.36 (0.43)	4.25 (0.32)
It looks easy to navigate	4.75 (0.37)	4.89 (0.15)	4.21 (0.65)	4.37 (0.23)
The words are clear and easy to understand	4.72 (0.35)	4.94 (0.15)	4.23 (0.47)	4.37 (0.45)
This screen has the right amount of information	4.44 (0.57)	4.86 (0.26)	4.04 (0.49)	4.30 (0.46)
This page is visually pleasing to me	4.37 (0.51)	4.60 (0.55)	3.71 (0.64)	4.13 (0.45)
It looks clear what to do next	4.37 (0.71)	4.80 (0.34)	3.64 (0.48)	3.92 (0.23)
This page looks user-friendly	4.45 (0.56)	4.85 (0.20)	3.93 (0.47)	4.17 (0.49)
Based on this page, I would return to this website	4.61 (0.34)	4.83 (0.18)	3.93 (0.62)	4.02 (0.60)
The tone of the material is sensitive for parents seeking help for their child's anxiety	4.64 (0.45)	4.86 (0.18)	—[c]	—
The material is relevant for parents seeking help for their child's anxiety	4.61 (0.27)	4.85 (0.19)	—	—
This page meets my needs for an online treatment program	4.64 (0.30)	4.77 (0.29)	3.96 (0.34)	4.18 (0.42)
The page meets what I would want from an online treatment program	4.56 (0.39)	4.82 (0.20)	3.96 (0.30)	4.17 (0.46)
This page meets my expectations as discussed in the workshop	4.57 (0.39)	4.86 (0.16)	3.79 (0.47)	4.05 (0.63)

[a]PCUQ: Program Content and Usability Questionnaire.

[b]Items were scored on a scale of 1 (strongly disagree) to 5 (strongly agree).

[c]Questionnaire item was not relevant for clinicians to answer.

Phase 2: Usability Testing

Methods

Participants

A total of 7 parents (n=6, 86% mothers and n=1, 14% father), 4 children (n=2, 50% girls and n=2, 50% boys), and 8 clinicians (n=4, 50% women and n=4, 50% men) participated in phase 2. Sample characteristics are presented in Table 1. In all, 71% (5/7) of the parents (all mothers), 75% (3/4) of the children, and 75% (6/8) of the clinicians participated in both phase 1 and phase 2. Participants were recruited using the same approach as phase 1.

Measures

Participants completed the technology use and PCUQ questionnaires, as described above and in Multimedia Appendix 1 [29,36,37]. Participants completed the PCUQ in reference to OSI (parents and clinicians) and the game (children) as a whole, rather than specific to each function of the website as in phase 1.

Usability Error Log

Usability errors during use of the parent and clinician websites were logged according to severity metrics common in usability testing [41,42]: (1) level-1 errors refer to cosmetic or minor factors such as typos, legibility, or esthetic preference; (2) level-2 errors are moderate issues; for example, inability to navigate successfully through the site; and (3) level-3 errors are critical or severe issues, such as technical issues that prevents the user from using a function of the site. The frequency of each error severity level was summed for each iteration.

Semistructured Interviews

Semistructured interviews were used to gather further information about the acceptability and ease of use of the website and game. Questions were open and nonspecific to encourage unprompted reports of what was most relevant. Specifically, parents and clinicians were asked the following: (1) What did you think of the website overall? (2) What did you find easy to use? (3) What did you find difficult to use? (4) What did you find easy to understand? (5) What did you find difficult to understand? (6) What did you like about it? (7) What did you dislike about it? (8) What do you think about how long it took to complete a module (parents only)? (9) What would you like to change about the website? (10) What would you like to add to the website? (11) What would you like to remove? (12) What do you think about the colors used? and (13) Is there anything else you would like to say about the website? At this point, we suggested the name, OSI, to parents and clinicians and asked for their feedback. For each element of the game (ie, home screen, monster flip game, and monster dress-up game) children were asked the following: (1) What did you like about the game? (2) What did you dislike about the game? (3) What did you find easy to use? (4) What did you find hard to use? and (5) What would you like to change about the game? Children were also asked what they thought about the sounds and music used in the game. Interviews were audio-recorded and transcribed verbatim for analysis.

Procedure

Participants attended individual usability testing sessions at the University of Reading at a time convenient to them. Parents and clinicians were shown the website relevant to them and asked to *think aloud* (ie, provide continuous commentary) [43] while carrying out a list of tasks (eg, parents were asked to work

through the module and bookmark a page and clinicians were asked to book an appointment for a therapy session) and were provided time to explore the website by themselves. A researcher was present to record the frequency and detail of usability errors using the usability error log. Both the participant and the screen were video-recorded, in case further clarification was required after the testing process. Then, parents and clinicians completed the PCUQ and semistructured interview. Usability testing sessions for the children followed a similar format. Children were asked to explore the game and say out loud what they thought of it as they played it (ie, the *think aloud* method [43]). A researcher was present to record observational notes to obtain a general idea of how children proceeded through the game. Then, the children completed the child PCUQ and semistructured interview.

The research team collated and summarized the feedback on each aspect of the website and the game from the first round of usability testing. Then, the website development company revised the website and the game in response to the user feedback. Then, the second iterations were presented to participants in a second round of usability testing, following the same procedures outlined above. Additional functions were also included in the subsequent iterations of OSI. Feedback from the second round of usability testing was used for further iteration, and a third (final) round of usability testing was conducted as described above. Feedback from the final round of usability testing was used to finalize the website and the game.

Data Analysis

Descriptive statistics were used to analyze the PCUQ responses and the frequency of usability errors for each iteration of the website for both parents and clinicians. Brief summaries of the semistructured interviews were used to identify immediate feedback on each iteration of the website and game that could be used to further iterate OSI. Then, a content-analysis approach was used to analyze interview transcripts across all 3 interactions to capture more detailed insights into the acceptability and ease of use of the website and game. Responses were assigned codes according to whether the comment reflected positive feedback or negative feedback or suggested improvement and the aspect of the design or functionality of the website or game discussed. Then, the codes were organized according to these categories to identify key themes and patterns across the 3 iterations for each set of interviews (parents', clinicians', and children's interviews). The analysis took into account both frequency and severity of usability issues discussed in the interviews. A summary of the key themes along with example quotations from the interviews are presented below.

Results

Technology Use

Parents and clinicians in phase 2 had regular access to the internet and a PC or laptop, and most of them also had regular access to a smartphone (Table 3). Most of the participants reported feeling confident with and liking these technologies. Most clinicians had no experience of delivering internet-based psychological therapies. Children reported regular use of the internet and tablets, with some use of PCs or laptops and smartphones. All children rated themselves as confident in using and liking these technologies.

Usability Testing Sessions

Feedback from parents and clinicians on working prototypes was predominantly positive across the 3 iterations, with mean scores on the PCUQ largely indicating *agree* or *strongly agree* (Multimedia Appendix 4). For most items on the PCUQ, ratings increased across the iterations, suggesting that usability had improved with the changes made to each iteration. Scores for "it is always clear what to do next" stayed within *neutral* to *agree* across iterations for clinicians. Children reported a similar trend for sustained or improved usability scores on the PCUQ for the majority of items (Multimedia Appendix 5); however, some items ("each screen has the right amount of information," "it is easy to use the home screen," and "each screen loaded quickly") showed a slight decline in scores at iteration 3.

Usability errors for parents and clinicians followed a similar pattern across the iterations (Figures 1 and 2). Overall, there were fewer level-3 errors (critical technical issues) than level-2 errors (moderate issues) or level-1 errors (minor or cosmetic issues) for all iterations. Level-3 errors stayed at a low level for parents across all iterations and none occurred for clinicians. Level-1 and level-2 errors tended to reduce across the iterations, with the exception of level-2 errors for clinicians that showed a slight increase at iteration 3, which may be owing to the introduction of new features to the case management system at this stage.

Figure 1. Mean number of usability error types for parents across the iterations of Online Support and Intervention for child anxiety.

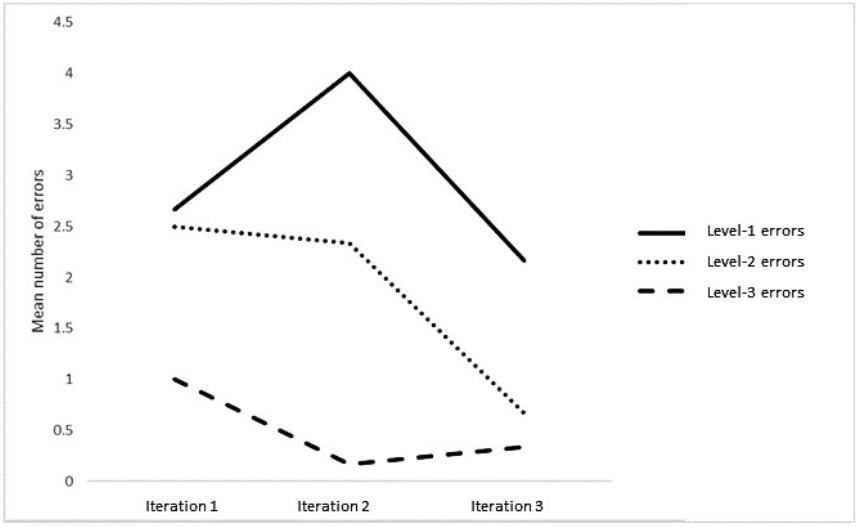
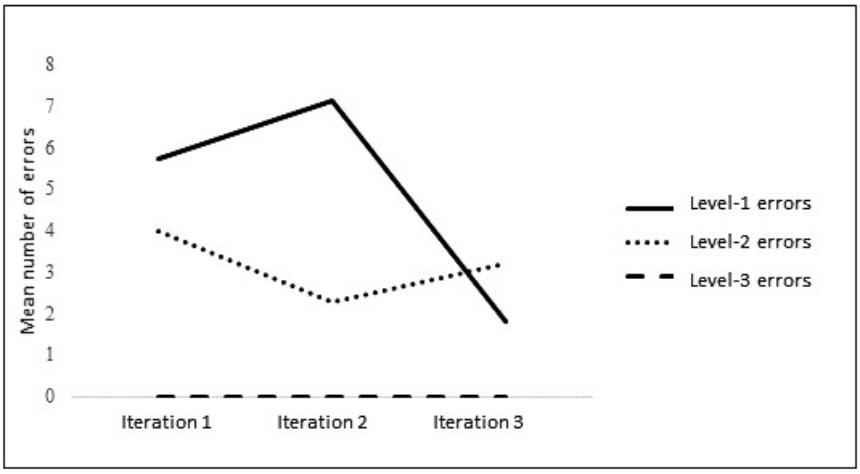


Figure 2. Mean number of usability error types for clinicians across the iterations of Online Support and Intervention for child anxiety.



Semistructured Interviews

Results from the semistructured interviews reflected the findings from the PCUQ and usability errors.

Parents

Parents were positive about the overall structure of the website, how the treatment material was presented, and the time required to complete the modules:

> *What I liked about it is it's something I can go back to in my own time when I can't remember exactly how to do something, and it's easier to access and use because it's in nice bite-size chunks, rather than having to flip through the book or my notes from the course.* [Parent 7; iteration 3]

> *I think the information is not too much, straight to the point and also, the fact that you're...it's not just words there are videos, so yes I think that's important. I think it's not long, I think it's a good time.* [Parent 2; iteration 2]

Parents were positive about the website—in particular, that it was easy to use and the materials were accessible:

> *I like the fact that you can at any point stop and go to any other section that you wish to, you don't have to complete that whole section, you can go backwards and forwards as much as you like and it's very quick and easy to do that.* [Parent 4; iteration 1]

> *Well actually, some of the functionality I thought might have been difficult, in other words, adding items to the agenda, moving items around, reviewing bookmarks that I've added, adding in comments and all those sort of things were good.* [Parent 7; iteration 2]

Of note, there was only 1 comment across all the parent interviews relating to technical issues*:*

> *The bit that was a bit frustrating was the, where it sometimes jumped back to the beginning which I think was a Mac-ism.* [Parent 7; iteration 2]

The look and feel of the website were also viewed positively; the OSI name, layout, and language used contributed to this:

> *I like that, OSI. I think it's simple, it's easy to understand and easy to remember. OSI. OSI for this, OSI for that, yeah.* [Parent 2; iteration 1]

> *It's pretty easy to use, it's well laid out so you know where everything is, the menu's quite easy to understand where all the things are, and so yeah. It's easy to navigate.* [Parent 2; iteration 2]
>
> *I think that the text is really good, I think that's gonna help it to be as straightforward and painless as possible.* [Parent 5; iteration 3]

Parents provided some useful feedback on the colors; in the first iteration, a parent noted that, "the blue and white is quite clinical. If I was to pick a colour I'd pick green, because it's restful" [Parent 1; iteration 1]. This feedback was used to develop the website, and at the next iteration, the same parent spoke positively about the revised colors:

> *It's definitely more pleasing to the eye now, with the colours that have been changed from the previous session that I did, the blue just didn't work for me...it just felt too medical and I think when you're in that whole, dealing with the whole anxiety thing it just dominates your whole world, so to be on it when that child is in bed or at school or whatever, to then still be very medical...the green is a lot more relaxing and kind of gently supportive really I suppose.* [Parent 1; iteration 2]

Other useful feedback at iteration 2 were related to the animation and videos:

> *I didn't like the animation. It was too long. And I didn't like the music. With it. Erm, I would have preferred the real people in that bit.* [Parent 4; iteration 2]
>
> *Well apart from the video, I couldn't understand the person talking, and I think subtitles or the optional subtitles might be useful.* [Parent 2; iteration 2]

Changes made at iteration 3 were noticed and elicited positive feedback:

> *I did really dislike the talking heads the last time, I much preferred the true person talking...I much preferred the video, the talking. The real person talking.* [Parent 4; iteration 3]

Parents talked about a key element of the treatment—the step plan, which they were keen to optimize, and they recognized it as something they would want to revisit:

> *I think I had a bit of a challenge with the step plan bit, I think that needs to be a bit finetuned and changing the names of it, and going to steps, but otherwise it's pretty straightforward.* [Parent 2; iteration 1]
>
> *I think if you were going back and you wanted to listen to it again just to pick out the main points, you'd be thinking ugh it's a bit...I think the look was fine, I just, if it was more concise.* [Parent 3; iteration 2]

This feedback was responded to, and at iteration 3, parents reported more favorably about the step plan video:

> *I much prefer the new step plan [video].* [Parent 3; iteration 3]

Children

Overall, children were positive about the game app and found it easy to use. For the monster flip minigame, all of them found the game accessible (eg, "it was easy to use. I like how it explained what to do before, so you knew what to do" [Child 3; iteration 2]), but provided enough challenge to be interesting (eg, "think the hardest part of the game is judging where he's gonna bounce" [Child 4; iteration 2]). As expected, some children found it harder than others to play; a child suggested that "there could be higher levels" [Child 1; iteration 3], whereas another child said that "the extreme one was too hard" [Child 3; iteration 3]; however, they still liked the game overall (eg, "it was a good background. I like how it like, showed where you were at the top" [Child 3; iteration 2]).

Regarding the dress-up game, all the children liked it, and all of them said that there was nothing they disliked about it:

> *I found the buying was easy to use...I like the clothes shop, because it was super easy.* [Child 4; iteration 2]

A child talked about the functionality of the dress-up game in terms of not knowing how to control the activity:

> *There was one thing, when I bought some of the clothes, I didn't realise I had to drag it on, I just tapped it and I thought it would just go on.* [Child 2; iteration 2]

However, the other children found it easy to use. Although this was not a universal problem, the game instructions were refined to address this issue.

Children liked the home screen and commented on particular details:

> *I like the view out the window.* [Child 3; iteration 2]
>
> *I like the ability that you could drag the log to the fire and that you could get a newspaper which would entertain him, and I liked the design of the house, and the buttons are easy to use.* [Child 2; iteration 3]

They asked for more colors to be used, but only in response to a specific question about whether they disliked anything about the home screen:

> *Maybe like, change the colour scheme a bit because it was pretty much all blue, maybe you could paint the house? Or like I said maybe get a new house.* [Child 2; iteration 3]

Others commented positively on the colors:

> *I liked how you could like, go to whichever place you wanted to, and I like the colour of it.* [Child 3; iteration 2]

Feedback on the initial iteration included requests for more options for customizing the character:

> *I don't like the fact that you can't change him, you can't choose his name, you can't choose his colour, you can't choose what he looks like.* [Child 4; iteration 1]

This was addressed in later iterations to the game with the addition of the dress-up game and the random name generator.

Clinicians

Overall, clinicians responded positively to the OSI case management system and acknowledged that any issues they had while using OSI may be because they were a novice user:

> *It was good, I liked it. It's quite easy to kind of navigate, it's quite obvious where to go for things, and when you're actioning something it's quite obvious what you need to do next. Like that it's not too cluttered, it's got kind of just what you need on there.* [Clinician 8; iteration 1]

> *The only thing I'm unsure of is the progress, the notes bit where you take like progress notes, but that's just because I haven't used the system much, after like one week I'd be, I'd know exactly where to go.* [Clinician 7; iteration 3]

Clinicians talked about specific key features of the website, including the calendar feature, the routine outcome measures (ROMs), and the notes function and how risk is managed within OSI (eg, "the week view would be useful. I think it would be helpful to have a month view as well" [Clinician 7; iteration 1]), and later noticed changes to these features without prompting (eg, "I like the calendar view, cos I think that's changed from before" [Clinician 8; iteration 2]).

Clinicians were particularly positive about the ROMs:

> *ROMs bit was the easiest bit, and thinking about new clinicians coming in and being able to see the ROMs all on screen, presented in that way, showing the clinically significant change, whether the scores are above or below the cutoff line, the subscales mapped out with the dates, like I'm struggling to think of how you could display that in an easier way...so that was a nice bit I think. I think for new practitioners, will demystify the process of ROMs.* [Clinician 4; iteration 2]

Some clinicians had suggestions for improvements, but the suggested changes were not necessarily echoed by other clinicians. For example, a clinician found all elements acceptable:

> *...everything was labelled quite clearly, particularly bits in the client information are quite good, so the risks, adding notes and ROMs. I thought all of that information was really clear and easy to access.* [Clinician 8; iteration 2]

By the third iteration, clinicians struggled to identify any further changes they would like to suggest:

> *I don't think there was anything I disliked. Nope. No nothing comes to mind I disliked...Well done. Am I allowed to say well done? Because having used so many unfriendly systems this is like a dream.* [Clinician 6; iteration 3]

> *Really good, really well structured and clean, and yeah it's got the right information.* [Clinician 4; iteration 3]

Final Iteration of OSI

Multimedia Appendices 6-8 show screenshots of the final iteration of the OSI parent website, clinician case management system, and child game app, respectively [44]. Both the parent and clinician OSI websites can be accessed via internet browsers on a computer (desktop or laptop), smartphone, or tablet device.

The parent works through 7 modules (Multimedia Appendix 9) that are released weekly and take approximately 30 minutes to complete. Each module follows the same format with compulsory ROMs, module content, summary of module, homework for the week, module quiz (optional), and module feedback (optional). The ROMs include parent-report versions of the Revised Children's Anxiety and Depression Scale (RCADS) [45], Child Anxiety Impact Scale (CAIS) [46], Child Outcome Rating Scale [47], Goal Based Outcomes [48], brief Spence Child Anxiety Scale [49], and the Session Rating Scale [47]. These ROMs are compatible with the Child and Young People Increasing Access to Psychological Therapies initiative in the United Kingdom [50]. In addition, the CAIS can detect meaningful clinical change in anxiety symptoms and interference [51], and the brief Spence Child Anxiety Scale works well as a brief measure of anxiety symptoms [49]. In line with Child and Young People Increasing Access to Psychological Therapies, all measures are collected weekly, except the CAIS and RCADS, the full versions of which are administered at the start and end of treatment, and a subscale is tracked weekly. Parents can immediately view the scores of the ROMs and information about how to interpret scores via the *your child's progress* tab. Modules are interactive, with questions to answer and worksheets to complete. The treatment material is presented as easy-to-read text, with videos and animations to demonstrate the strategies and provide parent testimonials. Parents can bookmark module pages for quick reference and add notes throughout about their own reflections or experiences. Resources from within and outside OSI are found in a *resources* tab. After completing each module, the parent has a 20-minute telephone review session with their therapist. The telephone session aims to review how the parent applied the strategies with their child and problem solve any difficulties. Details on the therapy session appointment times are found in the *therapy sessions* tab, along with a written summary from the therapist for previous therapy sessions. Parents can add to the upcoming therapist session agenda throughout the relevant module and via the *therapy sessions* tab. They can also reorder items on the agenda to prioritize items that are important to them to discuss.

The OSI case management system allows the clinician to view the service users they are supporting on OSI via the *client list* tab. On clicking a child's name, a detailed view of the child's OSI case file is presented. This includes their personal details and all interactive elements of the parent site. Parent's answers to questions and worksheets are shown under the *homework* tab for clinicians to review before the telephone review session. ROMs are scored and immediately available for review and download via the *ROMs* tab. Appointments for the telephone review session can be booked via the *appointments* tab, which also gives details of past and upcoming therapist sessions. Upcoming appointments can also be viewed via the *calendar* tab. Notes from the therapist sessions are found under *notes*,

and therapists can also add additional progress notes here. Clinicians can view the OSI treatment material presented in a PDF format via the *view treatment* tab. Details on how to contact technical support and frequently asked questions on using OSI are provided for both parents and clinicians via the *help guides* tab. Clinicians are provided with a training video and clinician manual for the OSI case management system.

The child game app is called *Monster's Journey: Facing Fears* and is available to download on smartphones or tablets via the Apple Store and Google Play Store. A registered parent OSI account is needed to access the game (for free). The game aims to help motivate the child to engage in the treatment strategies, and it is an optional part of the OSI treatment program. The game is introduced to families in module 3–*facing fears* and can be used as a reward option when the child faces their fear. Parents can reward their child with virtual coins via a parent portal in the game, which the child can use to unlock various features, such as different minigames, extra levels and modes of the games, and customization options. The game consists of a monster character who the child can name and personalize with different outfits. There are 3 minigames, which the child can choose to play. Each minigame has a range of modes and difficulty levels that can be unlocked using the virtual coins. Children can also earn a nominal number of virtual coins via *challenges* within the games. The home screen acts as a base for the monster and is where the child receives notifications of the reward of virtual coins and other gifts received during gameplay. The game is intended to be motivational and is not intended to be therapeutic in its own right. However, introductions to the minigame includes storylines about helping the monster to face its fears, and there are messages of encouragement to continue playing when the child is struggling with the gameplay and of positive reinforcement when they succeed. Parents are provided with guidance on how to introduce the game and manage screen time.

Discussion

Principal Findings

OSI was developed through a process of user-centered design and usability testing. The results presented here show that by adopting this approach, OSI meets the expectations and needs of the intended users (parents, children, and clinicians). The initial vision for OSI was confirmed and refined during the design workshops in phase 1 of development. This enabled participants to highlight what functions of OSI were important to them and how they would like these to look and work on the website and game. The initial positive ratings of the working prototypes of OSI presented during usability testing (phase 2) suggests that the active collaboration with users at the design stage was a successful and important part of the development process. The 3 cycles of usability testing allowed for further improvement of OSI and by the third iteration, participants reported high levels of satisfaction with how OSI looked, its ease of use, and the functions available.

It is noteworthy that clinicians reported that the OSI case management system was easy to use without any training. This suggests that OSI is intuitive to use; however, most of the clinicians participated in both phase 1 and phase 2 of the development process, and thus, had some degree of familiarity with OSI. Clinician ratings for "it is always clear what to do next" did not show the same degree of improvement across the iterations in phase 2 as the other items on the PCUQ. There was also a slight increase in the number of moderate issues (such as inability to successfully navigate through the site) at iteration 3. This could be owing to the introduction of additional features in the third iteration of the OSI case management system. Feedback gathered in the semistructured interviews highlighted that the clinicians felt that any difficulty in using potentially confusing elements of OSI (eg, the calendar) would resolve with regular use; however, changes were also made to address issues raised, and a clinician training package and clinician manual were subsequently developed to help clinicians to quickly adopt OSI as part of their routine clinical practice.

Parents consistently rated OSI as acceptable and easy to use throughout the design and usability process. This suggests that the initial workshop where parents decided on what features they wanted OSI to have and how they might look was crucial and successfully translated into acceptable and usable initial (phase 1) and working (phase 2) prototypes. Parents were overwhelmingly positive about OSI by the final iteration. It is encouraging that they reported it was simpler to use than they expected, the treatment material was appropriate in tone and presentation, and the time needed to work through modules was acceptable. This feedback is important given that engagement in and adherence to internet-based treatments is associated with treatment outcomes [52-54] but has been low in some previous studies [55-57]. Nevertheless, it will be important to continue to monitor and assess the acceptability of time needed to complete the modules and weekly questionnaires in future research.

Overall, the game app was positively endorsed by children. Some items to assess content and usability did not show a linear improvement across the iterations, and this is likely to be related to the addition of many new features across the usability testing period. Despite this, by iteration 3, children rated the game app as looking good and easy to use and understand, and they reported that they would use the game again. This is encouraging because the aim of the game is to help motivate the child to engage in the treatment strategies by acting as a reward mechanism; thus, a desire to play the game is essential. However, it is worth noting that the game is an optional part of treatment, and future research is needed to determine the extent of its use and whether it successfully motivates children to engage in the treatment strategies and ultimately enhances treatment outcomes. For example, future research could compare outcomes for children who use and do not use the game during treatment.

User-centered design and usability testing are considered as best practice for digital mental health innovation [10,18,19], and developers are encouraged to share their development process to help further understanding of how best to design digital mental health interventions [10]. We hope that the methods we used to develop OSI will provide a model that others can adapt for interventions for other target disorders or age groups. Although our study clearly illustrates the benefits

of user-centered design and usability testing, it is worth acknowledging some of the key challenges associated with the process that will be relevant for others who are developing digital mental health interventions. The process was lengthy, spanning 10 months. It also required careful planning with the technology company that developed OSI to ensure that the timings of the research protocol were achievable and in line with the time taken to develop each iteration of OSI. Time pressures sometimes meant that some features were not available for testing until later stages in the usability testing process. Nonetheless, usability ratings improved over time, suggesting that the collaborative design of these features helped to ensure they were easy and enjoyable to use. It should also be acknowledged that time and budget constraints meant that not all suggestions for improvements could be implemented. Our approach was to respond to anything that caused significant usability issues for most participants or was critical for successful delivery of the treatment. The high acceptability and usability scores indicate that this did not adversely affect ease or enjoyment of use.

Strengths and Limitations

This study has several strengths. Of primary importance, we adopted a bottom-up approach to the development. This allowed the participants to tell us what features they wanted and how they wanted them to look and work, which is the essence of participatory research [58]. By actively involving users at both the design stage *and* usability testing as part of the development process, we were able to not only understand the needs and wants for the website and game but also ensure that it met those expectations and was easy and enjoyable to use. Another strength is that we recruited participants who were familiar with receiving (parents and children) or delivering (clinicians) the treatment that OSI is based on. This enabled a rich discussion of the features that might be helpful in the internet-based translation of the treatment material and management of families receiving this treatment.

Despite the strengths, there are some limitations that should be acknowledged. Participants were predominantly from White British ethnic backgrounds, and parents were well educated and largely employed. The lack of diversity in sociodemographic characteristics means that we cannot be sure that OSI will be satisfactory and easy to use across other sociodemographic groups. Furthermore, the sample did not include those who were not regular internet users, and although 96% of UK adults (aged 16-54 years) report daily or almost daily use of the internet [59], there is marked variation in reasons for internet use and digital skills among the UK population [60]. However, efforts were made to mitigate these issues; for example, the text of the treatment material was considered *easy to read* in readability tests and a range of ethnic backgrounds was represented in the creation of the video and animations. Furthermore, each module has a feedback questionnaire, and thus, OSI can be further iterated based on user feedback from wider research and routine use. The minimum number of participants required for usability testing is often cited as 5 [61]; however, using larger sample sizes and ensuring that participants are representative of the target user group will increase the likelihood of detecting all usability issues [62]. We included >5 clinicians and parents who had experience of receiving and delivering child anxiety treatment, but only 4 children participated and all of them were aged between 9 and 12 years; thus, it is possible that our findings may not be applicable to younger children who might otherwise benefit from the treatment approach [30]. Although our sample size is consistent with previous usability testing of a child anxiety intervention [29], it is possible that there are usability problems that were not detected in this study. Finally, it is important to acknowledge that this study was conducted before the COVID-19 pandemic and associated physical distancing restrictions. It is possible that an increase in the use of digital tools during the pandemic may have changed user preferences and experiences of OSI, and it will be important to assess this through ongoing user feedback.

Conclusions

In conclusion, taking an iterative approach to development through user-centered design and usability testing has resulted in an internet-based treatment for child anxiety (OSI) that appears to meet the needs and expectations of parents, children, and clinicians and is easy and enjoyable to use. Now, it is important to establish the effectiveness of OSI, and further research designed to evaluate OSI in clinical and community settings is in progress. Indeed, it is intended that OSI will continue to iterate further in response to feedback in these settings to ensure that it is helpful to families struggling with child anxiety problems and to clinicians who are supporting them.

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Authors' Contributions

CH conceived, designed, and conducted the study and analyzed the quantitative data; CC had overall oversight of the study design and analyses; TR contributed to the development of Online Support and Intervention for child anxiety; and LT analyzed the qualitative data. All authors contributed to the writing of the manuscript.

Conflicts of Interest

CC receives royalties for the book on which this intervention is based; however, none of the authors make any financial gain from the intervention presented in this paper.

Multimedia Appendix 1
Phase 1 measures.
[DOCX File , 21 KB - formative_v6i4e29846_app1.docx]

Multimedia Appendix 2
Phase 1–children's feedback on game visuals options.
[DOCX File , 22 KB - formative_v6i4e29846_app2.docx]

Multimedia Appendix 3
Phase 1–children's feedback on Online Support and Intervention for child anxiety game mock-ups.
[DOCX File , 20 KB - formative_v6i4e29846_app3.docx]

Multimedia Appendix 4
Phase 2–parents' and clinicians' feedback on working prototypes of Online Support and Intervention for child anxiety.
[DOCX File , 22 KB - formative_v6i4e29846_app4.docx]

Multimedia Appendix 5
Phase 2–children's feedback on working prototypes of the game.
[DOCX File , 20 KB - formative_v6i4e29846_app5.docx]

Multimedia Appendix 6
Screenshots of the Online Support and Intervention for child anxiety parent website.
[PPTX File , 1005 KB - formative_v6i4e29846_app6.pptx]

Multimedia Appendix 7
Screenshots of the Online Support and Intervention for child anxiety case management system for clinicians.
[PPTX File , 389 KB - formative_v6i4e29846_app7.pptx]

Multimedia Appendix 8
Screenshots of the Online Support and Intervention for child anxiety child game app.
[PNG File , 568 KB - formative_v6i4e29846_app8.png]

Multimedia Appendix 9
Online Support and Intervention for child anxiety treatment content.
[DOCX File , 19 KB - formative_v6i4e29846_app9.docx]

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Abbreviations

CAIS: Child Anxiety Impact Scale
CBT: cognitive behavioral therapy
iCBT: internet-based cognitive behavioral therapy
NIHR: National Institute for Health Research
OSI: Online Support and Intervention for child anxiety
PCUQ: Program Content and Usability Questionnaire
RCADS: Revised Children's Anxiety and Depression Scale
ROM: routine outcome measure

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Original Paper

Exploring Web-Based Twitter Conversations Surrounding National Healthcare Decisions Day and Advance Care Planning From a Sociocultural Perspective: Computational Mixed Methods Analysis

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Abstract

Background: Within the cultures and societies of the United States, topics related to death and dying continue to be taboo, and as a result, opportunities for presence and engagement during the end of life, which could lead to a *good death*, are avoided. Several efforts have been made to help people engage in advance care planning (ACP) conversations, including completing advance care directives so that they may express their goals of care if they become too sick to communicate their wishes. A major effort in the United States toward encouraging such challenging discussions is the annual celebration of the National Healthcare Decisions Day.

Objective: This study aimed to explore ACP from a sociocultural perspective by using Twitter as a communication tool.

Methods: All publicly available tweets published between August 1, 2020, and July 30, 2021 (N=9713) were collected and analyzed using the computational mixed methods Analysis of Topic Model Network approach.

Results: The results revealed that conversations driven primarily by laypersons (7107/7410, 95.91% of tweets originated from unverified accounts) surrounded the following three major themes: *importance and promotion*, *surrounding language*, and *systemic issues*.

Conclusions: On the basis of the results, we argue that there is a need for awareness of the barriers that people may face when engaging in ACP conversations, including systemic barriers, literacy levels, misinformation, policies (including Medicare reimbursements), and trust among health care professionals, in the United States. This is incredibly important for clinicians and scholars worldwide to be aware of as we strive to re-envision ACP, so that people are more comfortable engaging in ACP conversations. In terms of the content of tweets, we argue that there is a chasm between the biomedical and biopsychosocial elements of ACP, including patient narratives. If used properly, Twitter conversations and National Health Care Decision Day hashtags could be harnessed to serve as a connecting point among organizations, physicians, patients, and family members to lay the groundwork for the trajectory toward a *good death*.

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KEYWORDS

advance care planning; National Healthcare Decisions Day; Twitter; good death; hashtag activism; topic modeling; social media; end of life

Introduction

Background

Death and dying are unavoidable realities for all humans but remain taboo and subsequently avoided topics within most Western societies, especially in the United States, which has been referred to as a death-defying culture [1-4]. Prince-Paul and DiFranco [3] argued that death and dying are public health issues [3]. Indeed, complications with end-of-life (EOL) processes extend across the globe as there are social, economic, political, and historic perspectives influencing communication about mortality [4,5]. The stigma surrounding death, lack of awareness, inadequate health literacy, negative public perceptions, systemic barriers, and cultural differences also influence society's reluctance to discuss issues related to potential EOL health care needs and expectations [5-14].

Since as early as the 1960s, many efforts have been made in the United States to promote engagement in advance care planning (ACP) conversations to encourage opportunities to express goals for EOL care and formally document those wishes in a written advance directive (AD) [4,12-14]. According to a (2017) consensus definition from a global panel of experts, "Advance care planning enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and health-care providers, and to record and review these preferences if appropriate" [13].

Part of this planning process includes the creation of an AD. According to the National Institute of Aging, ADs refer to written legal documents expressing one's values and preferences related to EOL care, which can be modified throughout one's lifetime [14]. This document is then retained and only goes into effect if a person is unable to speak for themselves. Recent efforts to promote ACP in the United States include *My Five Wishes*, *The Conversation Project*, *The Stanford Letter Project*, and *Death Cafes*. However, despite these efforts, low rates of ACP and the completion of ADs persist [15].

Presenting *opportunities* to engage in a public dialog about death and dying to normalize these difficult conversations and reduce the stigma surrounding death may improve public discourse and eventually lead to an improvement in ACP rates [3,16,17]. Specifically, recent work suggests that the presence of high engagement among health care participants throughout the EOL experience can increase the likelihood of a *good death* [17]. Although this does not mean that one's death will be completely painless or without complications, it does help ensure that the dying experience is as good as possible for all parties involved. A particular opportunity to promote engagement in planning and preparing for EOL care in the United States is National Healthcare Decisions Day (NHDD), an observance dedicated to communicating about EOL by advocating for ACP [18].

Scholars have pointed to the potential of the internet, as well as social media platforms, to facilitate discussions, information sharing, and social support around challenging health topics, such as cancer [19-21], and reduce mental health stigma [22]. In particular, Twitter has been studied as a tool for communicating about cancer [20], human papillomavirus vaccines [23], and Alzheimer disease [24]. Recent work has indicated that Twitter can be a useful tool for health care participants to communicate about ACP, suggesting that "Twitter is a new avenue for patients, clinicians, and advocates to engage with each other to better understand each other's perspectives related to ACP" [25]. Key to the diffusion of information and the creation of communities on Twitter is the use of hashtags, which could serve to unify discourse and induce a sense of support and belonging [26,27]. Coupling this with recent calls to reconsider approaches to ACP [9,28-30], we extend this work as this study situates Twitter as a social media tool and relevant NHDD hashtags as a mechanism to engage in conversations related to ACP.

Achievement of a Good Death

Although possibly appearing contradictory in nature, the concept of a *good death* carries a great deal of significance for patients, loved ones, and health care participants alike [17,31]. Although each person's perception may differ on how a good or successful death would be defined by them personally, there are commonalities with what this experience entails. Such experiences are constructed of elements related to physiological, social, existential, and spiritual components [32], which are then reflected in specific actions such as pain management, being in the presence of loved ones, and respecting the patient's values and wishes [33,34]. However, a *good death* manifests itself differently for each person, considering their history, cultural background, attitudes, health conditions, and personal views and attitudes toward death [35]. Although much work has been dedicated to establishing a more positive death experience, the ability to die well continues to be inhibited by several challenges, including poor communication, physical and systemic barriers, lack of knowledge related to the disease trajectory, and discontinuity of care [17]. A recent commission put forth a report to help refocus on and find value in death. Five principles were offered to help re-envision death and dying, including "the social determinants of death, dying, and grieving are tackled; dying is understood to be a relational and spiritual process rather than simply a physiological event; networks of care lead support for people dying, caring, and grieving; conversations and stories about everyday death, dying, and grief become common; and death is recognized as having value." [5]

In an attempt to make sense of the dying process and find value amidst death, we present the *Opportunity Model for Presence During the EOL Process* (OMP-EOLP) and argue that for a quality dying experience to take place, health care participants must be included at every step of a health care journey [17]. Opportunities for presence include integrating such conversations into the sociocultural context of individuals, which helps normalize and reduce the stigma of engaging in EOL conversations. Specifically, the biopsychosocial and spiritual elements of health care participants and their values and culture, including media exposure and language, make up the sociocultural context. As the conversation starts in a sociocultural context, it continues when either a terminal diagnosis is made or returns to a conversation regarding ACP throughout the normal aging process. Additional opportunities for presence during the EOL process include the place of care,

knowledge about family members' health status, and the moment of death. With high engagement at each step of the way and by having a *presence check*, the opportunity to die well is improved. We argue that from a public health perspective, ACP conversations using Twitter can influence engagement throughout the EOL process.

About NHDD

Occurring annually on April 16 in the United States, NHDD exists to inspire, educate, and empower the public by providing information regarding the importance of ACP [18]. First founded in 2008, the NHDD was created with the goal of providing clear, concise, and consistent information related to health care decision-making [36]. Since then, the initiative's goal has been to target the general public, health care providers, and facilities to provide free, simple, and uniform tools to guide this process [37]. Now managed by *The Conversation Project*, started by Ellen Goodman in 2010, NHDD is described as a *public engagement initiative* [18], which was started by Goodman when she and a group of colleagues started sharing personal stories related to *good* deaths or *hard deaths* they had witnessed. The NHDD serves to encourage patients to express their wishes regarding their health care. In turn, this effort also exhorts providers and facilities alike to respect such wishes, regardless of what is expressed or asked for. Although efforts related to NHDD comprise community interventions, interpersonal interactions, and in-person events, such efforts have also been conducted on the web. This includes the integration of web-based toolkits featuring ACP resources, as well as engaging viewers on social media platforms such as Twitter [25].

Hashtag Activism and NHDD's Presence on the Web

Key to the flow of information in web-based campaigns is the use of consistent and widely shared hashtags. From *#BlackLivesMatter* [26,27] to *#OccupyWallStreet* and *#MeToo* [38], hashtags have been used in recent years as an efficient way of solidifying networked activism and diffusing discourse around social issues. Beyond connecting social media users using similar linguistic symbols, hashtags are also useful for broadening discursive communities, for example, by attracting the attention of journalists and other elites [39]. Hashtags have been used to promote public health interventions, causes, and events and facilitate 2-way communication between public health officials and the public on multiple occasions, such as *#LiveFitNOLA* [40] and *#GetUsPPE* [41]. In fact, so potent is the use of hashtags for health campaigns and discussions that in the realm of vaccines, they were used both by those promoting science, such as the provaccine *#DoctorsSpeakUp* [42], and malicious actors who hoped to sow discord among Americans, such as the Russian Internet Research Agency's use of the antivaccine hashtag *#VaccinateUS* [43]. Most recently, Cutshall et al [25] focused on ACP and brain tumor stakeholders with *#BTSM* (brain tumor social media), connecting such hashtag engagement and related activism efforts and extending it to advance efforts toward EOL care, specifically ACP.

Methods

This Study

This study examines the intersection of ACP Twitter conversations surrounding hashtags related to NHDD and how communicated tweets fit into the sociocultural context as an opportunity for engaging in EOL conversations. Specifically, it looks at how EOL, ACP, and NHDD are discussed among Twitter users and what conversations might be able to tell us in terms of individuals' attitudes and potential behavioral intentions regarding ACP. In light of this, we pose the following research questions (RQs):

- RQ1: In regard to *NHDD*, what were the prominent topics of conversation in the tweets?
- RQ2: Who was leading the conversations regarding *NHDD*?

With this, we analyzed tweets published over a full year, between August 1, 2020, and July 30, 2021 (N=9713), to understand how social media had been used as a tool for promoting a day dedicated to making health care decisions, which we call discussions of ACP. For the purposes of this study, we use the term ACP to broadly encompass the whole process of engaging in conversations about EOL goals of care, regardless of whether an AD is completed.

Data Collection

As our theoretical focus is on the unification of language around hashtags, we curated a list of hashtags that were centered on NHDD by reviewing what the holiday was about and which hashtags were used. We also went to Twitter to search for related terms and then collected all tweets containing the following hashtags: *#nhdd*, *#advancecareplan*, and *#goalsofcare*. To identify discourse around the NHDD that did not use hashtags, we also collected tweets using the exact terms *national healthcare decision day*, *advance care plan*, *goals of care*, and *goals-of-care*. Using these keywords, we collected all available tweets published between August 1, 2020, and July 30, 2021 (N=9713) on Twitter using the company's academic application programming interface (7410/9713, 76.27% after removal of duplicates).

Procedure and Measures

Identifying Themes in the Corpus

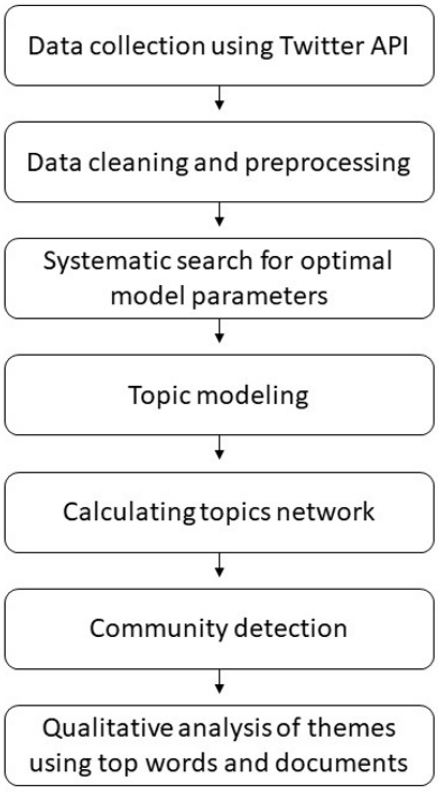
Our inductive modeling of the corpus relied on the Analysis of Topic Model Network (ANTMN) framework [44]. The ANTMN method suggests a four-step process: topic modeling, topic networking, community detection, and qualitative analysis, as shown in Figure 1. Topic modeling (in this case, using latent Dirichlet allocation) is an unsupervised machine learning method that identifies themes in large textual data [45]. The modeling's unsupervised, inductive nature makes it especially useful for work with corpora in which the set of possible topics and themes is not known a priori [46]. Topics are distribution lists of word probabilities based on their co-occurrences in the same documents (in our case, Twitter posts and tweets). Importantly, although the modeling stages were performed inductively and with no reliance on prior theory, after automated modeling, researchers interpreted the results by qualitatively studying the

most common words related to each topic and the most representative documents for each topic. Harnessing the breadth of the data, we also looked at dynamic changes in prevalence topics and themes over time.

Following the standards in communication research [46], we preprocessed the corpus by removing stop words, punctuation, numbers, and symbols and converted all text to lowercase. We refrained from stemming or lemmatization based on the recommended best practices in topic modeling [47]. For hyperparameter tuning, aimed at accounting for the short nature of the texts examined [43], we used 5-fold cross-validation iterating over a range of topic numbers (from k=5 to k=100, in *skips* of 5) and various levels of the α hyperparameter (α=.01, .05, .1, .2, and .5). We found that the model with k=30 and α=.01 offered optimal results based on perplexity scores [43]. Topics were labeled qualitatively by examining the top words, unique words, and documents representative of each topic. To avoid biases in modeling, the topic model was conducted on a sample without duplicates (7410/9713, 76.27%), and analyses of changes over time were conducted on the full sample (N=9713).

In ANTMN's second step, a network of topics was calculated based on the co-occurrence of topics in the same tweets (calculated as the cosine similarity over the document topic matrix). We used these similarities as links in the network where each topic served as a node and their co-occurrence as the link. To remove spurious links and reduce network density, we used a backbone method [48] to discard nonsignificant links. In the third step, we used a community detection algorithm based on the eigenvectors of matrices [49] to group the topics into broader themes. Finally, we qualitatively analyzed the model and its output and labeled each theme based on this close reading. Our qualitative analysis, described in the following section and in the *Results* section, is based on the automated identification of these themes.

Figure 1. Overview of the Analysis of Topic Model Network approach and methodology. API: application programming interface.



Qualitative Analysis

Following the ANTMN approach's fourth step [44], we engaged in qualitative discourse analysis [50], focusing on the language surrounding the making of health care decisions, the meaning surrounding ACP and EOL, and the context in which ACP conversations do or do not take place to understand the nuances of tweets related to NHDD in light of 3 specific theoretical and practical perspectives. The first is the NHDD mission and the ACP explaining the following:

> *National Healthcare Decisions Day [NHDD] exists to inspire, educate and empower the public and providers about the importance of advance care planning. NHDD is an initiative to encourage patients to express their wishes regarding healthcare and for providers and facilities to respect those wishes, whatever they may be [18].*

Second, we focused on Twitter discourse in the conceptual framework of the OMP-OELP [17], specifically the sociocultural context of ACP conversations. Finally, we examined Twitter as a tool that can be used for activism, particularly in advocating for engagement in ACP. A total of 4 authors, 2 of whom were experts in EOL communication and 1 a PhD-prepared registered nurse with specialty certification in palliative and hospice care, reviewed the tweets and model to become familiar with the most representative texts and words associated with each topic.

We were then able to begin to group similar ideas and content together. This process guided the labeling and definition of each topic. The final step in the qualitative analysis was reviewing the discourse for unique cases, defined as "data that demonstrate sharp contrasts with the major pattern that accounts for most of the data" [51,52], or, in this case, outstanding tweets that were relevant in the EOL process but were so exclusive that the nuance was important to take note of to see how the discourse remained thematically in the data set or stood on its own.

Results

Overview

Before analyzing the data in response to our RQs, we examined descriptive statistics indicating the most used hashtags, as well as the most liked and retweeted tweets, to better understand the discourse surrounding NHDD hashtags. Descriptive information of the gathered tweets is shown in Table 1.

Table 1. Descriptive information from the corpus.

Descriptive information	Value, n
Unique users	6974
Unique tweets	1986
Average character length	172

Top Hashtags

We identified multiple shared hashtags related to different goals or aspects involved in or affecting ACP. The first top hashtag we saw was *#NHDD* (728/9713, 7.5%), specifically linking tweets to conversations about NHDD. The second was *#COVID19* (371/9713, 3.82%); the third was *#goalsofcare* (202/9713, 2.08%); the fourth was *#PalliativeCare* (160/9713, 1.65%); and finally, the fifth was *#NationalHealthcareDecisionsDay* (141/9713, 1.45%). It is important to note that there is some overlap in the hashtags used (ie, *#NHDD* vs *#NationalHealthcareDecisionsDay*) because of differences in capitalization, spelling, or abbreviations. The top 10 hashtags used in tweets can be found in Table 2.

Table 2. Frequency of the top 10 hashtags used in tweets from the corpus (N=9713).

Hashtag	Frequency, n (%)
#NHDD	728 (7.5)
#COVID19	371 (3.8)
#goalsofcare	202 (2.08)
#PalliativeCare	160 (1.65)
#NationalHealthcareDecisionsDay	141 (1.45)
#AdvanceCarePlanning	132 (1.36)
#ICU	128 (1.32)
#advancecareplanning	108 (1.11)
#GOCCNJ	106 (1.09)
#hapc	101 (1.04)

Most Liked Tweets

We also analyzed different forms of engagement. This included tweets that received the most likes from other users across the data set. Shared here are the top 3 most liked tweets; the remaining tweets can be found in Table 3. First, the tweet with the greatest number of likes received a total of 893 likes and stated the following:

> *Maybe I'm crazy, but I think surgery interns should do a palliative medicine rotation. I learned how to have successful goals of care discussions from multi-disciplinary meetings where palliative was involved. It's an invaluable skill that most of us don't get formally taught.*

The next most liked tweet was from another individual, which received 594 likes. Here, they stated the following:

> *You need to let them talk and listen carefully. After that, you should try to phrase the goals of care with your own words. "Based on what you told me, we should probably focus on comfort and make sure he doesn't suffer any more."*

Finally, the third most liked tweet was from the same user referenced above. This message received 589 likes and stated the following:

> *One of my favorite consults is goals of care BEFORE high-risk CT [cardio thoracic] surgery. Why palliative care/GOC [goals of care] before surgery? It is because we need to have a high-quality conversation, in very challenging cases. In my opinion, there must be 2 phases of conversations.*

Table 3. Top 10 most liked tweets from the corpus.

Tweet	Likes, n
"Maybe I'm crazy, but I think surgery interns should do a palliative medicine rotation. I learned how to have successful goals of care discussions from multi-disciplinary meetings where palliative was involved. It's an invaluable skill that most of us don't get formally taught."	893
"You need to let them talk and listen carefully. After that, you should try to phrase the goals of care with your own words. 'Based on what you told me, we should probably focus on comfort and make sure he doesn't suffer any more'"	594
"One of my favorite consults is goals of care BEFORE high-risk CT surgery. Why palliative care/GOC before surgery? It is because we need to have a high-quality conversation, in very challenging cases. In my opinion, there must be 2 phases of conversations."	589
"A fun little thing I like to do as a palliative consultant is base my recommendations on the patient's goals of care."	427
"Two most common questions I ask when accepting a patient to the ICU (from any setting): (1) did you address goals of care? (2) can you please turn off the maintenance fluids?"	398
"If you're referring someone to me for a goals of care discussion I give you preemptive permission to discontinue their statin"	391
"A family meeting to determine goals of care over the PHONE (not even video) in a foreign language (with an interpreter) with an unknown number of people is a new kind of hell I hope to not revisit."	347
"#PalliativeCare friends, if you're in the hospital and doing Advanced Care Planning, ask the patient if nursing students can come and listen. In my 4 yrs of nursing school I never learned how to talk about ACP or about goals of care. It's an invaluable lesson to learn. #hapc"	344
"Working in the ICU last month taught me a lot of things. Yes, all providers need more training in end of life discussions. But we also need to unlearn the ableism that influences our goals of care and quality of life discussions."	342
"18. The number of families I updated today. 12. The number of days left on COVID unit 10. The number of minutes I sat down to eat. 6. The number of concurrent goals of care conversations I had in a 2hr span. 1. The one pt who told me she is ready to go. Time to rest for the day."	275

Most Retweets

Finally, another way we examined engagement was by evaluating the number of retweets in Table 2 among messages shared. Once again, we saw consistency in users, as the most retweeted tweets came from the same person with the second and third most liked tweets. As seen previously, this tweet received 127 retweets and stated the following:

> *One of my favorite consults is goals of care BEFORE high-risk CT [cardiothoracic] surgery. Why palliative care/GOC [goals-of-care] before surgery? It is because we need to have a high-quality conversation, in very challenging cases. In my opinion, there must be 2 phases of conversations.*

The second most retweeted message received a total of 123 retweets and was from the *Journal for Geriatrics Clinical Science.* Here they shared the following:

> *Frailty is a key predictor of COVID-19 prognosis, and its assessment alongside measures of acute morbidity, rather than age alone, might help clinicians in offering realistic goals of care in hospitalized patients with #COVID19. #geriatrics.*

Finally, the third most retweeted tweet was from *Intensive Care Medicine*, an international peer-reviewed medical journal for intensive care medicine. With a total of 119 retweets, they shared the following:

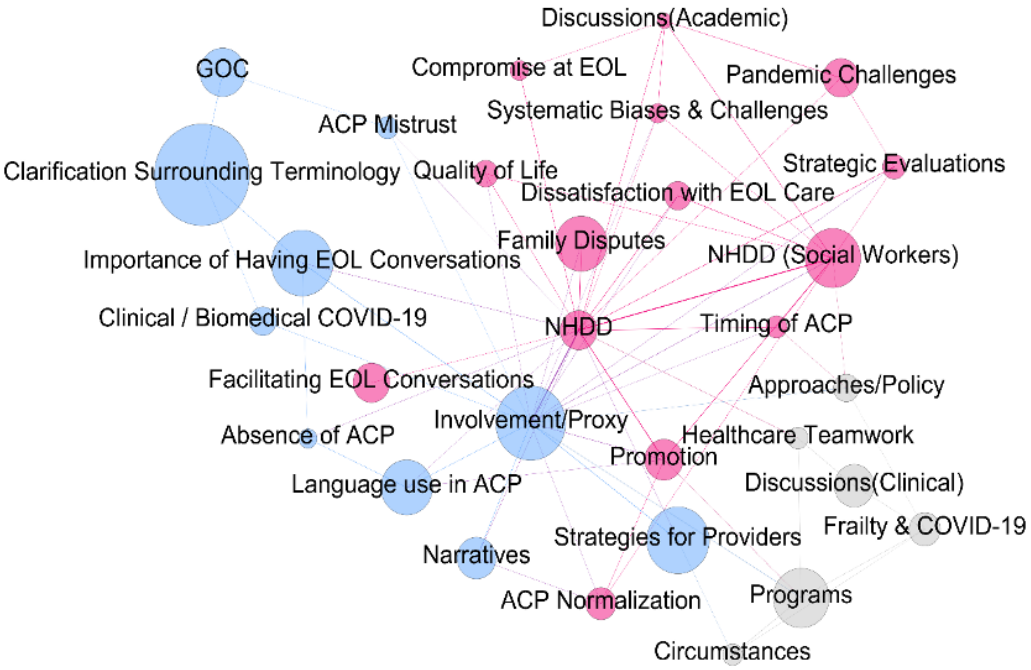
> *Long-term outcome of elderly [= 80y] #COVID19 pts admitted to #ICU: 6-month mortality...72% [likely underestimated] at upper end of recent literature on older critical pts. Data supporting more informed goals-of-care decisions for this #SARSCoV2 cohort*

Addressing the RQs

Overview

RQ1 asked what the prominent topics of conversation were in regard to NHDD during the studied year. A complete list of themes and their corresponding topics is provided in Multimedia Appendix 1. The ANTMN [44] model of 30 topics revealed 3 distinct themes. On the basis of a qualitative analysis of the most representative texts and words, we were able to label each of the 30 topics. Then, upon further qualitative analysis of the 3 themes, we were able to appropriately label and define 3 overarching main themes in the network to encompass conversations. The overarching themes (Figure 2) were *importance and promotion* (red), *the surrounding language* (blue), and *systemic issues* (gray). Each of these is described in greater detail in the following sections.

Figure 2. A topic network using the Analysis of Topic Model Network. The color of nodes indicates the community (theme) associated with each topic. Node size indicates topic prominence within the entire corpus. ACP: advance care planning; EOL: end of life; GOC: goals of care; NHDD: National Healthcare Decisions Day.



Importance and Promotion

The most prominent overarching theme within the corpus was *importance and promotion* (red). Such conversations centered on the notion of NHDD itself, promoting the day among users and highlighting various elements of the ACP process. In addition, in this theme, conversations iterated why ACP is a necessary component of health care interactions, why it should be implemented and not simply limited to the EOL process, and challenges that thwart ACP efforts and success rates.

For example, many users shared information about NHDD and its purpose, such as the following tweets:

> *Today is #NationalHealthcareDecisionsDay. This recognition is designed to educate and empower the public about the importance of ACP. For more information about National Healthcare Decision Day and how to start planning....*
>
> *Advance care planning can reduce a family's anxiety, depression, and stress". #PCC4U*
>
> *Module 4 | Activity 6: Advance care planning and goals of care....*

As shown previously, these conversations aim to increase the audience's awareness that NHDD was taking place; what it was; why it was promoting ACP; and subsequently, why ACP is such a vital component of the health care process.

Conversations using this theme also introduced the idea of creating an AD, including the timing, normalization, and facilitation of and compromises and challenges of EOL:

> *Getting advanced directives is complicated and often generates disagreements w/in family in terms of who has power of attorney. Important to have these in place including goals of care and communicate well.*

The nodes with the highest frequency included NHDD (social workers), family disputes, NHDD, promotion, and facilitating EOL conversations. On the basis of the model, we see that the relationships among NHDD, NHDD (social workers), and promotion is strong. The intersection of the timing of ACP between NHDD (social workers) and promotion illustrates that timing is an important part of the planning process.

The results of the discourse analysis revealed that the promotion efforts using NHDD hashtags reflected the mission of NHDD, which is to educate, inspire, and empower people to have ACP conversations. What we also see is the identification of problem areas or issues with ACP, which can be helpful to those initiating conversations from a clinical perspective and for awareness of the current state of ACP; that is, an agreement that having conversations is important but not that simple. Having one or more conversations about EOL wishes does not guarantee a smooth or high-quality EOL process. This is critical when applied to the OMP-EOLP, and public dialog is related to EOL taking place [3,14,16], in this case, via Twitter. The opportunity for presence is achieved through social media engagement. However, this is only 1 factor in the OMP-EOLP, and the continued high level of engagement of health care participants needs to follow the EOL trajectory. Although we cannot evaluate the success of this in this study, we argue for both academics and clinicians that an understanding of conversation at a public health level is necessary so that future efforts can be tailored more effectively to meet the needs of health care participants. A balance between promoting the positive aspects of ACP and understanding the barriers to ACP, including the ongoing pandemic, is essential.

Surrounding Language

The second theme, *surrounding language* (blue), focused on the language used for clarification and guidance within ACP

conversations. Specifically, we examined the linguistic choices and phrasing used when communicating about ACP. Within tweets using these topics, a large area of discussion described the need for clarification surrounding terminology. For example, dialog encompassed distinguishing goals of care from *code status* (physician orders for resuscitation or *do not resuscitate* [DNR]) and the continuing need to define goals of care for patients or care residents. Even among professionals, conversations noted how there were misunderstandings about what ACP entailed and how it differed from other aspects of care, particularly within the context of the patient's diagnosis, prognosis, treatment options, and care needs. For example, a user tweeted the following:

> *Palliative care in R/R [relapsed/refractory] aggressive lymphomas:*
>
> *- PC ≠ Hospice care or end-of-life care*
>
> *- PC integration is low: too late and less than in solid tumors*
>
> *- Identify triggers for goals of care discussions*
>
> *- Collaboration between specialists.*

Although most of this dialog pertained to clinical conversations (ie, strategies for providers, clinical and biomedical conversations related to ACP during COVID-19, and involvement of health care proxies), there was a small portion of dialog reflecting on patients' experiences with ACP. We found that ACP was discussed in light of personal narratives, noting their experiences and stories of how the presence or absence of ACP affected the dying experience. For example, a user tweeted the following:

> *From a darling, deteriorating, elder contemplating goals of care "Tell me, sweet nurse, shall I die slowly or quickly?" I choked back my tears and replied "How about a goal of peacefully and let time do what it will." Then we just sat in silence and held hands.*

Many narratives, such as the abovementioned one, describe sad, emotional experiences when the patient is either close to death and is forced to consider goals of care and EOL wishes or when a practitioner or loved one reflects on poor death experiences that could have been made better by successful ACP. Shared publicly, these narratives could act as a unique educational tool, harnessing storytelling to emphasize the benefits of ACP, as well as the struggles associated with completing it at later stages. Other narrative efforts included video games or apps developed to make ACP conversations easier, adapting more of an entertainment–education approach to further ACP efforts, which communicates the importance of ACP in a different language rather than in clinical conversations.

The results illustrate another way in which language clarified that the realities of ACP were through expressing mistrust in ACP processes, claiming that if they (patients) filled out ADs, it was an initiative for physicians to reduce their level and quality of care. This is an alarming misperception that emerged from the data. Furthermore, this mistrust appeared to be fueled by the misbelief that engaging in ACP would expedite the dying process for the patient. Such tweets featured charged and accusatory language, which points to misinformation surrounding ACP and EOL processes and provides insights into the potential reception of such information. An example included a health care professional tweeting the following:

> *Sometimes people mistakenly think DNR means "don't do anything." Remember, DNR only goes into effect when a patient codes [cardiac arrest]. A DNR order is not a substitute for a goals of care discussion. They are not the same thing. #MedTwitter #CriticalCare #GoalsOfCare*

This tweet was part of a larger conversation, discussing the misunderstandings of concepts such as a DNR order and how having a DNR order does not mean that physicians will not work as hard to care for them if completed. Identifying such misunderstandings in ACP demonstrates how Twitter can be used as a tool for activism to clarify the purpose, definitions, and information for those in the community.

Our results indicate that the language surrounding ACP tended to portray it as important but not without challenges, as evidenced by the fact that NHDD is a term that is euphemistic in its own right. By avoiding the use of clear terms surrounding death and dying, although well-intentioned, the lack of clarity can perpetuate confusion among health care providers and the public alike. On the basis of qualitative analysis, goals of care were intertwined with ACP, and a point of discussion and disagreement is whether goals of care equate to ACP. Other similar tweets shed light on how various social issues, such as racism and prior negative health care experiences, also fuel this mistrust, which leads to greater barriers that get in the way of the ACP process. The connection with the OMP-EOLP is that the sociocultural factors of health care participants are at play in ACP conversations on Twitter. It is critical for health care providers to be aware of this mistrust in underrepresented communities. For example, the well-documented mistrust of the health care system in the African-American community stems from unethical research practices such as the Tuskegee Syphilis study [53]. Support for this connection is illustrated in the Social Determinants of Health framework, wherein there are factors at play that are not biomedical but instead, a result of where we live, work, and age that influences our health [5,54-56].

Systemic Issues

The third overarching theme closely aligned with language use was *systemic issues* (gray). In examining these conversations, such issues or barriers related to ACP were discussed within clinical settings. The conversations documented issues related to the settings in which care was taking place, disparities in care with regard to socioeconomic groups, and subsequent costs related to care. For example, a tweet explained how "many barriers exist [in ACP] due to implicit bias. Lack of appropriate testing, follow-up, and assumptions about goals-of-care – all leading to poor outcomes...." In other words, owing to perhaps prior negative health care experiences or negative attitudes toward EOL discussions and planning, patients can subsequently experience poor outcomes at the EOL. Issues related to COVID-19 and frailty were also common, which elaborated on care options and decisions related to patients diagnosed with COVID-19. Current research related to ACP and COVID-19

indicates that the number of people filling out ACPs is on the rise; however, that does not equate to a successful EOL experience [57].

On the basis of the qualitative results, we see systemic issues uniquely related to marginalized populations, including prisons, specifically, how these populations faced greater barriers in health care settings, which were exemplified at the EOL [58,59]. Further complicating access to EOL care in prisons is COVID-19, when, for the first time, most prisoners are aged ≥55 years, which also begins to overlap with the most vulnerable population for COVID-19 [60]. For a population that includes those who are most vulnerable to COVID-19, with difficulties in practicing social distancing in addition to chronic illness and access to health care, the barriers to ACP are overwhelming.

Another unique consideration for ACP is in the context of Alzheimer disease and dementia-related care. In our data set of the 30 most representative tweets on each of the 30 topics (900/7410, 12.15%), Alzheimer disease was the only specific disease called out, aside from COVID-19, when discussing ACP. However, only a small number of tweets in our manually coded corpus mentioned this (5/7410, 0.07%). As Alzheimer is a terminal disease that attacks the brain and memory functions, we argue that the need for ACP is much stronger. Previous studies on Twitter and Alzheimer disease indicate that there is a stigma associated with the disease [61]. Topics in this theme called attention to barriers in conversations, as well as the differences in care that emerged. Future work should consider diverse and marginalized populations, their unique needs, and how intervention and communication materials may need to be targeted and/or tailored to make processes, such as ACP, more accessible and achievable. In addition, owing to negative past experiences or distrust in health care–related entities, special precautions and care may be needed to facilitate conversations.

Leading NHDD Conversations

Next, RQ2 asked who was leading these conversations regarding the NHDD. Overall, the users appeared to be mostly health care professionals and health-related organizations. However, only 4.09% (303/7410) of tweets were from verified accounts, wherein the identity was verified from Twitter as a public figure or institution, and the remaining 95.91% (7107/7410) were from unverified users; that is, users promoted NHDD on their own as an individual Twitter user, and the message did not directly come from a public figure or institution. From an activism standpoint, NHDD appears to be common among health care professionals but is not promoted specifically by verified accounts. Although this study cannot draw definitive conclusions about the individuals who were tweeting, the heavy use of medical jargon and references to personal experiences working as clinicians suggest that many users were health care professionals.

From the analysis of tweets, we observed dialog among what appeared to be clinical health care professionals, presumably physicians, discussing the medical treatment plans of patients. We also observed a back and forth in tweets wherein messages were congratulatory in nature or provided shoutouts to other professionals on academic-related achievements (ie, conference presentations and paper publication). Tweets were saturated with heavy medical jargon and abbreviations such as *CT*, which means cardiothoracic; *#pallonc*, which means palliative oncology; *#hapc*, which means hospice and palliative care; and the following example, which is full of medical jargon and is further complicated by shorthand for words and potential typographical errors:

> *Keep sats 90 or higher, dex 6mg for 10d if o2 < 92-94%, early GOC talk, chemical dvt ppx for all, remdes maybe?, if really considering abx check procal (only ~2% have bacterial CAP), keep net neg, trial proning, HFNC?> NIV, more goals of care :(*

Loosely translated, the above passage is referring to treatment for a COVID-19 patient and reads as follows:

> *It is important to keep oxygen saturation above 90%, to administer dexamethasone (which is a steroid) 6 mg for 10 days if oxygen saturation and lt (unclear, could be goal for oxygen saturation level) 92-94%, early goals of care talk, chemical deep venous thrombosis prophylaxis for all, remdesivir maybe? If really considering antibiotics check procalcitonin (only around 2% have bacterial community acquired pneumonia), keep net negative, trial proning (lying face down), high flow nasal cannula & gt (unclear, could be referring to gastrointestinal tube (gt) but it is unclear, could also be typo for gtt (drops)), non-invasive ventilation, more goals of care. :(*

The examples illustrate how such conversations among physicians, scientists, and those with occupations related to the medical field are a part of the conversation, but those without the lexicon are unable to follow and understand the conversation.

On the basis of individuals identifying themselves as social workers in their tweets or tweets from large social work organizations, another profession that appeared to be leading conversations regarding ACP and NHDD was that of social workers. Research indicates a lack of consensus among health care practitioners as to who is best suited to lead ACP conversations [62]; however, we see that social workers are currently a part of this process, which past work looking at ACP may have overlooked. Here, social workers may have a large presence in tweets as their profession generally involves them in EOL conversations and, subsequently, in ACP and the completion of AD forms. An example of the presence of social workers included a tweet from the National Association of Social Workers' Colorado chapter, which stated the following:

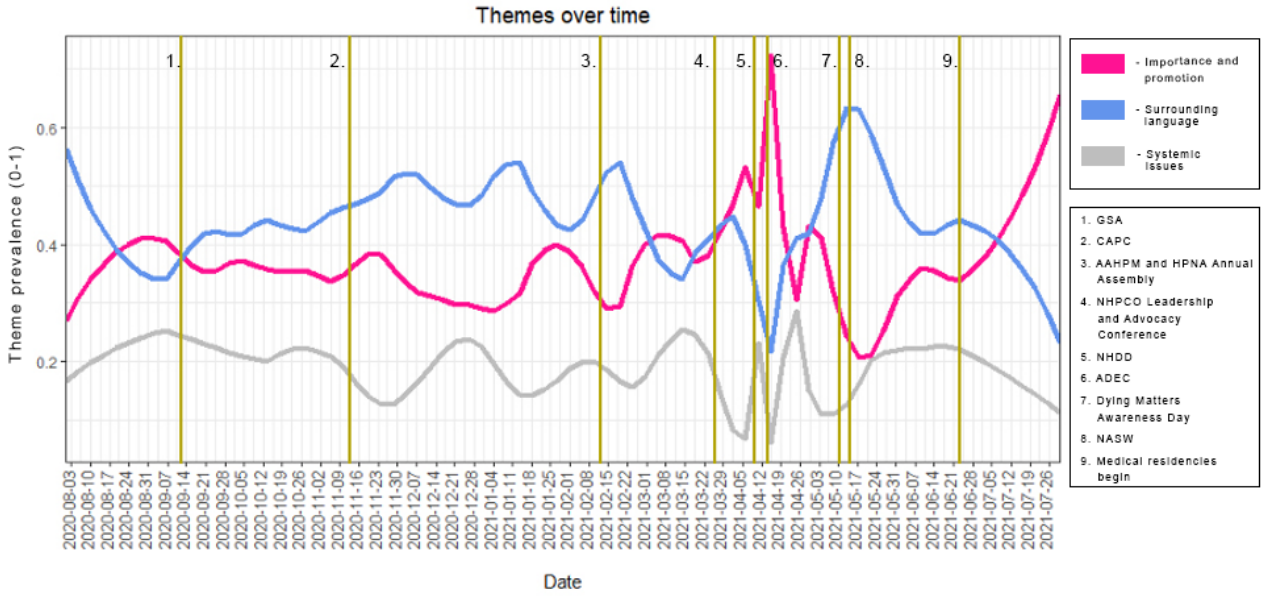
> *April 16th is National Healthcare Decisions Day, which #NASW supports. #NHDD*
>
> *inspires, educates empowers the public and providers about the importance of advance care planning. #Socialworkers have an important role in advance care planning*
>
> *#Covid19.*

By identifying who is leading conversations for NHDD, we can identify a gap in the united front of health care professionals and laypersons advocating for EOL conversations while also educating the public about EOL resources. Knowing who is involved in such conversations is important as it allows us to

better target resources for pre-existing conversations related to EOL wishes and planning. Combining efforts on the part of social workers and other medical practitioners may strengthen and increase the chances of not only AD completion but also following through on adhering to wishes that patients have put forth. We observed a lack of connection in the use of hashtags between clinical (biomedicine) and psychosocial–spiritual providers and family members, perpetuating silos separating the approach and process of ACP.

To examine changes in the composition of tweets over time in terms of thematic use, we examined the frequency and thematic content of tweets throughout the 1-year period and overlaid the major conferences related to NHDD and EOL care (Figure 3). On the basis of this, we can see the spike in tweets around NHDD itself and other conferences taking place throughout the year (indicated in yellow in Figure 3). The problem is that the movement in tweets was not consistent, and presence was more common around professional and academic events than appearing to be a normal or consistent part of the dialog between professionals and laypersons alike, further supporting the notion that ACPs are a siloed effort.

Figure 3. Frequency of themes measured over time from August 2020 to July 2021. Yellow lines indicate professional and academic events coinciding with the timeline. AAHPM: American Academy of Hospice and Palliative Medicine; ADEC: Association for Death Education and Counseling; CAPC: Center to Advance Palliative Care; GSA: Gerontological Society of America; HPNA: Hospice and Palliative Nurses Association; NASW: National Association of Social Workers; NHDD: National Healthcare Decisions Day; NHPCO: National Hospice and Palliative Care Organization.



Discussion

Comparison With Previous Work

NHDD is a niche hashtag that promotes a day in the United States dedicated to educating and empowering people to consider their options for making health care decisions in the event that they are faced with a terminal diagnosis or traumatic event that leaves them unable to speak for themselves. We argue that ACP conversations using Twitter, from a public health perspective, can influence engagement throughout the EOL process. On the basis of the results of the mixed methods study, we argue that who is sharing the information and *how* they do so are important in the engagement process.

The analysis indicated that most tweets were from health care organizations and appeared to be from medical professionals. However, we cannot definitively make assumptions about each user's profession based on the corpus. That said, based on the content in conversations and seeing as it was medically based and filled with technical jargon, we can determine involvement as some form of health care provider or practitioner. In addition, individual users sometimes referenced their own experiences on the job either in hospitals or medical settings, such as medical students or acting physicians. The involvement of such professions in these conversations would make sense, given that Twitter is a social media platform that is used for engaging in public, large-scale, health-related, and oftentimes stigmatized conversations (Tenzek et al, unpublished data, 2022) [19,61]. In practice, this can be helpful for health professionals who need to locate continuing education credits or are interested in attending workshops related to ACP. Furthermore, the social work profession had a large presence in the analysis. Scholars have argued that any health professional could initiate a conversation related to ACP, which is critical in light of COVID-19 [63]. Research suggests that any one of the team members may be the one to engage in a conversation related to ACP with patients, and recently, chaplains have been identified as key professionals in helping with ACP, moving ACP conversations upstream [3,5,57]. We argue that being aware of the opportunities for engagement at different times in the health care experience becomes important for a quality EOL, and collaboratively communicating within the team becomes even more critical to providing quality care [17].

Language, Barriers, and Activism

Next, *how* the message is communicated is also of great importance. Recent work suggests that language choice, including specific words and simplicity, is critical to how people

receive messages related to ACP [64,65]. The results of this study point to the presence of information about this incredibly difficult, complex, and stigmatized topic, which is shared in ≤280 characters. We see in the current results is that it is mostly professionals and clinical terminology about the EOL process from health care providers' perspectives, generally independent from overarching health care facilities or organizations. The professionals who had the right jargon could follow and contribute to the conversation; however, those without the medical dictionary and appropriate hashtag legend to make sense of all the information in tweets may not receive the messages or bypass them if they cannot understand. This means that individual physicians and health care workers are taking this initiative upon themselves to share with and educate others; however, this may be problematic. This study contributes to previous research that argues that engaging in public dialog about ACP must meet the public's perceptions and beliefs about ACP and not of those who already believe ACP is important and have taken action [7]. Furthermore, upon observation, the NHDD hashtag does not directly communicate to audiences that it is an effort to help people plan for death. We should question whether the language choice was intentional in an effort to help audiences be more receptive to a goal-related conversation about health care decisions in general or if the avoidance further reinforces the taboo nature wherein US culture and societies silence this difficult conversation (Tenzek et al, unpublished data, 2022). On a global scale, we see efforts in England called *Dying Matters* and *Good Grief* and *Good Death* in Scotland, where there is no question about what will be discussed. We argue that in the sociocultural context, using language as an opportunity for engagement is critical, and further studies should examine people's perceptions of willingness to talk about dying based on the hashtag being used.

Although the hashtag NHDD promotes ACP conversations, what we also see is the identification of systemic barriers, including sociocultural elements related to literacy levels, misinformation, policies (including Medicare reimbursements), and trust among health care professionals. Our analysis revealed unique ACP considerations, including patients with Alzheimer disease and prison populations, which are complex and stigmatized issues in health care. Using the Social Determinants of Health framework [5,54-56] in connection with the OMP-EOLP, we suggest a shift in ACP conversation to focus more broadly on the issues of literacy, access, and trust in health care as a resource for individuals. A recent study found that although 80% to 90% of people may be aware of ACP and believe that it is important, less than half (10%-41%) actually named a proxy or filled out a form [7]. It appears that education and awareness may not be the biggest barriers to ACP; people are aware that it exists, but there may be little action toward identifying specific wishes for care along the EOL continuum from diagnosis through death [17]. Morrison et al [30] argued that unless the health care system supports goal-centered care and provides resources to follow through with physician-patient conversations and consequential delivery of care, ACP outcomes will fall short of the intended goal; that is, providing the care at EOL that the patient wants. We see this conversation taking place on a global scale, as internationally, there are efforts to bring value back into the EOL [5].

Finally, in terms of activism and based on the argument of having to address ACP at the public health level, Grant et al [7] suggest, "public messaging that introduces these services to the public should differ from the skilled communication that clinicians perform at the bedside of patients with a serious illness" [7]. In doing so, part of the health care experience is ACP throughout a lifetime, not only at EOL, thus shifting ACP conversations upstream [3,66]. This is incredibly important for clinicians and scholars to be aware of as we strive to re-envision ACP so that people are more comfortable engaging in ACP conversations. In terms of the content of tweets, we argue that there is a chasm between the biomedical and biopsychosocial elements of ACP, including patient narratives. Aligning with Cutshall et al [25], if used properly, Twitter conversations and certain hashtags can be harnessed to serve as a connecting point among organizations, physicians, patients, and family members. It is a difficult but worthy effort to lay the groundwork for the trajectory toward a *good death*.

Limitations

Although this study served as an analysis to examine conversations surrounding NHDD, this work explored a snapshot in the time surrounding NHDD in 2021. However, NHDD has been occurring for 13 years. The analysis also captured NHDD hashtags during the ongoing global pandemic, when death was omnipresent across news platforms [5]. We were not able to compare hashtag use in a pandemic, nor were we able to definitively determine the authors of the tweets. On the basis of our findings and a recent report of the *Lancet* Commission to reimagine death, the pandemic may have further stigmatized, instilled fear, or created hesitancy toward engaging in EOL conversations [5]. Future work should explore prior conversations to reveal trends or changes in conversations over time and delve further into the implications that COVID-19 has had on how we discuss dying. Our observation is that the tension between recent efforts at reimagining and upstreaming ACP, both in the United States and on a global level, and the negative impacts of COVID-19–related deaths present new challenges in finding the value in dying.

A second limitation is that the tweets examined were only from publicly shared accounts. This means that other conversations about NHDD and ACP could exist that we could not capture. This may explain why most tweets were from professionals or organizations where the day was promoted and known within the context of EOL. The key is figuring out how to continue to promote and inform the public in the United States about NHDD and, subsequently, about ACP. As the use of social media continues to be part of our daily lives, we argue that Twitter can also be used to promote EOL processes. Third, although Twitter is becoming more popular as a way of engaging in discussions encompassing diverse perspectives without geographical boundaries, current trends in social media use indicate that other social media platforms such as Facebook and Instagram have more users. In addition, with the rise of TikTok during the COVID-19 pandemic [67], researchers should consider moving toward building a bridge that connects social media messages related to ACP across platforms and users alike. Finally, future studies may go beyond the text of tweets to

examine external links [68], visual communication [69], and communication across different social media [70].

Conclusions

Overall, this study explored Twitter conversations surrounding the NHDD and, subsequently, ACP. Twitter conversations were centered on topics related to promotion, language, and systemic issues. Tweets portrayed ACP as a crucial and necessary tool, especially within the EOL context; however, Twitter users also raised concerns and criticisms about ACP that require additional research to disentangle and create specialized campaigns to address barriers and bias in the health care system. Although several prominent conversations did occur across Twitter, the present analysis shows that there is still work to be done regarding the successful integration of ACP into common everyday practice and conversation. This study allows us to see what is present and subsequently lacking in ACP conversations. In turn, the findings can aid in structuring interventions to help better promote NHDD and help practitioners and patients alike reap the benefits of ACP. Ultimately, the findings can provide more opportunities for conversations about ACP and hopefully encourage open communication about EOL decision-making and planning as a foundation for future presence through the EOL process.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Overarching themes, individual topics, theme notes, and exemplar tweets from each topic.
[DOCX File , 40 KB - formative_v6i4e35795_app1.docx]

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Abbreviations

ACP: advance care planning
AD: advance directive
ANTMN: Analysis of Topic Model Network
DNR: do not resuscitate
EOL: end-of-life
NHDD: National Healthcare Decisions Day
OMP-EOLP: Opportunity Model for Presence During the End-of-Life Process
RQ: research question

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Original Paper

An mHealth Self-management System for Support Children With Acute Lymphocytic Leukemia and Their Caregivers: Qualitative Co-design Study

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Abstract

Background: The unique features of smartphones have extended their use in different fields, especially in the health care domain. These features offer new opportunities to support patients with chronic conditions by providing them with information, education, and self-management skills. We developed a digital self-management system to support children with cancer and their caregivers in Iran (low- and middle-income country).

Objective: This study is aimed at the development and preliminary evaluation of a cancer self-management system (CanSelfMan) tailored to the needs of children with cancer and their parents or caregivers.

Methods: This study was conducted in collaboration with a multidisciplinary team between January and February 2020 at MAHAK's Pediatric Cancer Treatment and Research Center. We developed a self-management system in six stages: requirement analysis, conformity assessment, preparation of educational content, app prototyping, preliminary evaluation, and developing the final version.

Results: A total of 35 people (n=24, 69% parents and n=11, 31% children) volunteered to participate in the study. However, only 63% (15/24) of parents and 73% (8/11) of children were eligible to participate. By adopting a user-centered design approach, we developed a mobile app, CanSelfMan, that includes five main modules (knowledge base, self-management tips, self-assessment report, ask a question, and reminders) that provide access to reliable information about acute lymphocytic leukemia and the self-management skills required for side effect measurement and reporting. A web-based dashboard was also developed for oncologists and included a dashboard to monitor users' symptoms and answer their questions.

Conclusions: The CanSelfMan app can support these groups by providing access to reliable information about cancer, facilitating communication between children or parents and health care providers, and helping promote medication adherence through a reminder function. The active participation of the target group can help identify their needs. Therefore, through the involvement of stakeholders such as patients, caregivers, and oncologists in the design process, we improved usability and ensured that the final product was useful. This app is now ready to proceed with feasibility studies.

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KEYWORDS

digital health; eHealth; mHealth; mobile app; smartphone; mobile phone; self-management; patient education; children; caregivers; acute lymphocytic leukemia; user-centered design

Introduction

Background

More than 90% of children worldwide live in low- and middle-income countries (LMICs) where accessing high-quality health care is difficult or expensive [1]. On the basis of the Global Cancer Inventory reports, by 2025, the number of new cancer cases will be higher in LMICs than in other regions [2]. Although the incidence of cancer is very low in children compared with adults, it is still the second leading cause of mortality among children, even in high-income countries [3]. It is predicted that, by 2030, approximately 60 million children will die worldwide because of cancer before the age of 5 years [4]. Iran is a developing country with a population of approximately 84 million. Similar to most LMICs, there are no precise statistics on childhood cancer in Iran [1]. The results of a systematic review showed that the incidence rate of pediatric cancer in Iran is 16.5 per 100,000, which is slightly higher than that in other countries [5]. Moreover, reports related to provincial registries indicate that leukemia (with a prevalence of 30%) is the most prevalent type of cancer among children in Iran, similar to other countries [6-8].

Approximately 80% of all the cases of leukemia in children are of the acute lymphoblastic type [9]. The common treatment for this disease is chemotherapy, which causes severe side effects [10-12]. The intensity of the symptoms and their effects on the child are sometimes so high that without the ability to control and manage these symptoms, they may lead to hospitalization or even withdrawal from the treatment plan by the patients and their families [13,14]. Furthermore, patient management at home is highly challenging for patients, families, and caregivers [15]. These challenges include the ability to manage complex therapeutic protocols (eg, diagnosis and measures to control the symptoms), proper nutrition diets, coping with psychological side effects, and interacting with the health care system during the treatment plan [16]. These challenges are especially complicated in children and adolescents with chronic conditions, and adherence to therapeutic protocols in this group is <50% [17]. Therefore, empowering patients by providing information and self-management skills is a key factor in reducing side effects and improving their quality of life [18], especially for the parents who usually do not have sufficient knowledge of the disease, treatment, and symptom management [19].

The results of studies specifically examining the role of educational interventions among children with acute lymphocytic leukemia (ALL) and their parents indicated that information provision and increasing parents' knowledge about the disease greatly supported the family, enhanced parents' ability to take care of their children, and considerably improved the family's quality of life [20-23]. Consequently, patient education and the provision of information are major responsibilities of health care providers during the treatment period [24]. However, factors such as the multiplicity of tasks and limited time for education are the primary barriers to the full exercise of this responsibility [25,26]. As a result, they cannot spend enough time on patient education [27], and most of this instruction is provided by nurses via educational pamphlets or in-person sessions [20,28], which alone does not greatly affect health-related behaviors and outcomes [29]. For instance, approximately 40% to 80% of the information provided orally to patients is immediately forgotten, and half of the information is probably recalled incompletely or erroneously [30]. Using pamphlets does not seem to be a good method because it eliminates interactions and provides the same level of information for people with different levels of literacy and needs [31]. Therefore, there is a need for new methods to empower and enhance the knowledge of this group [32].

One such method is self-management, which is currently one of the best methods for cancer management [33]. Self-management emphasizes the role of education in preventive and therapeutic care activities [16]; highlights the role of the patient or caregiver in symptom identification, assessment, and reporting to health care providers; and helps the adoption of suitable measures for symptom prevention or control [34,35]. Usually, self-management interventions are implemented with the participation of health care specialists [16]; therefore, with the participation of clinical specialists, patients, and families, they can enhance patients' knowledge and empower them to achieve therapeutic goals in different stages of treatment [33,35]. Studies show that even short periods of self-management education provided by health care specialists have positive effects on clinical outcomes [25] and increase the patient's ability to control their chronic condition, thereby improving their quality of life [33,36]. An important feature of self-management interventions compared with conventional patient education programs is the customization feature that makes it suitable for use by every person [37].

This feature is made possible using information and communication technology tools such as smartphones [38]. The unique features of smartphones, such as accessibility, internet connectivity, and supported third-party apps, have extended their use in different fields, especially in the health care domain [39,40]. These features offer new opportunities to support patients with chronic conditions and provide them with information, education, and self-management skills. The World Health Organization introduces mobile health (mHealth) as a "domain of digital health aiming to provide or receive health-related information and services by using mobile communication and portable devices, e.g., cell phones, patient monitoring devices, personal digital assistants, and other wireless devices" [41,42]. The use of mHealth provides an opportunity for children and their families to receive information and education without visiting health care centers and specialists, control their condition through self-management, and enhance their quality of life [43,44].

Although the successful implementation of self-management programs requires the participation of all 3 groups, the results of a scoping review conducted in the requirement analysis stage revealed that numerous studies have been conducted in different countries, which developed mHealth interventions to support children with cancer and their families [45]. However, only a few studies engaged all stakeholders and developed self-management systems specifically to support children with ALL and their parents, which is the most prevalent type of pediatric cancer.

For instance, Wang et al [46] designed the Care Assistant app that provides access to clinical information and economic and social support for parents of children with ALL. In fact, the main users and audience of the app were caregivers. Heneghan et al [47] also developed a smartphone app to enhance medication adherence in adolescents with ALL. This app includes a list of relevant drugs and reminders for taking drugs.

Objectives

There is no comprehensive solution that can garner the cooperation and participation of all three groups (children, parents, and oncologists) and address their different needs. Therefore, in line with the World Health Organization's strategy in terms of performing interventions to increase the survival rate of children with cancer in LMICs by 2030 [48], we intend to develop and test a self-management system that provides information about ALL and self-management skills and facilitates interaction with oncologists for children and their parents.

Methods

Setting

This study was conducted between January and February 2020 at MAHAK's Pediatric Cancer Treatment and Research Center. MAHAK is a highly specialized pediatric cancer hospital in Iran. This center has 100 hospital beds and covers >25,000 children with cancer from all over the country (Iran) and neighborhood countries. According to the latest official reports, >6000 children with cancer receive chemotherapy at this center annually [49].

Participants and Recruiting Method

All participants were recruited from MAHAK's Pediatric Cancer Treatment and Research Center in the north of Tehran (Iran). We used a banner that provided information about the study (in the MAHAK outpatient chemotherapy clinic) to recruit interested individuals in this study. A total of 35 individuals (n=24, 69% parents and n=11, 31% children) volunteered to participate in the study. However, only 63% (15/24) of parents and 73% (8/11) of children were eligible to participate. The inclusion criteria for children were having ALL, being diagnosed, being aged at least 7 years old (able to express the disease and the associated problems), and being under treatment for more than a year. The inclusion criteria for the parents were being literate in Persian and having at least one child with a diagnosis of ALL who was receiving treatment for 1 year. These purposive samples of children with ALL and their parents allowed for the aggregation of data related to the development and primary evaluation of this study. Health care providers (oncologists) were also recruited from this center. The inclusion criterion for this group was having at least 10 years of clinical experience in the oncology department. Children were excluded if they were illiterate, were patients with end-stage cancer, experienced mental health problems, and were unable to use a smartphone. Parents were excluded if they did not have the ability to work with a smartphone, did not have reading and writing literacy, or were unwilling to provide informed consent.

Ethical Considerations

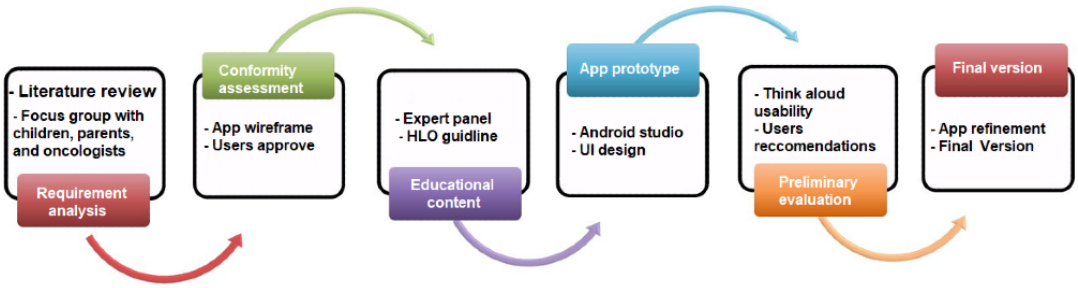
This research received ethical review approval from Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1396.1316). All focus group (FG) meetings took place at the MAHAK hospital and were led by a team member (AM) with experience in conducting FGs. To avoid the dominance of professional feedback and blend the knowledge and expectations of other stakeholders, the identification of user needs was examined separately from 3 perspectives. For each FG, approximately 5 participants were invited. To attend the FG sessions, these children came to a meeting place with their parents. The children and their parents signed informed consent forms before each FG. For children, appropriate written and verbal information about the study and FG was provided, and informed consent was obtained from their parents to participate in the study. They also completed brief demographic questionnaires that provided information about age and sex, as well as their disease-related information.

Study Design

Overview

We adopted the user-centered design approach (Figure 1), in which all the stages of design, development, and evaluation were performed with the participation of the end users [50,51]. On the basis of this approach, the system was designed with the participation of children with ALL, their parents, and a multidisciplinary team (software engineers, medical informatics specialists, oncologists, pediatricians, and psychologists) in the following stages. Moreover, a qualitative methodology (FGs) was applied to identify the most relevant requirements from the users' perspective.

Figure 1. User-centered design process in this study [16]. HLO: Health Literacy Online; UI: user interface.



Requirement Analysis

There was no standard regarding the components and content of a self-management system for cancer; thus, we conducted a review to identify the common features and components of such apps for children and adolescents with cancer and their families. The FG method was then adopted to identify user requirements. A total of 3 separate meetings (1 session per group) were held for children with ALL, their parents, and specialists. These meetings were held in the conference hall located on the fourth floor of the MAHAK. The sessions lasted 40 minutes for children (based on the FG guidelines for children) [52,53] and 90 minutes for adults and specialists. All sessions were recorded, and qualitative data were analyzed using thematic analysis. Descriptive statistics were used to characterize the study participants.

Conformity Assessment

Conformity assessment was a team effort with the collaboration of end user representatives and design team members. On the basis of a series of high-level requirements identified in the previous step, we developed wireframe prototypes (the app's user interface [UI] version, which is not executable and made by sketcher software). Wireframes were examined by 38% (3/8) of children with ALL (aged 7-14 years) and 20% (3/15) of parents. The aim of this session was to ensure the adaptation of the initial design to the users' identified needs.

Preparing Educational Content

To prepare the educational content, we used guidelines provided by the Cancer Council [54], American Cancer Society [55], Cancer Care Ontario [56], and Children's Cancer and Leukemia Group [57], which are reputable organizations and institutions active in the pediatric cancer field. After being reviewed by 3 oncologists, a pediatrician, and a pediatric psychologist, the selected content was translated (to Persian) and organized based on the Health Literacy Online guidelines. This guideline assists in the development of educational content that is understandable by people with different health literacy levels [58,59].

App Prototyping

The prototype was developed after requirement analysis, conformity assessment, and preparation of educational content. This version almost resembled the final version, and users were able to experience the app and communicate with a UI.

Preliminary Evaluation

In the next stage, to ensure the accurate performance of the app, a preliminary evaluation was performed using think-aloud (TA) usability testing. An important advantage of using TA in the preliminary stage of design is the identification and correction of UI problems before developing the final version [60].

This evaluation was performed with 33% (5/15) of parents and 63% (5/8) of children with ALL, and 33% (5/15) of parents who were willing to participate in the study and had an Android smartphone. In this meeting, the researcher explained how the app works and is used. Each user then performed a number of predetermined tasks on the app while orally expressing their thoughts about functionality, problems, ideas, and exceptions. The researcher then recorded these ideas.

App Development

A final version was developed based on the results obtained from the preliminary evaluation. To ensure that the final version of the CanSelfMan app (a cancer self-management app) meets user expectations, an appropriate evaluation must be undertaken.

Results

Stage 1: Requirement Analysis

First, a review study was conducted as there were no guidelines or standards on the features and components of self-management apps for children with ALL. On the basis of the results, the modules of symptom evaluation, disease information, communication with specialists, and reminders had the highest frequency [45]. For requirement analysis, the results were then discussed in FG sessions with parents and children with ALL. Approximately 21% (5/24) of parents were excluded as only 2 months had passed since their child was diagnosed, 13% (3/24) as their child was in the end stages of cancer, and 4% (1/24) as they did not have a smartphone. Additionally, 27% (3/11) of children were excluded from the study as they were in the end stage of cancer. The first FG session involved volunteering parents (10/15, 67%; 6/10, 60% women). The parents' mean age was 35 (range 28-43) years, with an education level above high school diploma. The second FG session involved 63% (5/8) of children with ALL (Table 1). The third FG session was held with 6 specialists (n=3, 50% pediatric oncologists; n=1, 17% radiotherapy oncology specialist; n=1, 17% pediatrician; and n=1, 17% pediatric psychologist), and their ideas about the self-management system feature were collected.

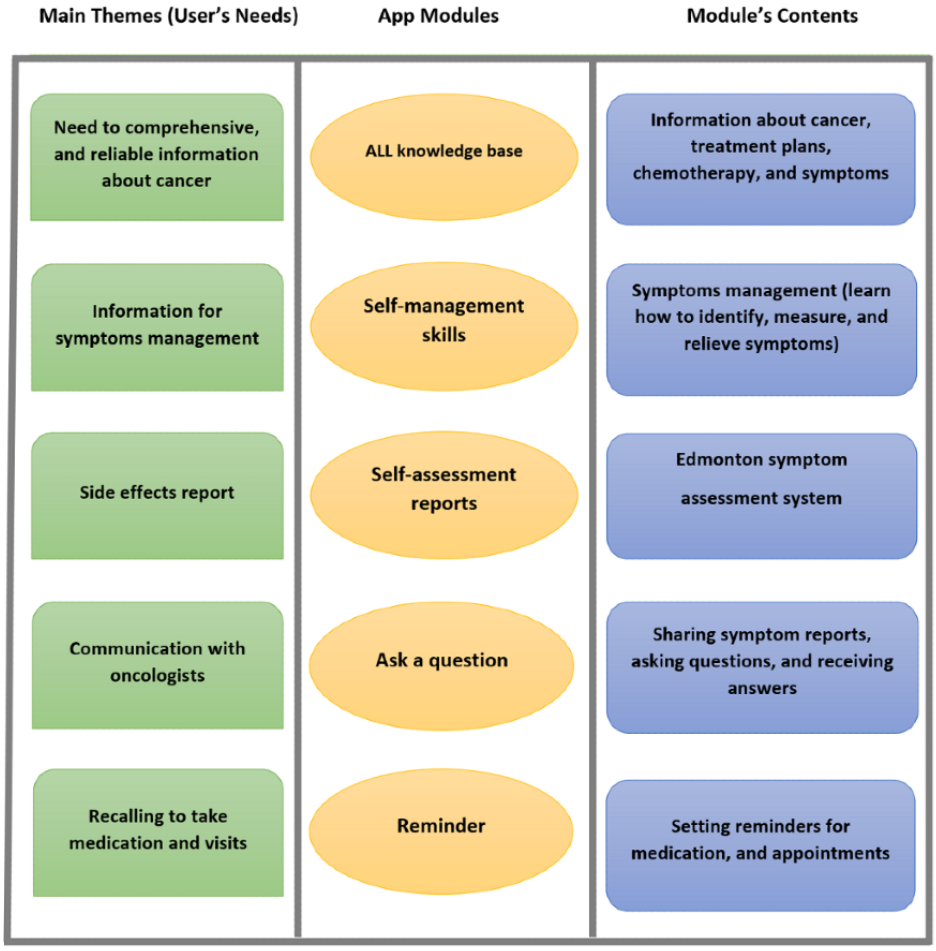
To identify the main themes, all sessions were recorded, transcribed, and thematically analyzed independently using HM and AM. Interestingly, the main themes obtained through thematic analysis were almost the same as those obtained from a review study conducted in the initial stage. Based on the themes identified from the FG sessions, the app modules were determined (Figure 2).

Table 1. Demographic characteristics for children and parents.

Study phases	Focus group sessions		Think-aloud session	
	Children (n=5)	Parents (n=10)	Children (n=5)	Parents (n=5)
Age (years), mean (SD; range)	9 (1.9; 7-14)	35 (2.9; 28-43)	11 (1.1; 7-14)	32 (2.8; 25-46)
Gender, n (%)				
Female	3 (60)	6 (60)	2 (40)	3 (60)
Male	2 (40)	4 (40)	3 (60)	2 (40)
Marital status, n (%)				
Married parent	N/A[a]	4 (80)	N/A	5 (100)
Single parent	N/A	0 (20)	N/A	0 (0)
Education level, n (%)				
Secondary school	N/A	1 (10)	N/A	1 (20)
Diploma	N/A	5 (50)	N/A	2 (40)
Bachelor's degree and above	N/A	4 (40)	N/A	2 (40)

[a]N/A: not applicable.

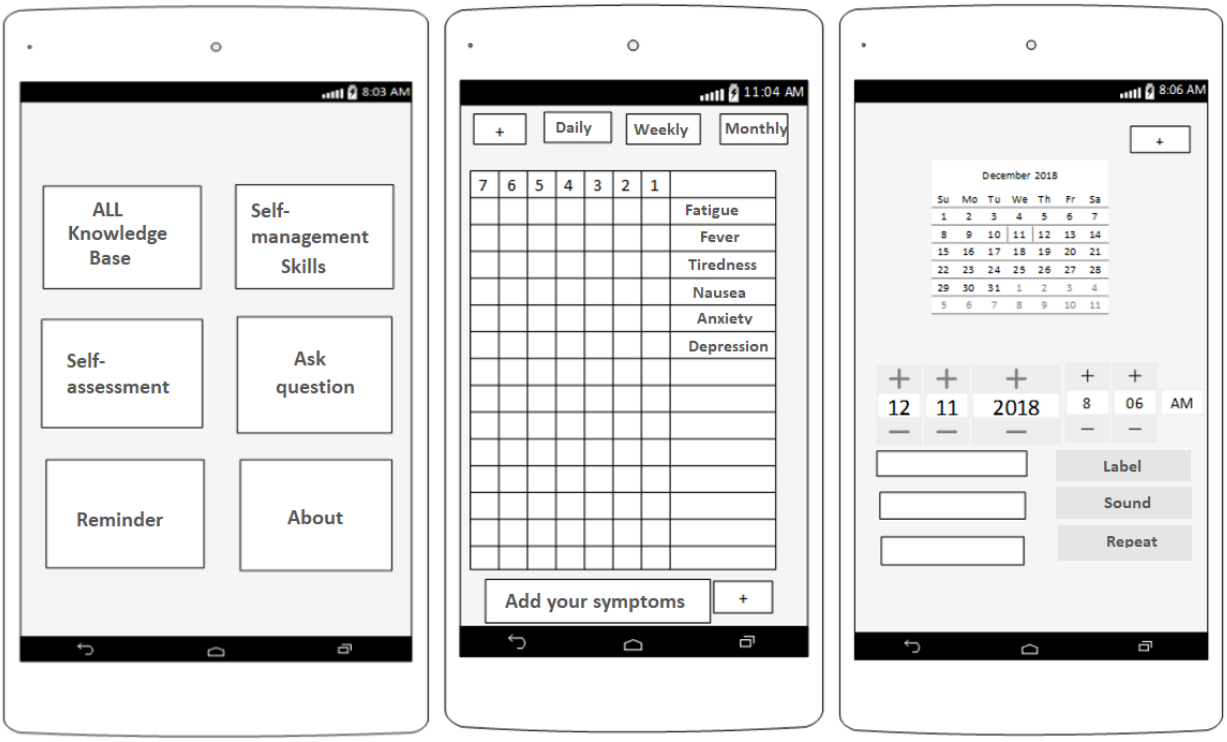
Figure 2. Focus groups extracted main themes, app module, and their content [61]. ALL: acute lymphocytic leukemia.



Stage 2: Conformity Assessment

These requirements were subsequently used to develop wireframe prototypes and technical requirements for the development phase. A total of 3 children with ALL (n=2, 67% girls; mean age 10, SD 1.4 years) and 3 parents (n=2, 67% men; mean age 39, SD 1.8 years) as representatives of the end users (selected from FG participants) were selected and took part in this session. In this session, two members of the design team (a software engineer and a medical informatics specialist) attended as well. The aim of this session was to confirm the initial design based on the users' views and modify it if necessary. In this 45-minute session, a list of the app's functionalities was first provided. Finally, for a better understanding of the user requirements, the wireframe was presented to the participants (Figure 3). At the end of the session, all the participants mentioned that the prototype was based on the requirements identified in the FG sessions.

Figure 3. Example of app wireframe for conformity assessment sessions. ALL: acute lymphocytic leukemia.



Stage 3: Preparing Educational Content

In the next step, a 90-minute expert panel was held with oncologists (4 oncologists with 15 years of experience, a radiotherapy oncology subspecialty with 14 years of experience, and a pediatric subspecialty with 11 years of experience) and a medical informatics specialist to determine the educational content. After review by this group, 4 main guidelines were selected (the Cancer Council and the American Cancer Society's guidelines for providing information and the Cancer Care Ontario and Children's Cancer and Leukemia Group guidelines for preparing self-management content). Selected content was then translated (to Persian) and organized based on the Health Literacy Online guidelines. This guideline assists in the development of educational content that is understandable by people with different health literacy levels [58,59].

Sage 4: App Prototyping

In stage 4, a prototype was implemented using the Java programming language and SQLite database in Android Studio. For the web-based version, we used the PHP programming language and MySQL database. The first prototype had five modules: information about ALL, self-management tips, self-assessment form, ask questions, and reminder function. This version was fully executable.

Stage 5: Preliminary Usability Evaluation

The first prototype was evaluated using the TA method with 10 representatives of the user groups (n=5, 50% children, with n=2, 40% girls; n=5, 50% parents, with n=3, 60% women). This method was performed individually. Before starting the test, in 5 minutes, some explanations about the app and TA evaluation were provided by HM. The app was then installed on the user's smartphone, and some predetermined tasks were performed. At the same time, the user orally provided comments on the problems, ideas, functionality, and expectations. The researcher recorded each user's comments. Some suggestions and problems expressed by children and parents at this stage are provided in Textbox 1.

Textbox 1. Think-aloud primary evaluation results.

Think-aloud comments

- "I wish we could select a profile picture."
- "I worked with a game app before; it had a cartoon character. I wish this app had a cartoon character that I could see on every page. It would look more attractive."
- "In the symptom evaluation part, score smileys can't be seen for symptoms of the last row. You have to scroll up every time to see them. I wish they were fixed so that it'd be easier to fill out the questionnaire, and you wouldn't have to scroll up."
- "In the evaluation part, it'd be more practical if you could view the results in the form of charts and send them to a specific Oncologist."
- "The font is too small and illegible in the information about the disease part; I wish we could change the font size."
- "In my favorites part you can't remove an item from the list. When I added a topic to the list, I couldn't remove it later."
- "In the reminder part, you can't choose all days of the week. You can select the minutes only in quarters. You can't exit the app."

Stage 6: Develop Final Version

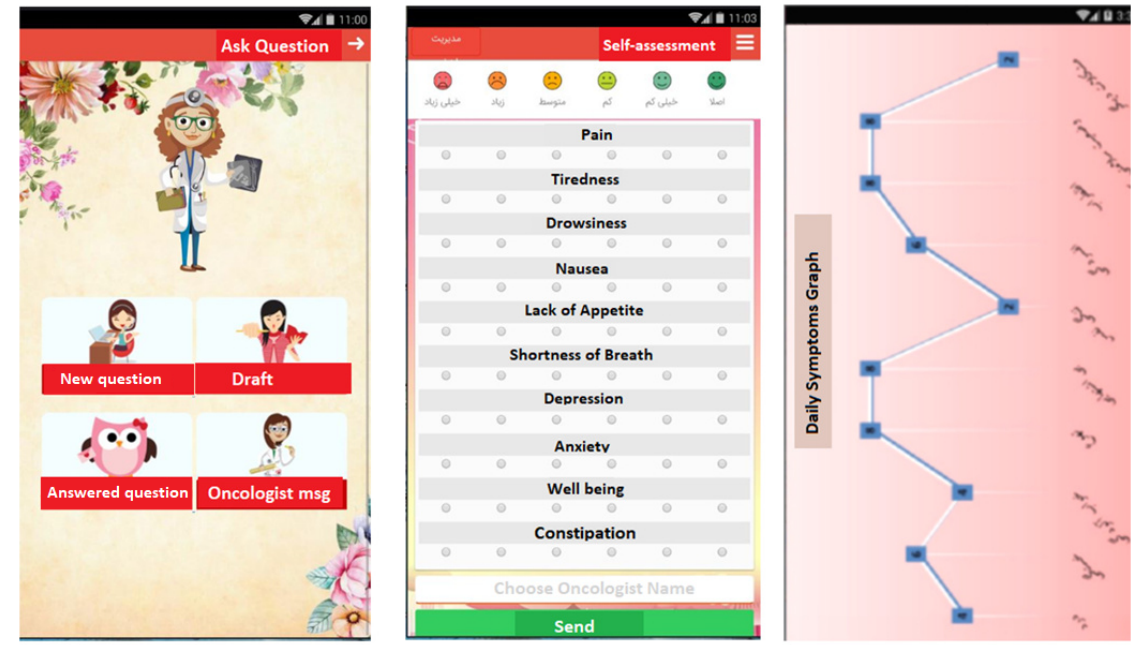
Immediately after the preliminary evaluation, modifications were made, and the final version of the CanSelfMan app was developed. The app had 2 different versions for children and parents and a web-based dashboard for oncologists (Multimedia Appendixes 1 and 2). The CanSelfMan UI was specifically designed using gamification elements to provide a better user experience. On the basis of the user's suggestion, an owl character was selected as the app symbol (Figure 4). This character was selected based on the Dove, Owl, Peacock, and Eagle Psychological Test that divides people based on their characteristics into four groups: dove (symbolizing peace and kindness), peacock (extroverted and showy), owl (logical and smart), and eagle (courageous and decisive) [62]. The final version had five modules: ALL knowledge base, self-management tips, self-assessment report, ask questions, and reminders. The module provides explanations about the app and how to use it.

The ALL knowledge base provides information on the definition, etiology, diagnostic methods, medications, and common treatment protocols for ALL. The self-management module included information on identification of symptoms, evaluation, and control via pharmaceutical and nonpharmaceutical methods, physical exercise, and nutritional information. A standard Edmonton Symptom Assessment System–Revised questionnaire was used in the self-assessment report module. This questionnaire (on a 10-point scale) is commonly used in cancer care centers as a tool for the self-evaluation and reporting of symptoms by patients. After consulting with oncologists for legibility and to facilitate the completion of the form by children, a visual equivalent was used for the options for easier use and response [63,64]. In this part, the user could complete the evaluation form and view the results via graphic charts, send them to the oncologists, or present them to oncologists during in-person visits. The next module was *ask a question*, which enabled direct communication between children or parents and the oncologist (Figure 5). The users could ask their questions by completing and sending the form and choosing the oncologist's name. The important point in this module is the response time to the questions; this time was set at a maximum of 24 hours, as agreed by the oncologists. Moreover, medical recommendations based on the reported symptoms could be sent. The next module was the *reminder* module. Users could create reminders for different topics (taking medications and oncologist's appointments). The app notified the user at specified times.

The web-based version of the app provided a dashboard to view the reports and presented questions and answers to the patients and parents. This version was designed for oncologists. Its main page displayed the questions and reports received from the patients. The oncologist could select a question and answer it. In self-report management, the oncologist could view the reports sent by the users and, if necessary, make suggestions or send messages.

Figure 4. Owl character and the CanSelfMan (cancer self-management) app main page.

Figure 5. The CanSelfMan app (cancer self-management) screenshots of (ask question and self-assessment module).



Discussion

Principal Findings

Most new technologies are not popular among users as they do not participate in them or consider their needs [65]. On the basis of studies, the main reason for the lack of use of mHealth apps is that they are developed without the participation of end users; therefore, in most cases, the outcomes are not compatible with user requirements and will probably not be used by them [47,66]. To resolve this problem, a user-centered design approach was adopted, which is an evidence-based approach based on the understanding of users' needs by involving their participation in all stages of the design and development process [66,67]. This method plays a key role in user interest and acceptance and increases the chances of intervention effectiveness [68]. Therefore, we used this method to develop the CanSelfMan app. All three user groups (children, parents, and oncologists) participated in the stages. Similarly, Ben-Zeev et al [69] developed a self-management system by collaborating with a multidisciplinary team of oncologists, nurses, software engineers, and end users.

In this study, we used a qualitative approach (FG) to identify system requirements and primary evaluations by collecting narrative information, including people's experiences and

feelings. This approach typically uses small sample sizes to investigate users' expectations and beliefs regarding the natural environment rather than looking for generalizable outcomes for larger samples [70]. There is no clear standard for the number of children in an FG; however, generally, between 4 and 5 participants seems enough to acquire sufficient data [53,61].

For example, to design Sisom (an app for symptom reporting by children with cancer and direct communication with health care specialists), Arvidsson et al [51] involved children aged 6 to 12 years. Similarly, to design the Care Assistant app, Wang et al [46] used FG sessions to identify parents' needs and provide access to clinical information and economic support. In the preliminary stages of designing the CanSelfMan app, to ensure that the final version meets user needs, we used wireframes before the final UI design to confirm the user requirements. Presenting a preliminary UI design provides users with an overall view of the final product, which may minimally differ from what the users had seen through the wireframe. Therefore, users' participation in confirming/providing suggestions about the preliminary design garnered their trust and reduced the risk in accepting the final product [71]. After confirming the preliminary design, a prototype was developed that contained all the specified modules and had a full UI. The TA usability test was performed at this stage. It is one of the most important evaluation methods in the preliminary stages that identifies possible defects in the UI design and program logic (product) before developing the final version [60,72].

In this study, we used the TA method to evaluate the CanSelfMan app prototype with the participation of two user groups (5 children and 5 parents). On the basis of the TA results, we developed the final version of the CanSelfMan app. Similarly, Baau and Markopoulos [73] compared the use of TA and poststudy interviews with children and found that the TA method identified more usability issues than the interviews. Owing to the labor-intensive nature of the TA approach, the sample size was typically small. However, small numbers do not indicate a small data set, and small sample sizes can still yield valid information [74]. Nielson [75] suggested that samples as large as 5 participants would provide adequate information using this method.

To develop an app for pain control and evaluation in adolescents with cancer, Jib et al [76] used this method for the preliminary evaluation of the app and collection of users' feedback. To attract users and motivate them to use the app, we used warm colors and cartoon characters. Using visual and gamification elements can lead to increased user motivation and reduce the sense of boredom, especially in children and adolescents [32]. The use of an owl cartoon character in different parts of the UI and the creation of avatars followed the same goal. In a similar study to develop an app for pain management in children and adolescents with cancer, Stinson et al [77] used graphic elements and warm colors to increase children's cooperation. This technique increased the use of the app and completion of the pain reporting forms [77].

The goal of designing this app was to support children with ALL and their parents in dealing with cancer and enable their communication with health care specialists. The end users of this app are classified into three general groups: (1) children aged >7 years who can use the app independently, (2) children aged between 5 and 7 years who cannot use the app independently and need the help of parents, and (3) parents who can use the app and its features independently or act as a proxy for using this app for their children aged <5 years. A web-based version was also developed for oncologists, which provided interactions with children and parents. This interaction included questions and answers about the disease and treatment or requests for changing the in-person appointment dates. Self-assessment, symptom reporting to the oncologist, and receiving feedback create an information flow that increases the interaction between patients or parents and oncologists [78]. This is more important when interacting with children because of the difficulty in communicating with them and their lack of verbal cooperation about the symptoms they experience [79]. Symptom reporting and evaluation are a common part of cancer self-management apps. Parents' reports are a proper source for the symptom evaluation and reporting of children aged <5 years, children with cognitive problems who have developmentally lower levels of understanding of the disease and symptoms, or children who cannot perform self-reporting because of their conditions [62]. Even when children cannot report their condition, parents' reports can offer a complementary view about the child's condition as parents have accurate knowledge about the child's health and are closely involved in the process of medical decision-making; however, their reports should not lead to the ignorance of children's views [80,81]. Therefore, based on the important role of the parents in taking care of children, and because of the limited abilities of children, especially when they are aged <8 years, any intervention whose target group is children should also involve parents in the intervention design as an inseparable part.

Strengths, Limitations, and Suggestions

In this study, we developed the CanSelfMan app in 2 different versions for children aged >7 years, and another version for their parents can be used for children aged <7 years. One of the highlights of our study was the participatory design approach to developing the app. All stages of app development and evaluation were performed with the participation of end users. This approach, owing to the focus on users and their needs, can increase user acceptance and user satisfaction with the final product. Another key strength of our study was the presence of people from different academic disciplines or professional specializations in the design team (software engineers, medical informatics specialists, oncologists, pediatricians, and psychologists). This variety of expertise and differing views benefited the study and helped us cover different aspects of the system and respond to users' needs from a broader and more diverse perspective. In addition, most of the mHealth interventions focused on children aged >8 years, and few studies targeted those aged <8 years. A reason for this might be the uncertainty about children aged ≤7 years regarding their ability to understand information about cancer and symptom assessment. However, evidence has shown that most children, aged as young as 5 years, can fill in symptom assessment questionnaires alone or with their parents' help [81].

The main limitation of this study was related to the small number of participants in the requirement analysis and evaluation phases. On the other hand, the CanSelfMan app was developed based on the requirement analysis of children with ALL and their parents in only 1 cancer treatment center. Therefore, the generalization of the study findings is limited because of the fact that the data were gathered from a single facility with a limited age group of patients. We accepted that this may have increased the risk of bias. It is likely that the participants' views in this study are not necessarily those of all children with ALL or their parents. Therefore, additional research is needed to examine more children's and parents' perspectives before wider implementation. However, as the purpose of this study was to develop a self-management system and not to investigate the effect of this app, the small number of participants in this process was not an obstacle to achieving this goal. We conducted only a primary usability evaluation; thus, future studies should include a larger sample size with a wider age range of participants and allocate more time for participants to test the UI and evaluate usability, which will be the focus of our future study. In addition, the clinical findings of this intervention have not yet been studied; thus, further clinical trials are required to demonstrate the efficacy of this product in relation to routine care.

Conclusions

The use of mHealth can facilitate access to accurate information about cancer in patients and their families. To access these services, users should only have a smartphone and little knowledge about the use of these tools. Despite these confirmed advantages, most mHealth studies have been conducted in developed and high-income countries, and the share of underdeveloped or developing countries in these studies is minimal. Meanwhile, a rise in the incidence rate of childhood cancer is predicted in future years (which will mainly occur in LMICs). Therefore, we developed a CanSelfMan system (smartphone app + web-based dashboard) to enhance self-management skills in children with ALL and their parents or caregivers. The CanSelfMan app can support these groups by providing access to reliable information and symptom management skills and facilitating communication between child/parents and oncologists. It can also be used in specialized cancer centers, especially LMICs, to increase access to these services. Future evaluation studies need to investigate the program's effectiveness and cost-effectiveness.

Acknowledgments

This study was conducted as part of the PhD study of HM at the Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The CanSelfMan (cancer self-management) app web version tutorial.
[MOV File , 16558 KB - formative_v6i4e36721_app1.mov]

Multimedia Appendix 2
The CanSelfMan (cancer self-management) app tutorial.
[MOV File , 4432 KB - formative_v6i4e36721_app2.mov]

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Abbreviations

ALL: acute lymphocytic leukemia
FG: focus group
LMIC: low- and middle-income country
mHealth: mobile health
TA: think-aloud
UI: user interface

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Original Paper

Feasibility, Acceptability, and Preliminary Outcomes of a Cognitive Behavioral Therapy–Based Mobile Mental Well-being Program (Noom Mood): Single-Arm Prospective Cohort Study

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Abstract

Background: The prevalence of anxiety, depression, and general distress has risen in recent years. Mobile mental health programs have been found to provide support to nonclinical populations and may overcome some of the barriers associated with traditional in-person treatment; however, researchers have voiced concerns that many publicly available mobile mental health programs lack evidence-based theoretical foundations, peer-reviewed research, and sufficient engagement from the public.

Objective: This study aimed to evaluate the feasibility, acceptability, and preliminary outcomes of Noom Mood, a commercial mobile cognitive behavioral therapy– and mindfulness-based program.

Methods: In this single-arm prospective cohort study, individuals who joined Noom Mood between August and October 2021 completed surveys at baseline and 4-week follow-up. Per-protocol analyses included those who completed both surveys (n=113), and intention-to-treat analyses included all participants (N=185).

Results: A majority of the sample reported that the program is easy to use, they felt confident recommending the program to a friend, and they perceived the program to be effective at improving stress and anxiety. There were significant improvements in anxiety symptoms, perceived stress, depressive feelings, emotion regulation, and optimism in both the per-protocol and intention-to-treat analyses (all $P<.001$). Participants reported benefiting most from learning skills (eg, breathing and cognitive reframing techniques), interacting with the program features, and gaining awareness of their emotions and thought patterns. Participants also made a number of suggestions to improve product functionality and usability.

Conclusions: Results suggest that Noom Mood is feasible and acceptable to participants, with promising preliminary outcomes. Future studies should build on these results to evaluate the effects of Noom Mood using more rigorous designs.

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KEYWORDS

mHealth; mobile mental health; mental health; stress; anxiety

Introduction

The World Health Organization stresses the importance of mental health, which they broadly define as a state of "well-being in which an individual realizes his or her own abilities and can cope with the normal stresses of life" [1]. Many individuals are affected by difficulties with mental health [2]; for example, anxiety disorders are highly prevalent worldwide

and are estimated to affect 18% of individuals in the United States alone [3,4]. Lifetime prevalence for depression is approximately 17% [2]. Furthermore, it is increasingly recognized that the general population can benefit from mental health support, regardless of whether clinical thresholds for mental illness are met [5,6]: as many as 57% to 84% of US adults have reported subclinical but substantial amounts of stress or worry in recent years [7,8]. Estimates suggest that anxiety, depression, and stress are associated with greater risk of mortality and hundreds of billions of dollars in economic burden per year [9,10].

Although a number of empirically supported treatments for mental health difficulties are available, myriad barriers exist that make it difficult for many people to access traditional in-person support, including cost, long waiting times to see providers, and limited provider availability, especially for individuals living in remote areas [11-15]. The COVID-19 pandemic has also increased barriers to accessing in-person support, potentially increasing willingness to seek digital support [16,17]. In addition, many individuals avoid seeking treatment due to stigma or to mistrust of the mental health system more generally [11,13].

In recent years, there has been a proliferation of interest in and development of mobile mental health programs. Use of these programs has tripled in recent years [18], and multiple reviews suggest that mobile mental health apps have the capacity to improve mental health and emotion regulation in the general population [19,20]. Mobile mental health has the potential to address many of the aforementioned barriers to treatment [21,22]; perhaps most importantly, mobile mental health allows for support or psychoeducation that is not restricted by time, location, or provider availability. In addition, digital (ie, via smartphone) delivery increases accessibility and autonomy in allowing for largely self-directed care [5,23]. Such programs facilitate self-monitoring of mood or activity, a well-known strategy to change undesired behaviors [5]. Lastly, mobile platforms allow for objective measurement of behavioral indicators, such as the number of articles read, and, therefore, allow individuals to track which strategies are most effective in helping them achieve behavioral change.

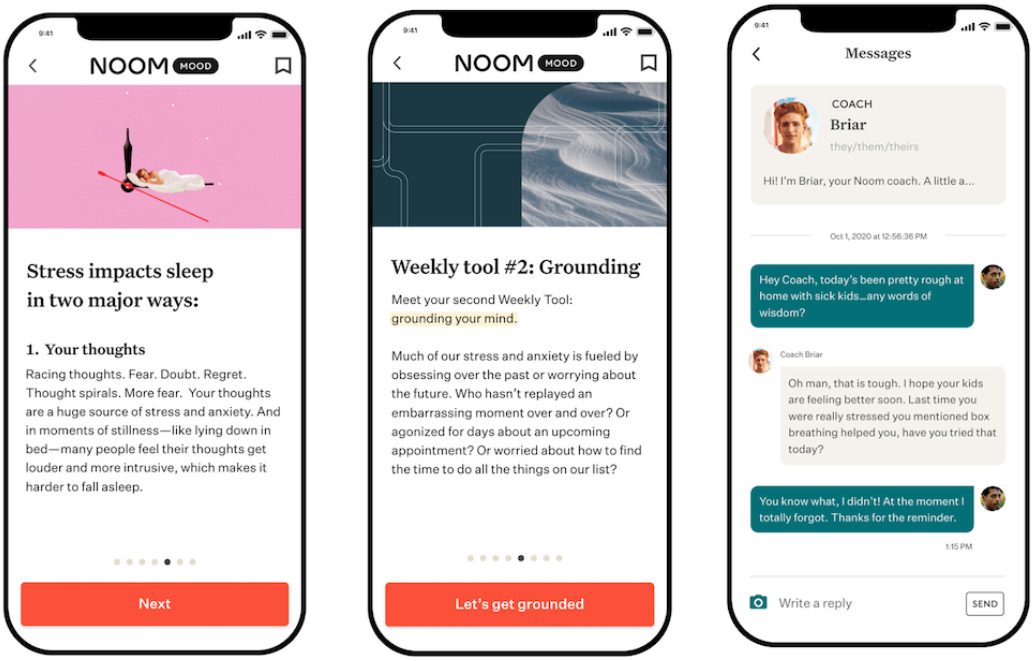
Despite this proliferation of readily accessible mobile mental health programs, researchers have raised several concerns that merit attention and that can be viewed through the lens of implementation science (see Proctor et al [24] for an in-depth discussion of implementation science variables as they apply to outcome studies). First, many mobile health (mHealth) programs available to the public are not based on evidence-based theoretical frameworks [25]. Moreover, users are self-selected, meaning that the problems they are experiencing may or may not map onto the content including the mobile app (ie, problems with appropriateness) [25]. Second, whether evidence based or not, many programs are used briefly and then discarded (ie, problems with adoption) or do not reach a broad enough segment of the population to be useful (ie, problems with penetration) [18,26]. Research has found that thousands of programs have been released on app stores that retain a very limited number of active users over time; for example, studies have shown that 97% of users do not use these mental health apps at day 15 [26,27]. This represents an obvious challenge for mental health programs, as intervention engagement has been associated with better outcomes in a multitude of studies [28-30]. Lastly, few of these mobile mental health programs include a research component to evaluate feasibility, acceptability, or outcomes of any sort; of programs based on theoretical frameworks, only approximately 6.2% have associated peer-reviewed research [25,31,32].

As such, this study was designed to address these gaps in the literature by examining the feasibility, acceptability, and preliminary outcomes of Noom Mood, a widely available commercial mHealth program that incorporates evidence-based recommendations for mobile mental health programs [5]. In particular, this study aims to contribute to the substantial gap in the evidence base, identified by implementation science researchers and review papers on mobile mental health, in data from commercial programs [25,31,33,34]. Another contribution of this study stems from Noom Mood's inclusion of personal coaching for guidance and implementation of cognitive behavioral therapy (CBT) techniques, but not clinical therapy. Few studies have examined widely available mental health programs guided by personal coaching; many existing studies examine mental health programs that are entirely self-guided (ie, without individualized coaching support), are designed to provide clinical therapy or serve as an adjunct to therapy, or provide personalized coaching in other contexts (eg, employer-provided coaching or for specific conditions) [35-38].

Noom Mood is a structured, skills-based approach to stress and anxiety management. Noom Mood uses strategies from empirically supported treatments that have been shown to improve mental health outcomes, such as anxiety, depression, and stress (eg, CBT, dialectical behavior therapy [DBT], acceptance and commitment therapy [ACT], and mindfulness-based stress reduction [MBSR]) [39-43]. Importantly, preliminary evidence has shown that CBT and MBSR can be deployed on a mobile platform and that these programs are associated with improvements in mental well-being in nonclinical and clinical populations [23,44]; however, as described previously, more empirical evaluation is needed of evidence-based, commercial programs. Program components include the following: (1) a daily curriculum consisting of psychoeducational articles for users to read, (2) individualized coaching offered through in-app messaging, (3) weekly skills-based activities, and (4) a mood-logging feature. All four components are expected to improve mental well-being (eg, reduce perceived anxiety and depressive symptoms and perceived stress). The curriculum, activities, and coaching were derived from evidence-based frameworks (ie, CBT, DBT, ACT, and MBSR) that have been shown to be effective in improving these outcomes, so these three components would be expected to be most directly related to outcomes. The fourth component of mood logging is based on behavior change techniques of self-monitoring, helping users to build self-awareness of their mood and associated behaviors [45]. More specifically, the daily curriculum was developed in collaboration with clinical psychologists and was designed to translate evidence-based treatments and psychoeducation into a format that is useful for individuals within a self-help framework. For example, each

day, participants are presented with a short article that explains conceptual terms and principles (eg, cognitive defusion from ACT), provides practical tips and quizzes to build knowledge, and guides users through a relevant practical activity (eg, how to practice cognitive defusion over the next week; Figure 1). Because of the utility of skills-training activities that help to apply evidence-based principles into daily life [5,46,47], Noom Mood introduces individuals to a short 10- to 15-minute practical activity based on evidence-based frameworks, such as breathing techniques and cognitive reframing at the beginning of each week. The activity is implemented for 1 week, with a practice on day 7 in which individuals reflect on the skill learned and how well it worked for them (Figure 1). Lastly, Noom Mood includes a messaging feature that allows participants to communicate directly with health coaches (Figure 1). Coaches help users to understand and engage in activities, encourage reflection and awareness of patterns, and provide validation for emotional experiences based on CBT techniques. Coaching protocols were adapted to this mental well-being context from the Noom weight management program, for which coaching has been refined and tested and shown to provide guidance on activities, emotional self-awareness, and emotional validation [48]. Noom Mood coaches are trained in CBT techniques but are not licensed clinicians, as Noom Mood does not provide clinical assessment, diagnoses, or treatment and is not a replacement for therapy. The coaching feature was included to address concerns that have been cited in previous studies of evidence-based programs [48-50]. Specifically, human contact from remote coaches within otherwise self-guided digital programs may encourage engagement and improve outcomes [48,51,52]. One randomized controlled trial (RCT) found that engagement check-ins from coaches improved engagement in a web-based depression program [53].

Figure 1. Screenshots of the Noom Mood program.



The first step in evaluating any new mHealth platform is to investigate stakeholders' views on the feasibility and acceptability of the proposed product [24,50]. Feasibility is defined as the extent to which end users feel that they could and would use the product in their lives for the purposes for which it was designed [54]. Acceptability is defined as the extent to which stakeholders find the product satisfactory with regard to its content and perceived credibility [54]. Results from feasibility and acceptability testing are then used to refine and update the platform to align with stakeholders' suggestions more closely.

The primary goal of this study was to evaluate the feasibility and acceptability of Noom Mood, as well as to gather preliminary data on whether the program might be associated with improved well-being. We hypothesized that users would find the platform to be feasible and acceptable. Furthermore, we hypothesized that participants who used the program would report some benefit in terms of improved anxiety symptoms, stress, depressive feelings, emotion regulation, and optimism by the end of the 4-week study.

Methods

A single-arm prospective cohort design was used to test feasibility and acceptability of Noom Mood, as well as initial symptom and well-being outcomes.

Ethics Approval

The study was approved by the Advarra Institutional Review Board (protocol No. 00055306).

Procedure and Participants

Participants were recruited from the pool of individuals who had voluntarily signed up for the Noom Mood program. A randomly selected subset of adults who voluntarily enrolled in the Noom Mood program between August and October 2021

were invited to participate. All participants provided informed consent prior to participation. Inclusion criteria for participants were as follows: located within the United States, English speaking, and aged 18 years or older. Participants were invited to complete the baseline questionnaire within 1 business day of signing up for the Noom Mood program. Those who completed the baseline questionnaire were invited to complete the follow-up survey 4 weeks later. Study completers were compensated with a US $20 gift card for their participation. Participants did not receive the program for free during or after the study. The entire study occurred remotely, including online administration of surveys via email.

Noom Mood Program

The Noom Mood program was deployed as described above. At the time of this study, approximately 15 psychoeducational articles were presented to participants each week. In addition to the curriculum, participants had access to mood-logging features, and they were encouraged by coaches to engage in the curriculum and to log their mood once per day.

Measures

Feasibility

Feasibility was assessed at 4-week follow-up.

System Usability Scale

The System Usability Scale (SUS) [55] is a 10-item scale assessing stakeholders' views of ease of use. Items were modified to substitute "program" for "system." Participants were asked to rate their agreement with each usability statement (eg, "I thought the program was easy to use") on a scale of 1 ("strongly disagree") to 5 ("strongly agree"). After reverse-scoring relevant items, sum scores were multiplied by 2.5 to create a final score ranging from 0 to 100. Research indicates that SUS scores above 68 are considered above average and scores below 68 are below average. Internal reliability for the SUS was excellent (α=.90).

Program Engagement Data

As in past work [56], feasibility was also evaluated via the amount of time participants spent engaging with the program. Engagement data consisted of usage and self-report data recorded by the program for 4 weeks. Self-report and usage data were collected by the mobile program and stored on a secured cloud server from Amazon Web Services [57]. Data were deidentified prior to extraction from the database. Engagement measures included the frequency with which participants completed mood logs, number of times the app was opened, number of articles read, number of messages sent to the coach, and number of activities completed. Data were also extracted to evaluate the number of days the user was active, which was defined as the number of days with at least one in-app action. In order to measure real-world engagement, participants were not given specific minimum engagement requirements to remain in the study.

Acceptability

Acceptability was assessed at 4-week follow-up.

Credibility and Expectancy Questionnaire

The Credibility and Expectancy Questionnaire (CEQ) [58] is a 6-item scale that was originally designed to assess perceptions of treatment credibility and expectancy for improvement in psychotherapy. To render the scale more appropriate for use in this study, questionnaire items were modified slightly (ie, "program" was substituted for "therapy" and "stress and anxiety" was substituted for "symptoms"). Items in the CEQ range either from 1 to 9 or from 0 to 100, depending on the item. In line with the CEQ's factor structure and following previous work [59], we computed average credibility and expectancy scores reflected by the first three and last three items of the scale, respectively. Internal reliability was excellent (credibility subscale: α=.90; expectancy subscale: α=.93).

Program Satisfaction Questionnaire

We asked the following open-ended questions: (1) What is the main benefit you received from Noom's stress and anxiety management program? (2) How can we improve Noom's stress and anxiety management program for you? (3) What was the most helpful part of the program? and (4) What was the least helpful part of the program? Because of the variety of answers possible, content analysis was used to code each response into categories and calculate the percentage of responses allocated to each category. The categories were created using latent Dirichlet allocation (LDA), a machine learning approach for automatic clustering of text data [60]. LDA is an unsupervised approach that automatically identifies latent clusters of words (ie, categories) that cluster within unclassified data. Each word cluster was assigned a label, or category name, by a master coder with experience with the program. For each question, each participant response was given a score (0 or 1) for each category since one response could apply to multiple categories. Interrater reliability between the master coder and another coder blind to the study's hypotheses and design ranged from 0.72 to 1.0 for all categories, suggesting good to excellent reliability [61].

Symptom and Well-being Outcomes

Symptom and well-being outcomes were assessed at baseline and 4-week follow-up.

7-Item Generalized Anxiety Disorder Scale

The 7-item Generalized Anxiety Disorder scale (GAD-7) [62] is a 7-item scale that assesses the extent to which individuals experience symptoms of anxiety (eg, "Feeling nervous, anxious, or on edge") on a scale of 0 ("not at all") to 3 ("nearly every day"). Internal reliability for the GAD-7 was good (α=.82 and α=.87 for baseline and follow-up, respectively).

4-Item Perceived Stress Scale

The 4-item Perceived Stress Scale (PSS-4) [63] is a 4-item scale assessing the frequency with which individuals experience various symptoms of stress (eg, "How often have you felt that you were unable to control the important things in your life?") on a scale of 0 ("never") to 4 ("very often"). Internal reliability for the PSS-4 was adequate (α=.68 and α=.69 for baseline and follow-up, respectively).

8-Item Patient Health Questionnaire Depression Scale

The 8-item Patient Health Questionnaire depression scale (PHQ-8) [64] is an 8-item scale that assesses the extent to which participants experience feelings of depression (eg, "feeling down, depressed, or hopeless" or "little interest or pleasure in doing things") on a scale of 0 ("not at all") to 3 ("nearly every day"). Internal reliability for the PHQ-8 was good (α=.84 and α=.85 for baseline and follow-up, respectively).

Difficulties in Emotion Regulation Scale–Short Form

The Difficulties in Emotion Regulation Scale–Short Form (DERS-SF) [65,66] is an 18-item scale assessing emotion dysregulation. It comprises six subscales: emotional awareness, clarity about the nature of one's emotions, acceptance of one's emotions, access to effective emotion regulation strategies, ability to engage in goal-directed activities while experiencing negative emotions, and ability to manage one's impulses during negative emotions. These subscales (α=.74-.91 and α=.76-.91) and the DERS-SF total score (α=.89 at both time points) demonstrated good internal consistency at baseline and follow-up, respectively.

Life Orientation Test–Revised

The Life Orientation Test–Revised (LOT-R) [67] is a 10-item scale that assesses trait optimism. Individuals are asked to rate their agreement with each statement (eg, "In uncertain times, I usually expect the best.") on a scale of 0 ("strongly disagree") to 4 ("strongly agree"). Internal reliability for the LOT-R was good (α=.86 and α=.85 at baseline and follow-up, respectively).

Statistical Analysis

Analyses were conducted in SPSS software (version 27; IBM Corp). For acceptability and feasibility, survey responses were descriptively analyzed with mean scores and percentages of participants that chose each response. For open-ended acceptability responses, content-analyzed categories are presented descriptively with the percentage of responses that fall into each category. Descriptive statistics were also conducted for engagement measures to evaluate feasibility. For preliminary outcomes, paired 2-tailed *t* tests were conducted to evaluate changes on all quantitative variables from baseline to week 4. Both per-protocol and intention-to-treat analyses were conducted. The per-protocol sample consisted of participants who completed both assessments (n=113) and included those who started the program but stopped using it. Intention-to-treat analyses included data from all participants who began the study (N=185); baseline scores were carried forward for participants who did not complete the week-4 assessment. Effect sizes were calculated using Cohen *d* [68].

Results

Participant Characteristics

Participants' demographic characteristics are presented in Table 1. A total of 185 unique Noom Mood users enrolled in the study and completed the baseline survey. Of these, 113 (62.1%) participants completed the follow-up survey. Participants who completed both baseline and follow-up surveys did not differ significantly from those who completed only the baseline survey in terms of any demographic variables or baseline survey values.

Table 1. Participant characteristics.

Demographics	Per-protocol sample (n=113)	Intention-to-treat sample (N=185)
Age (years), mean (SD)	36.8 (9.8)	37.3 (10.4)
Gender, n (%)		
Male	15 (13.3)	32 (17.3)
Female	94 (83.2)	141 (76.2)
Other	2 (1.8)	3 (1.6)
Prefer not to say or N/A[a]	2 (1.8)	9 (4.9)
Ethnicity, n (%)		
Hispanic	13 (11.5)	20 (10.8)
Not Hispanic	97 (85.8)	153 (82.7)
Prefer not to say or N/A	3 (2.7)	12 (6.5)
Race, n (%)		
White	99 (87.6)	153 (82.7)
Black or African American	5 (4.4)	7 (3.8)
Asian or Pacific Islander	3 (2.7)	11 (5.9)
Other	0 (0)	1 (0.5)
Prefer not to say or N/A	6 (5.3)	13 (7.0)
Employment status, n (%)		
Employed	88 (77.8)	144 (77.8)
Not employed	12 (10.6)	18 (9.7)
Retired	1 (0.9)	2 (1.1)
Disabled	5 (4.4)	6 (3.2)
Student	5 (4.4)	6 (3.2)
Prefer not to say or N/A	2 (1.8)	9 (4.9)
Education, n (%)		
High school, GED[b], or less education	7 (6.2)	10 (5.4)
Some college or associate degree	24 (21.2)	37 (20.0)
College graduate	45 (39.8)	67 (36.2)
Graduate degree	35 (31.0)	62 (33.5)
Prefer not to say or N/A	2 (1.8)	9 (4.9)

[a]N/A: not applicable.

[b]GED: General Education Development.

Feasibility

Responses to the SUS are presented in Table 2. As noted above, scores of 68 or higher on the SUS indicate above-average ratings of system usability. A majority (79/109, 72.5%) of participants had overall system usability scores of 68 or higher (mean 77.40, SD 19.45), which is considered an indication of good usability [59]. Most participants reported that the program was easy to use (85/110, 77.3%), and they thought that other people would be able to learn to use the program very quickly (93/109, 85.3%).

Program engagement data are presented in Table 3. Engagement data are presented as weekly averages (ie, the number of times the participant engaged in the behavior over the course of the study divided by the total number of weeks). Participants engaged within the app several times per week on average. Over 4 weeks, the per-protocol sample averaged 14.1 (SD 9.02) app opens, with 2 mean app opens per week. They had an average of 12.1 days with an in-app action, amounting to 1.7 active days per week. The intention-to-treat sample opened the app, on average, 13.7 (SD 8.6) times over 4 weeks, with an average of 1.96 app opens per week. They completed at least one in-app action on an average of 11.2 (SD 8.7) days, which amounted to 1.6 active days per week.

Table 2. Participants reporting good feasibility and acceptability.

Survey measure[a]	Value
System Usability Scale item, n (%)	
I would like to use this program frequently. (n=109)	62 (56.9)
I found the program unnecessarily complex.[b] (n=110)	81 (73.6)
I thought the program was easy to use. (n=110)	85 (77.3)
I would need the support of a technical person to be able to use this program.[b] (n=108)	95 (88.0)
I found the various functions in this program were well integrated. (n=109)	76 (69.7)
I thought there was too much inconsistency in the program.[b] (n=109)	87 (79.8)
I would imagine that most people would learn to use this program very quickly. (n=109)	93 (85.3)
I found the program very cumbersome to use.[b] (n=109)	77 (70.6)
I felt very confident using the program. (n=108)	78 (72.2)
I needed to learn a lot of things before I could get going with the program.[b] (n=107)	89 (83.2)
System Usability Scale score of 68 or higher (n=109), n (%)	79 (72.5)
System Usability Scale overall score, mean (SD)	77.4 (19.4)
Credibility and Expectancy Questionnaire item, n (%)	
At this point, how logical does the program seem to you? (n=110)	101 (91.8)
How successful do you think this program was in reducing stress and anxiety? (n=109)	83 (76.1)
How confident would you be in recommending this program to a friend who experiences stress and anxiety? (n=108)	87 (80.6)
By the end of the program, how much improvement in stress and anxiety do you think will occur?[c] (n=108)	63 (58.3)
At this point, how much do you really feel that the program will help to reduce stress and anxiety? (n=108)	85 (78.7)
By the end of this program, how much improvement in stress and anxiety do you feel will occur?[c] (n=107)	62 (57.9)

[a]The table includes participants who chose 4 or greater (out of 5) on the System Usability Scale or 5 or greater (out of 9) on the Credibility and Expectancy Questionnaire, except where indicated.

[b]These participants chose 2 or less (out of 5) on the System Usability Scale.

[c]These participants chose at least 50% out of 100%.

Table 3. Average total engagement over 4 weeks.

Type of engagement	Per-protocol sample (n=110)[a], mean (SD)	Intention-to-treat sample (n=181)[a], mean (SD)
App opens	14.11 (9.02)	13.72 (8.60)
Articles read	37.12 (28.87)	34.39 (27.44)
Mood logs	10.59 (9.54)	10.00 (10.79)
Days with one in-app action	12.14 (9.03)	11.24 (8.68)
Messages sent to coach	9.71 (10.33)	8.24 (9.09)
Activities[b]	1.33 (2.68)	1.30 (2.54)

[a]Sample sizes represent all participants for whom matching data from the database could be identified.

[b]Activities were calculated over 3 weeks because one offline activity was not tracked by the program.

Acceptability

Responses to the CEQ are presented in Table 2. Of note, the table displays the frequency and percentage of participants who chose at least a 5 (“somewhat”) out of 9 (“very much”) on the CEQ. The vast majority of participants (101/110, 91.8%) rated the program as at least somewhat logical (mean 7.1, SD 1.9, range 1-9). Most (83/109, 76.1%) thought the program was at least somewhat successful at reducing stress and anxiety (mean 5.6, SD 2.2, range 1-9). Many participants (87/108, 80.6%) also felt at least somewhat confident in recommending the program to a friend (mean 6.1, SD 2.3, range 1-9). Most participants (85/108, 78.7%) felt the program would help to reduce stress and anxiety at least somewhat (mean 5.7, SD 2.3), with more than half (63/108, 58.3%) expecting it to reduce their stress or

anxiety by 50% or more (mean 4.9, SD 2.5, with 0 referring to 0% and 10 referring to 100%).

Responses to the Program Satisfaction Questionnaire are presented in Table 4. Participants reported benefiting most from the skills and techniques they learned or practiced (eg, breathing techniques and thought reframing; 38/106, 35.8%). Participants also reported benefiting from the program's features or capabilities (eg, mood tracking and articles; 31/106, 29.2%) and greater awareness (eg, learning and reflection) encouraged by the program (30/106, 28.3%). Specifically, participants found the articles (18/106, 17.0%), coaching (18/106, 17.0%), and qualities of the program (eg, manageable, convenient, and "great" attitude; 16/106, 15.1%) to be the most helpful parts of Noom Mood.

For potential areas of improvement, most participants did not provide a response or indicated that they had no suggested improvements (37/106, 34.9%). The next most common response was "other" (21/106, 19.8%), or participants requested a new feature or program idea (19/106, 17.9%). "Other" responses included increasing the frequency of reminders, expanding areas of content (eg, support for procrastination), and slowing the pace of tasks. Participants also preferred a lower cost (16/106, 15.1%), with some mentioning the potential to be reimbursed, as well as a more personalized experience (9/106, 8.5%) and greater flexibility (9/106, 8.5%), such as the ability to progress while skipping articles, accessing future articles, or repeating an activity for another week.

When asked to describe the least helpful parts of Noom Mood, most participants did not provide a response (40/106, 37.7%). The next most common response was "other" (21/106, 19.8%); responses noted that the program contained too much repetition and that the pacing of the program needed improvement. Lastly, some participants (17/106, 16.0%) described coaching as the least helpful aspect of the program, noting that they would prefer to interact with a coach with specialized expertise or to receive more personalized responses.

Table 4. Response frequencies in each category for the Program Satisfaction Questionnaire.

Category	Participant responses (n=106), n (%)[a]
Main benefit of Noom Mood	
Skills and techniques	38 (35.8)
Program features or capabilities	31 (29.2)
Awareness (ie, learning and reflection)	30 (28.3)
Emotional experience and management	27 (25.5)
Other	18 (17.0)
None or no response	15 (14.2)
Areas to improve	
None or no response	37 (34.9)
Other	21 (19.8)
New feature or program idea	19 (17.9)
Cost	16 (15.1)
Coaching	15 (14.2)
Personalization	9 (8.5)
Flexibility	9 (8.5)
Articles	6 (5.7)
Activities	3 (2.8)
Most helpful part of Noom Mood	
Coaching	18 (17.0)
Articles	18 (17.0)
None or no response	17 (16.0)
Qualities of the program	16 (15.1)
Skills and techniques	15 (14.2)
Activities	14 (13.2)
Awareness (ie, learning and reflection)	9 (8.5)
Other	9 (8.5)
Mood tracking	5 (4.7)
Everything	3 (2.8)
Least helpful part of Noom Mood	
None or no response	40 (37.7)
Other	21 (19.8)
Coaching	17 (16.0)
Activities	9 (8.5)
Mood tracking	7 (6.6)
Articles	6 (5.7)
Personalization and interactivity	5 (4.7)
Cost	4 (3.8)
Everything	2 (1.9)

[a]Each response could be placed in more than one category. Categories were derived from individuals' open-ended responses.

Symptom and Well-being Outcomes

From baseline to 4 weeks, there was a significant reduction in anxiety symptoms for both per-protocol samples (Table 5; t_{112}=10.92, *P*<.001, *d*=1.03) and intention-to-treat samples (t_{184}=9.48, *P*<.001, *d*=0.70) with large and medium effect sizes, respectively. There was also a significant improvement in perceived stress (per-protocol sample: t_{112}=7.69, *P*<.001, *d*=0.72; intention-to-treat sample: t_{184}=7.09, *P*<.001, *d*=0.52) and depressive feelings (per-protocol sample: t_{110}=7.88, *P*<.001, *d*=0.75; intention-to-treat sample: t_{181}=7.40, *P*<.001, *d*=0.55) with medium effect sizes. Finally, there were significant improvements in emotion regulation (per-protocol sample: t_{105}=5.93, *P*<.001, *d*=0.58; intention-to-treat sample: t_{178}=5.79, *P*<.001, *d*=0.43) and optimism (per-protocol sample: t_{104}=–5.04, *P*<.001, *d*=–0.49; intention-to-treat sample: t_{175}=–5.15, *P*<.001, *d*=–0.39) with small to medium effect sizes.

Table 5. Symptom and well-being outcomes from baseline to 4 weeks.

Outcome	Per-protocol sample (n=113)[a]					Intention-to-treat sample (N=185)[b]				
	Baseline, mean (SD)	4 weeks, mean (SD)	ΔMean (% change)[c]	*P* value	Effect size[d]	Baseline, mean (SD)	4 weeks, mean (SD)	ΔMean (% change)[c]	*P* value	Effect size[d]
Anxiety symptoms (GAD-7[e])	13.30 (4.31)	8.54 (4.61)	–4.76 (–35.81)	<.001	1.03	13.28 (4.39)	10.18 (5.14)	–3.10 (–23.32)	<.001	0.70
Perceived stress (PSS-4[f])	8.96 (2.39)	7.08 (2.29)	–1.88 (–21.03)	<.001	0.72	8.89 (2.41)	7.73 (2.48)	–1.16 (–13.07)	<.001	0.52
Depressive feelings (PHQ-8[g])	11.67 (5.47)	7.77 (4.98)	–3.90 (–33.39)	<.001	0.75	11.99 (5.55)	9.40 (5.66)	–2.59 (–21.61)	<.001	0.55
Emotion regulation (DERS-SF[h])	45.97 (11.86)	39.39 (11.30)	–6.57 (–14.30)	<.001	0.58	47.01 (13.09)	42.95 (13.49)	–4.05 (–8.63)	<.001	0.43
Optimism (LOT-R[i])	7.05 (3.49)	8.16 (3.15)	1.11 (15.75)	<.001	0.49	7.33 (3.57)	8.09 (3.39)	0.75 (10.30)	<.001	0.39

[a]Per-protocol analyses only included participants who completed both survey assessments.

[b]For intention-to-treat analyses, baseline responses were carried forward for nonresponders.

[c]Negative values indicate decreases compared to baseline.

[d]Effect sizes constitute Cohen *d*.

[e]GAD-7: 7-item Generalized Anxiety Disorder scale.

[f]PSS-4: 4-item Perceived Stress Scale.

[g]PHQ-8: 8-item Patient Health Questionnaire depression scale.

[h]DERS-SF: Difficulties in Emotion Regulation Scale–Short Form; negative values on the DERS-SF indicate better emotional regulation (ie, fewer difficulties with emotional regulation).

[i]LOT-R: Life Orientation Test–Revised; positive values on the LOT-R indicate more optimism.

Discussion

Principal Findings

In reviews of mental health programs, researchers have voiced concerns about limited published research on commercial programs, and that programs either have limited public engagement or are not based on evidence-based theory [18,25-27,31,32]. Given the identified need for evidence from this type of commercial program [25,31], this pilot study evaluated the feasibility, acceptability, and preliminary outcomes of Noom Mood, which is widely publicly available, based on CBT and MBSR techniques, designed to encourage engagement among the general public, and includes personal coaching. Our results suggest that the program was usable, feasible, and acceptable to participants. In addition, self-reported anxiety symptoms, stress, depressive feelings, emotion regulation, and optimism improved from baseline to 4 weeks.

Feasibility and Acceptability

Feasibility

Overall, participants rated the program as feasible. The average system usability score was 77.4, which surpasses the threshold for good usability [69], and more than 75% of participants reported that the program was easy to use. These scores are in line with feasibility and usability scores from other mobile programs [70-73]. Similar to levels of engagement reported in studies of comparable mobile mental health programs [46,70,74], participants in this study engaged with Noom Mood regularly, opening the program approximately two times per week and performing an action within the app once every 2 to 3 days (11 of 28 days). Participants engaged most with the articles and least with activities. Of note, it is possible that participants completed activities offline throughout the week, which is how they were designed, but did not mark them as complete in the app. As such, it is likely that the data collected on activities underestimate participant engagement in this aspect

of Noom Mood, given that many activities focus on offline experiences (eg, practicing breathing exercises or grounding techniques). Future studies will aim to assess actions completed offline in relationship to symptom outcomes.

Acceptability

The vast majority of participants found the program to be logical (92%) and effective at reducing stress and anxiety (76%). Importantly, 81% of participants felt confident in recommending the program to a friend. These findings are similar to other studies of mobile mental health programs and suggest that the program was perceived to be acceptable to users [35,70,73]. Additionally, at the follow-up assessment, more than half of the participants reported that they expected that the program would eventually reduce their stress or anxiety by an additional 50% or more. Future work should investigate long-term outcomes and whether these participant expectations are borne out.

Participants reported benefiting most from skills training; program features such as articles, activities, and coaching; learning to better manage their emotions; and reflective processes such as learning, reflecting, and increasing their awareness. Participants reported benefiting from taking the time to reflect on how they were feeling and increasingly becoming aware of their emotions and thought patterns. Many participants also mentioned benefiting from the structure and accountability of a designated program. Participants appreciated the overall tenor of the program; one participant reflected that "the attitude it strikes is a great balance of cheeky humor but realistic so it's not overly strict nor overly cheesy. Makes me connect with it well and stick with it." Other participants, however, reported that they hoped for a more serious tone to the articles. At the time of the study, the program incorporated jokes and hashtags for the sake of relatability, and has since been modified in response to participant feedback.

Participants also indicated that the program could be improved to better help individuals progress in a way that best suits an individual's idiosyncratic wants or needs. For example, some participants wanted a slower pace, whereas others requested more daily reminders. Additionally, some participants provided feedback that they wanted more specialized interactions with coaches. While individuals were informed that Noom Mood is not a replacement for therapy and does not provide clinical assessment or treatment, it is possible that participants were expecting the coaching feature to function more similarly to therapy. However, some participants provided feedback stating that responses given by coaches did not feel personalized and felt too generic. It is also possible that some participants may not have been good candidates for a self-help approach. As mentioned previously, in the literature, there is limited understanding of how participants would experience a commercial mobile mental health program with personal coaching, rather than therapy. This study contributes initial understanding that, in this context, coaching can be helpful, but it can also raise confusion about the role of a coach when providing guidance and support rather than therapy. Future iterations of the program should, thus, be sure to set expectations for this feature clearly.

Participants also relayed some suggestions for program improvements that would provide support in varying environments or situations, such as support for moms with young children, skills to reduce procrastination, video and audio recordings, and easily accessible summaries of activities or articles, all of which should be considered in future programs. Since the time of the study, audio recordings have been added to the program. Some participants reported that they would prefer that the program be offered at a lower cost, and some mentioned they would like the program to be covered by health insurance plans. In order to increase accessibility, future initiatives and programs should consider efforts to provide reimbursable experiences (eg, through employee wellness initiatives).

Preliminary Outcomes

Anxiety Symptoms, Perceived Stress, and Depressive Feelings

From baseline to 4 weeks, anxiety symptoms improved by 36% (d=1.03) in per-protocol analyses and 23% (d=0.70) in intention-to-treat analyses. In addition, stress reductions were 21% (d=0.72, per-protocol analysis) and 13% (d=0.52, intention-to-treat analysis), and depressive feelings decreased by 33% (d=0.75, per-protocol analysis) and 22% (d=0.55, intention-to-treat analysis). These effect sizes are comparable to those reported in studies of other mobile mental health programs with the same study length and outcome measures [44,75-80]. Specifically, anxiety and stress decreased in ways that were comparable to or greater than anxiety reductions shown in previous studies, whereas depression showed comparable, though smaller, effect sizes [44,75,78,79]. Of course, this may reflect the fact that the program focuses more on stress and anxiety management than on depression. Of all our outcome measures, anxiety showed the biggest effect sizes, which contrasts with some studies that have found that anxiety scores did not improve as much as other symptom measures, such as depression [75,80].

Emotion Regulation and Optimism

In this study, we found that emotion regulation improved by 14% (d=0.58, per-protocol analysis) and 8.6% (d=0.43, intention-to-treat analysis). Emotion dysregulation is hypothesized to underpin a wide range of psychological difficulties [81]; in fact, transdiagnostic interventions, such as DBT or the Unified Protocol [82], focus on emotion dysregulation as the primary treatment target. Notably, however, emotion regulation is rarely included as an outcome variable in mobile mental health programs, despite its empirical and theoretical relevance to mental health and well-being [19]. In two studies of mHealth programs conducted with young adults [83] and homeless youth [84] that measured emotion regulation as an outcome variable, results showed no significant improvements in emotion regulation capacity.

We found significantly higher optimism at 4 weeks compared to baseline (15.7% or d=0.49, per-protocol analysis; 10% or d=0.39, intention-to-treat analysis). To our knowledge, this is the first mobile mental health study to measure changes in optimism, though some studies of mobile mental health

programs have found improvements in other positive psychological constructs, such as life satisfaction, general mental well-being, or quality of life [46,85-88]. A robust literature base demonstrates that optimism is inversely correlated with depression and anxiety and positively correlated with measures of life satisfaction and self-reported health variables [89,90]. Importantly, optimism may influence physical and mental health by encouraging adaptive coping [85]. Consistent with previous findings, both baseline and 4-week optimism scores were significantly negatively correlated with time-matched anxiety symptoms, stress, and depressive feelings, and optimism scores were positively correlated with emotion regulation (ie, higher optimism is correlated with greater capacity to regulate one's emotions). Future studies should evaluate optimism and its associations with other mental health outcomes.

Limitations

This pilot study had several limitations. First, without a control group, it was not possible to separate the effects of the program itself from improvement over time (ie, regression to the mean and maturation). In addition, other interventions were uncontrolled; that is, program participants may have been participating in active therapy or may have been taking psychotropic medications while they were participating in this study. Nevertheless, it is unlikely that these findings are purely spurious, as the effect sizes are similar to those found in active treatment groups in RCTs, and they are much larger than those found in control groups (eg, see Bakker et al [75]). Now that preliminary feasibility and acceptability have been established, future studies should use randomized designs to confirm that these results were due to the program itself. Also, the study was conducted over 4 weeks, and it is unclear whether results would change over longer periods of time. Further, the study examined the program as a whole, making it difficult to isolate which specific program components led to changes in outcomes. Future studies should use causal methods to explore this further. In addition, the sample was primarily female, White, and highly educated, which is typical of studies of mobile mental health programs [19]. Future research should evaluate to what extent these results would generalize to other populations and actively recruit from hard-to-reach populations. Lastly, this study did not assess other variables that may have caused improvement in symptoms, such as psychiatric services, individual or group therapy, and participants' use of other self-help materials.

Conclusions

In this study, we explored the usability, feasibility, acceptability, and preliminary effectiveness of Noom Mood, a publicly available, mobile mental well-being program based on CBT and MBSR with personal coaching. The program follows 11 of Bakker et al's [5] evidence-based recommendations for mobile mental health programs: it is based on CBT; addresses both anxiety and low mood; is designed for use by nonclinical populations; includes reporting of thoughts, feelings, and behaviors; recommends activities; provides mental health information; encourages non–technology-based activities; includes gamification or intrinsic motivation to engage; shows logs of past app use (eg, patterns of logged mood); uses reminders to engage (eg, messages from the coach); and provides a simple and intuitive interface and interactions. Our results suggest that Noom Mood was usable, feasible, and acceptable to participants, with promising preliminary improvements in anxiety symptoms, stress, depressive feelings, emotion regulation, and optimism. Future directions should include (1) the incorporation of changes suggested by participants in this study and (2) more rigorous testing of outcome variables, such as through randomized designs.

Conflicts of Interest

Authors MM, ASH, ESM, CNM, HB, and AM are employees at Noom, Inc, and have received salary and stock options for their employment. LR received payment from Noom, Inc, for their role as a consultant on this project and for their contribution as an author on this paper. LR is also a co-owner of the Triangle Area Psychology Clinic; a consultant to, and a DBT trainer for, Behavioral Tech, LLC; and an employee of University of North Carolina School of Medicine. There are no specific conflicts to report with those entities, and none of those entities were involved in their contribution to this project.

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
CEQ: Credibility and Expectancy Questionnaire
DBT: dialectical behavior therapy
DERS-SF: Difficulties in Emotion Regulation Scale–Short Form
GAD-7: 7-item Generalized Anxiety Disorder scale

LDA: latent Dirichlet allocation
LOT-R: Life Orientation Test–Revised
MBSR: mindfulness-based stress reduction
mHealth: mobile health
PHQ-8: 8-item Patient Health Questionnaire depression scale
PSS-4: 4-item Perceived Stress Scale
RCT: randomized controlled trial
SUS: System Usability Scale

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Original Paper

Using the Technology Acceptance Model to Characterize Barriers and Opportunities of Telemedicine in Rural Populations: Survey and Interview Study

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Abstract

Background: Health care access issues have long plagued rural Americans. One approach to alleviating the challenges and poor health outcomes for rural individuals is through the use of telemedicine, sometimes called telehealth. It is important to understand factors that may be related to telemedicine adoption or nonadoption, particularly in underserved rural settings.

Objective: This pilot study examines telemedicine perceptions among rural, underserved populations using the Technology Acceptance Model, which serves as a framework to explore the adoption of telemedicine services by those who have used it. This study also explores the differences between user and nonuser perceptions of telemedicine.

Methods: Paper surveys and phone interviews were conducted in rural Northern Lower Michigan.

Results: Perceived usefulness and perceived ease of use explained 91% of the variability in attitude toward telemedicine (R^2=0.91; $F_{1,15}$=73.406; P<.001). Ease of use was a significant predictor (mean 2.36, SD 1.20; P<.001), but usefulness (mean 3.16, SD 0.81; P=.20) was not. Furthermore, there were significant differences in individual perception of telemedicine between users and nonusers. For example, nonusers believed they would receive better care in person (users: mean 3.30, SD 1.22; nonusers: mean 1.91, SD 1.14; $F_{1,32}$=10.126; P=.003). The quantitative findings were reinforced by the qualitative results from the phone interviews.

Conclusions: Overall, the Technology Acceptance Model is an appropriate model to understand the attitudes toward telemedicine that may lead to its adoption by rural Americans.

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KEYWORDS

telehealth; technology acceptance model; pilot study; rural; Michigan; health care access; telemedicine; phone interviews; paper surveys

Introduction

Americans living in rural areas are more likely to have lower levels of education and live below the average income of the country when compared to their urban counterparts. They are more likely to die from all the leading causes of death in the United States and are more likely to have a disability that leaves them unable to work [1]. Additionally, health care access issues have long plagued the 14.5 million rural Americans [2] who face a severe shortage of health care workers and fewer hospital beds per capita than their urban counterparts [3]. These health care access challenges have been exacerbated during the COVID-19 pandemic. One approach to alleviating these challenges and the related poor health outcomes in rural areas is telemedicine, also often referred to as telehealth. Telemedicine can deliver health care through technologies such as mobile phones or computers. Telemedicine programs can address transportation barriers in geographically dispersed rural regions by allowing patients to remotely connect with their providers and enabling access to specialty providers for consultation from afar [4].

Although telemedicine has been around for decades, the COVID-19 pandemic and the resulting reimbursement policy changes accelerated the service's growth and awareness among the public [5-7]. In fact, telemedicine has become a viable way—and for some the only way—to see a health care provider. The adoption of telemedicine services during the pandemic has grown exponentially. The Centers for Disease Control and Prevention reported that 43% of health centers could provide telemedicine services in 2019, and 95% of health care centers reported using telemedicine services by April 2020 [8]. Despite expanded reimbursement, the rapid implementation of telemedicine for health care delivery during the pandemic has excluded approximately one-third of rural Americans, who may lack access to the necessary broadband internet needed for telemedicine [9,10]. Other telemedicine barriers affecting rural populations include limited access to technology at home, low digital literacy, and apprehension regarding telemedicine as a viable health service [11].

Therefore, it is important to understand factors related to telemedicine adoption and nonadoption, particularly by individuals in underserved rural settings. For this study, we examined the adoption of telemedicine through the lens of the Technology Acceptance Model (TAM) [12]. This model posits that perceived usefulness and perceived ease of use predict an individual's attitude toward using the technology. Perceived usefulness has been defined as "the degree to which an individual believes that using a particular system would enhance his or her job performance." Perceived ease of use is generally defined as how easy a system is to use. Greater perceived usefulness and perceived ease of use for a particular system should be predictive of more favorable attitudes toward the technology or the system itself. Together, these factors determine an individual's behavioral intentions to use the technology. Several studies have demonstrated that this model has predictive value in the context of health and technology [13-15].

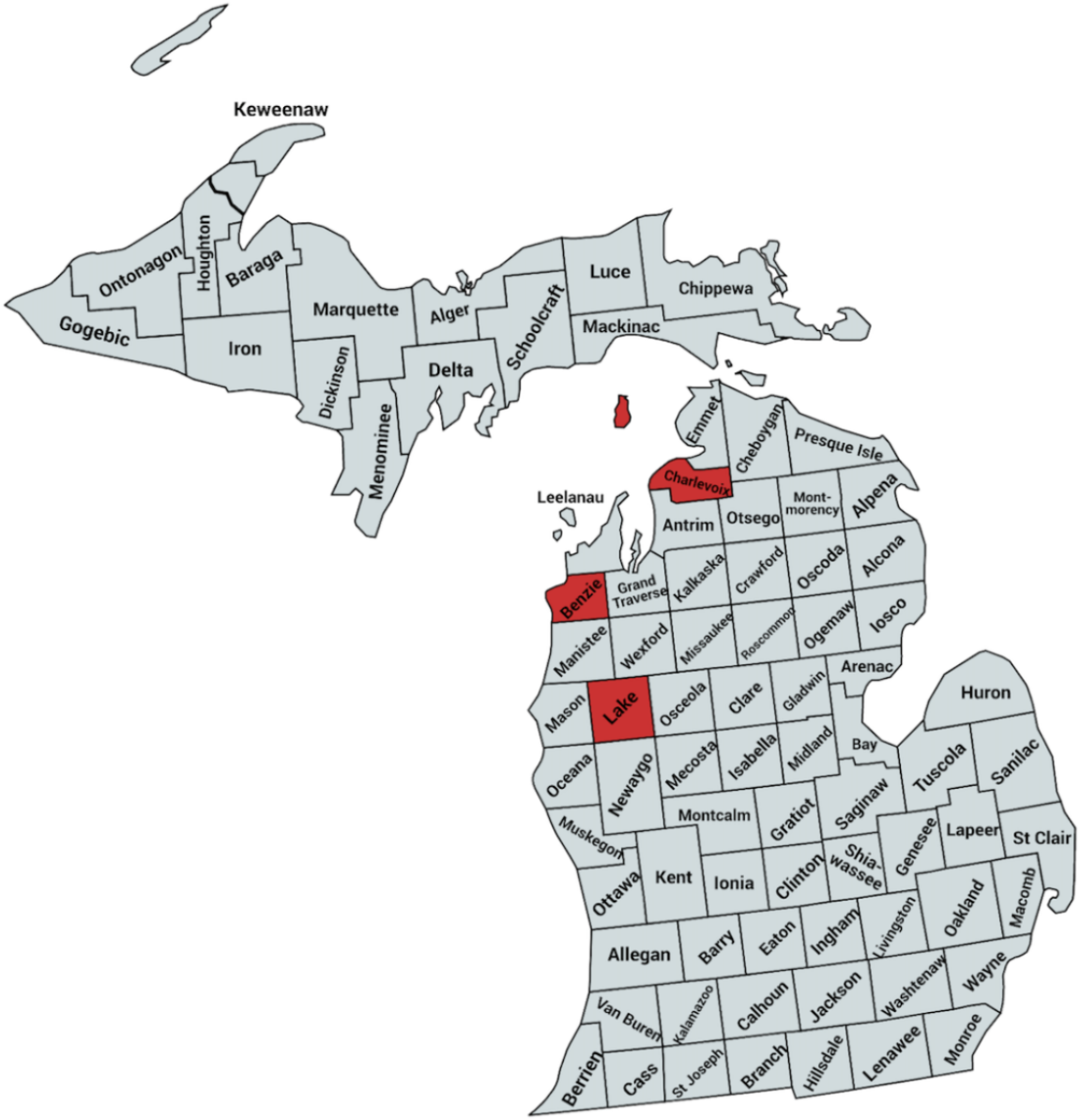
The purpose of this study is to examine telemedicine perceptions among rural, underserved populations (specifically patients) in Northern Lower Michigan using the TAM, which serves as a framework to explore the adoption of telemedicine services by those who have used it. Additionally, the study explores how users and nonusers differ in their perceptions and barriers to using telemedicine, which would provide essential information for the implementation of these services.

Methods

Location and Recruitment

In this cross-sectional study, study locations in rural Northern Lower Michigan were selected in collaboration with our community partners and represented rural regions with health care access barriers. Benzie County was selected because it is the smallest county in the state of Michigan and represents a remote rural county with a Rural-Urban Continuum Code (RUCC) of 9 (codes 1-3 denote metropolitan areas, 4-6 suburban, and 7-9 rural) [16]. Its ratio of population to primary care physicians is higher than the state average (1610:1 vs 1030:1) [17]. Lake County (RUCC of 9) was selected because it is the poorest county in Michigan and has the highest ratio of population to primary care physicians in the state of Michigan (11,880:1). Beaver Island, part of Charlevoix County, was selected as it is rural and only accessible by plane or ferry (in warmer weather) and has a RUCC of 7. See Figure 1 for a map of the surveyed areas.

Figure 1. Map of the surveyed areas in red. In Charlevoix County, only Beaver Island was surveyed (map created with MapChart).



From March to September 2020, researchers provided survey packets to 2 food pantries and an island-based health center in these 3 counties. The food pantry and health center staff handed out the packets to their clients, while keeping a record to ensure only one packet was provided per household. Participants had to be at least 18 years of age and consented to the survey by mailing it back to the researchers. The survey packet included a welcome letter, the paper survey, a self-addressed stamped return envelope, an invitation to participate in a voluntary follow-up phone interview, and a US $2 bill. Paper surveys were used to reach this remote population, comply with COVID-19 research restrictions, and account for uneven technology access among the population.

Respondents were asked if they would be willing to participate in a phone interview to better to understand some of their perceptions regarding telemedicine services. To indicate interest, they completed a contact form to send back with the survey. Interview participants were given a US $20 gift card to a store of their choosing. The phone interviews were conducted by 3 researchers using a semistructured interview guide based on survey responses. All interviews were audio-recorded and transcribed verbatim. The 3 researchers reviewed the recordings and highlighted any commonalities between the respondents.

Ethics Approval

Michigan State University and Munson Healthcare Institutional Review Boards approved this study (STUDY00004682) and all data collection materials.

Data Collection

The paper survey in this study was modified based on a survey used in previous studies regarding use, perceptions, and technology access [18]. The survey asked respondents their previous experience using telemedicine services, perceptions of telemedicine (using a Likert-type response scale, from 1=strongly agree to 5=strongly disagree), insurance and employment status, overall health status, technology access, and primary care provider status. Perceived usefulness was measured using 5 statements (eg, “I generally use telemedicine

when my provider isn't open," "I have used telemedicine because I didn't want to get infected in the waiting room by other people"). Perceived ease of use was measured using 4 statements (eg, "It was convenient to receive care through telemedicine," "It was easy to arrange an appointment"). Attitude toward telemedicine was measured using 5 statements (eg, "The quality of care through telemedicine is excellent," "If I had the opportunity, I would use telemedicine again"). The complete survey can be found in Multimedia Appendix 1.

The semistructured interview guide was developed through a review of the responses to the survey, the TAM constructs, and general use and perceptions of telemedicine.

Statistical Analysis

Descriptive statistics were used to characterize the study population. The reliabilities of survey questions were reported using Cronbach alpha. In addition, frequencies and percentages were evaluated for variables describing barriers to telemedicine use from nonusers and intentions to use telemedicine from previous users. We conducted a factor analysis using principal component analysis with a varimax rotation. The analysis was able to cluster the TAM variables into the constructs of interest. A multivariate linear regression model was conducted to evaluate the relationship between the continuous TAM variables (ease of use and usefulness) and the outcome of attitude toward telemedicine; assumptions of the linear model were specifically tested. Finally, ANOVA was conducted to compare group differences between users and nonusers on multiple outcomes of interest, including perceptions of in-person care and telemedicine care, the ease of seeing their primary care provider, concerns about insurance, continuity of care, and communication. Statistical significance for all analyses was set as $P<.05$. Data screening was performed for missing data and outliers and the assumptions of multiple regression analysis methods were considered.

Results

Respondent Demographics

Characteristics of the 59 survey respondents are shown in Table 1. The majority of respondents lived in Benzie County, Michigan (n=30, 51%), followed by Beaver Island, Michigan (n=16, 27%) and Lake County, Michigan (n=13, 22%). Most respondents identified as female (n=41, 69%) and White (n=41, 69%). A large proportion of respondents indicated having an annual income less than US $20,000 (n=29, 49%) and that they were retired (n=20, 34%) or unable to work (n=10, 17%). In addition, nearly half did not attend college (n=25, 42%). There were 11 (19%) respondents who indicated that they do not have access to the internet in their homes. Overall, 25 (42%) respondents reported having used telemedicine in the past.

Table 1. Paper survey respondent demographics.

Variable	All respondents (N=59), n (%)	Users (n=25), n (%)	Nonusers (n=16), n (%)
Location			
Beaver Island, Michigan	16 (27)	7 (28)	5 (31)
Benzie County, Michigan	30 (51)	15 (60)	8 (50)
Lake County, Michigan	13 (22)	3 (12)	3 (19)
Gender identity			
Female	41 (69)	18 (72)	11 (69)
Male	14 (24)	5 (20)	5 (31)
Prefer not to answer or no response	4 (7)	2 (8)	0 (0)
Birth year cohort (years)			
1934-1940	4 (7)	0 (0)	2 (12)
1941-1950	9 (15)	3 (12)	3 (19)
1951-1960	19 (32)	8 (32)	6 (38)
1961-1970	8 (14)	3 (12)	2 (12)
1971-1980	8 (14)	6 (24)	1 (6)
1981-1990	5 (8)	3 (12)	0 (0)
Prefer not to answer or no response	6 (10)	2 (8)	2 (12)
Race and ethnicity			
American Indian, Alaska Native, or Native Hawaiian	3 (5)	2 (8)	0 (0)
Black or African American	3 (5)	0 (0)	1 (6)
White	41 (69)	19 (76)	10 (62)
Prefer not to answer or no response	12 (20)	4 (16)	5 (31)
Household income (US $)			
<20,000	29 (49)	12 (48)	6 (38)
20,000-34,999	12 (20)	6 (24)	5 (31)
35,000-49,999	4 (7)	2 (8)	0 (0)
50,000-74,999	2 (3)	0 (0)	1 (6)
75,000-99,999	1 (2)	0 (0)	1 (6)
Prefer not to answer or no response	11 (19)	5 (20)	3 (19)
Education			
No schooling completed	1 (2)	0 (0)	0 (0)
Grades 1 through 11	2 (3)	0 (0)	0 (0)
Regular high school diploma	16 (27)	6 (24)	4 (25)
GED[a] or alternative credential	6 (10)	3 (12)	1 (6)
Some college credit, but less than 1 year of college	5 (8)	2 (8)	3 (19)
1 or more years of college credit, no degree	10 (17)	3 (12)	2 (12)
Associates degree (eg, AA, AS)	3 (5)	2 (8)	1 (6)
Bachelor's degree (eg, BA, BS)	4 (7)	2 (8)	2 (12)
Master's degree (eg, MA, MS, MEng, MEd, MSW, MBA)	6 (10)	3 (12)	3 (19)
Doctorate degree (eg, PhD, EdD)	1 (2)	1 (4)	0 (0)
Prefer not to answer or no response	5 (8)	3 (12)	0 (0)
Current employment status			
Employed for wages	7 (12)	5 (20)	1 (6)

Variable	All respondents (N=59), n (%)	Users (n=25), n (%)	Nonusers (n=16), n (%)
Self-employed	3 (5)	0 (0)	2 (12)
Out of work and looking for work	3 (5)	1 (4)	1 (6)
Out of work, but not currently looking for work	2 (3)	2 (8)	0 (0)
A homemaker	2 (3)	0 (0)	1 (6)
Retired	20 (34)	5 (20)	9 (56)
Unable to work	10 (17)	3 (12)	1 (6)
Other	7 (12)	6 (24)	0 (0)
Prefer not to answer or no response	5 (8)	3 (12)	1 (6)
Internet access			
Via cellular data plan for a smartphone/other mobile device	31 (53)	18 (72)	8 (50)
Via broadband internet	23 (39)	10 (40)	7 (44)
Via satellite internet	9 (15)	3 (12)	4 (25)
Via dial-up internet	2 (3)	1 (4)	1 (6)
Don’t know	2 (3)	0 (0)	0 (0)
I do not have access to the internet	11 (19)	2 (8)	2 (12)

[a]GED: general educational development.

Quantitative Results

Reliability

The reliabilities of survey statements on 3 variables were reported: perceived usefulness (Cronbach α=.73), perceived ease of use (Cronbach α=.87), and attitude toward telemedicine (Cronbach α=.93).

TAM Results

Perceived usefulness and perceived ease of use explained 91% of the variability in attitude toward telemedicine (R^2=0.91; $F_{1,15}$=73.406; P<.001). Ease of use was a significant predictor of attitude toward telemedicine (mean 2.36, SD 1.20; P<.001), but usefulness (mean 3.16, SD 0.81; P=.20) was not. See Table 2 for the full regression analysis.

Table 2. Regression analysis: usefulness and ease of use as a predictor of attitude toward telemedicine.

Effect	Unstandardized B	SE	Standardized β	*t* value (*df*)	*P* value
Usefulness	–0.174	0.128	–.119	–1.357 (17)	.20
Ease of use	0.997	0.087	.999	11.404 (17)	<.001

User and Nonuser Perceptions

Significant differences were observed between users and nonusers on their perceptions of in-person care compared to telemedicine. When comparing previous users of telemedicine to nonusers, the nonusers believed they would receive better care in person compared to telemedicine (users: mean 3.30, SD 1.22; nonusers: mean 1.91, SD 1.14; $F_{1,32}$=10.126; P=.003). Nonusers also believed that health care providers would not be as caring via telemedicine (users: mean 4.09, SD 1.15; nonusers: mean 2.91, SD 1.04; $F_{1,31}$=8.199; P=.007). Finally, the results demonstrated significant differences between users and nonusers on worries about continuity of care (users: mean 4.05, SD 0.95; nonusers: mean 3.00, SD 0.78; $F_{1,31}$=9.957; P=.004), with nonusers having more worries regarding the continuity of care than past users of telemedicine. There were no significant differences between users and nonusers on the ease of seeing their primary care provider (P=.26), concerns about insurance (P=.31), concerns about experiencing worse communication (P=.74), or worries about their primary care provider receiving their information (P=.18). See Table 3 for the full results and statistics.

Table 3. Means, standard deviations, and 1-way ANOVA in outcomes of users compared to nonusers of telemedicine.

Outcome	Users, mean (SD)	Nonusers, mean (SD)	*F* test (*df*)	*P* value
Easy to see provider	2.78 (1.30)	2.27 (1.01)	1.343 (1,32)	.26
Better care in person	3.30 (1.22)	1.91 (1.14)	10.126 (1,32)	.003
Insurance concerns	3.45 (1.41)	2.91 (1.51)	1.051 (1,31)	.31
Worse communication	3.32 (1.46)	3.50 (1.35)	0.111 (1,30)	.74
Provider not caring	4.09 (1.15)	2.91 (1.04)	8.199 (1,31)	.007
Continuity of care concerns	4.05 (0.95)	3.00 (0.78)	9.957 (1,31)	.004
Concerns about provider not receiving information from visit	3.95 (1.09)	3.45 (0.69)	1.915 (1,31)	.18

Qualitative Results

Of the survey respondents, 8 individuals indicated interest in participating in the phone interviews and all completed the interviews. The participants were made up of 1 (12%) man and 7 (88%) women, with 5 (62%) participants from Beaver Island, 3 (38%) from Benzie County, and none from Lake County. There were 5 (62%) participants who had used telemedicine in the past. Examples of interview questions are shown in Textbox 1.

Ease of use was reinforced as a key driver of using telemedicine, with the participants indicating that it was often easier to see a provider through telemedicine when compared to the travel time and costs associated with in-person care. Among telemedicine users, positive perceptions of their experiences were expressed in interviews; they would continue to use it and recommend it to others who might be hesitant. Mirroring our quantitative results, trust in their primary care provider was a key theme. It was important for those who have used telemedicine and a reason why some have not. Another barrier mentioned for using telemedicine was the individuals' access to internet. Many stated that rural internet access was not always stable. There was sometimes only 1 internet provider that was slow, unreliable, or not responsive to their needs. Examples of participant responses are shown in Table 4.

Textbox 1. Sample qualitative interview questions.

- How does your technology access or connectivity impact your willingness to use telemedicine services?
- Why did you use telemedicine? / Why haven't you used telemedicine?
- Were you able to have your visit from your home or did you have to go someplace else?
- Describe the process of setting up a telemedicine appointment, from scheduling to the visit.
- How would you describe the communication between you and your provider during the telemedicine visit?
- What are things you liked about your telemedicine visit(s)?
- What are things that you didn't like about your visit?
- How (if at all) have your past experiences with telemedicine impacted your future use of telemedicine?
- Would you recommend telemedicine to a relative or friend? Why or why not?

Table 4. Sample participant responses.

Theme/category	Illustrative quote
Ease of use	• I didn't have to go through all the trouble of traveling, taking a whole day to go for a doctor's office visit and then sitting in a waiting room.
Positive perception of telemedicine experience	• And I think it's very effective in what it's trying to accomplish. For example, I'm on Beaver Island and I have a teleconference with a doctor off island, the doctor I have on island could be there with me. In other words, we're sharing information. I think it's effective and incredibly beneficial for anybody that has issues that need to be dealt with that way. • I like this wonderful service, especially because I live in a remote area of Michigan, and it is a little bit complicated to get to a doctor. For me, telemedicine is really a wonderful service.
Access to internet as a barrier to telemedicine	• They're [internet providers] utterly unresponsive. They couldn't care less about the people on the island because they don't have to.
Trust	• Probably the connections that they are *[sic]* have with the doctor. If they feel comfortable with their doctor, whether they talking to them over the phone or seeing them face-to-face.

Discussion

Principal Findings

This study sought to understand the adoption of telemedicine among people in very rural communities who were accessing food pantries and a community health center amid the COVID-19 pandemic through the lens of the TAM. The results suggested that the TAM is an appropriate model to view the attitudes toward telemedicine that may lead to its adoption by rural Americans. For this population, perceived ease of use was a stronger predictor of telemedicine use than perceived usefulness. Furthermore, there were significant differences in individual perceptions of telemedicine between users and nonusers.

Although perceived usefulness was not significant on its own, it still represents a concept that should be further explored with this population. There are several possible explanations for this finding. For example, a recent study found that some individuals had concerns regarding the privacy and security of telemedicine visits [19]. Perhaps these concerns impacted perceptions of usefulness in this study. Additionally, perceptions of usefulness may be impacted by limited availability and quality of internet-enabled devices, lack of access to high-speed broadband, or health and technology literacy limitations, as participants mentioned these factors in their statements. Another issue noted in other studies is that people like to see their primary care physician in person [18]; more work should be done to explore if this applies for all types of visits.

Practical Implications

A positive finding from this data was that, once patients have used telemedicine, they generally become more receptive toward it. This mirrors past data regarding users and nonusers of telemedicine during the COVID-19 pandemic [18]. Although this does not suggest that all medical or health visits should be conducted via technology, patients could try telemedicine for simple, quick visits (eg, medication follow-ups, refills) to become more comfortable with technology for future visits. Additionally, these results should have implications on policy changes [20]. For example, in the United States, the Biden infrastructure plan intends to increase access to quality and affordable high-speed internet [21]. Medical schools should offer medical students and residents more opportunities to learn about telemedicine, not just what it is and how it is used, but also how to integrate it into clinical practice, train staff, and prepare patients for their visit. This is especially true for clinics serving primarily older and rural patient populations.

There are limitations of this study that should be mentioned. First, this study examined a specific demographic cohort of mostly low-income, White, older, retired, or disabled participants in Northern Lower Michigan who are traditionally difficult to reach for research, especially during the COVID-19 pandemic. However, it should be noted that gaining insight from this population is important for researchers and policy makers. Although this demographic may not be representative of all rural populations, access issues transcend locations. Further research should be conducted to learn how telemedicine is perceived in various rural populations and locales. Future studies are needed to understand rural individuals' acceptance of and attitudes toward telemedicine with continued testing and exploration of the TAM within these difficult-to-reach populations. These preliminary data can help other researchers determine if the same constructs remain significant for targeting tailored interventions for their community. This study found that by working with the community and distributing paper surveys through food banks, we were able to access difficult-to-reach populations who provided valuable insights about telemedicine. These findings are useful for future research on this population. Based on these data, we have begun implementing interventions to help increase the use of telemedicine and improve access to health care in these rural areas and throughout other rural regions of Michigan.

Conclusion

During the COVID-19 pandemic, telemedicine has allowed for continued health care while adhering to strict social distancing policies. This unforeseen experiment has proven that telemedicine has "come of age" after decades of underutilization. This study offers a deeper understanding of attitudes toward and acceptance of telemedicine by vulnerable rural populations in the United States. If telemedicine is used proficiently and consistently, rural populations can gain improved health benefits, which would promote health equity and improve health outcomes.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Paper survey.
[DOCX File , 99 KB - formative_v6i4e35130_app1.docx]

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Abbreviations

RUCC: Rural-Urban Continuum Code
TAM: Technology Acceptance Model

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Original Paper

Quantitative User Data From a Chatbot Developed for Women With Gestational Diabetes Mellitus: Observational Study

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Abstract

Background: The rising prevalence of gestational diabetes mellitus (GDM) calls for the use of innovative methods to inform and empower these pregnant women. An information chatbot, Dina, was developed for women with GDM and is Norway's first health chatbot, integrated into the national digital health platform.

Objective: The aim of this study is to investigate what kind of information users seek in a health chatbot providing support on GDM. Furthermore, we sought to explore when and how the chatbot is used by time of day and the number of questions in each dialogue and to categorize the questions the chatbot was unable to answer (fallback). The overall goal is to explore quantitative user data in the chatbot's log, thereby contributing to further development of the chatbot.

Methods: An observational study was designed. We used quantitative anonymous data (dialogues) from the chatbot's log and platform during an 8-week period in 2018 and a 12-week period in 2019 and 2020. Dialogues between the user and the chatbot were the unit of analysis. Questions from the users were categorized by theme. The time of day the dialogue occurred and the number of questions in each dialogue were registered, and questions resulting in a fallback message were identified. Results are presented using descriptive statistics.

Results: We identified 610 dialogues with a total of 2838 questions during the 20 weeks of data collection. Questions regarding blood glucose, GDM, diet, and physical activity represented 58.81% (1669/2838) of all questions. In total, 58.0% (354/610) of dialogues occurred during daytime (8 AM to 3:59 PM), Monday through Friday. Most dialogues were short, containing 1-3 questions (340/610, 55.7%), and there was a decrease in dialogues containing 4-6 questions in the second period (P=.013). The chatbot was able to answer 88.51% (2512/2838) of all posed questions. The mean number of dialogues per week was 36 in the first period and 26.83 in the second period.

Conclusions: Frequently asked questions seem to mirror the cornerstones of GDM treatment and may indicate that the chatbot is used to quickly access information already provided for them by the health care service but providing a low-threshold way to access that information. Our results underline the need to actively promote and integrate the chatbot into antenatal care as well as the importance of continuous content improvement in order to provide relevant information.

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KEYWORDS

chatbot; gestational diabetes mellitus; user data; log review; eHealth; diabetes; pregnancy; dialogue

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance that arises and is discovered during the second or third trimester of pregnancy [1]. Globally, it affects 1 in 7 pregnant women [2]. In 2019, 5.09% (2769 of 54,407) of pregnant women were diagnosed with GDM in Norway [3], but the condition is assumed to occur in up to 10% of all Norwegian pregnancies, varying by ethnic origin [4,5]. GDM is associated with numerous pregnancy complications affecting both the mother and the fetus [2,6-8], and women with GDM have an increased risk of later developing type 2 diabetes [9,10]. To ensure good health for both the mother and the fetus, a thorough follow-up of women with GDM is required. In reducing the consequences of GDM [7,8,11-13], antenatal training in self-managing blood glucose measurements and nutritional and physical activity education are cornerstones in current clinical care [8,14,15]. Follow-up is provided both by the primary and specialist health care based on blood glucose values [15]. Information provided should aim to strengthen the women's autonomy to cope with the diagnosis, enabling them to make the best decisions for their own health [8,16]. Traditionally, information is provided in person by medical professionals in addition to written information and referral to official websites. Studies indicate that women with GDM experience a lack of personally adapted information, which may contribute to a sense of insecurity [17,18]. This calls for new ways of complementing the established care. Furthermore, the rising prevalence of GDM will likely increase the need for antenatal care consultations [15], and the use of new technologies like chatbots could be a valuable asset in future health care [19].

Use of information and communications technology has the potential to improve public health by increasing efficiency, lowering costs, and improving quality of care [20]. Different health technology solutions may have positive effects on the self-management of diabetes [19], an asset especially important for women with GDM. Chatbots are conversational agents based on artificial intelligence that interact with users in a natural language, either text-based or voice driven, independent of time and location [21,22]. There is a growing number of health chatbots developed for different purposes [23]. Developed by health care personnel and users, Dina, Norway's first health chatbot, was launched in 2018 and made freely available for women with GDM [24]. Dina provides information on GDM and relevant topics related to the condition in accordance with national recommendations. Chatbots providing health information and support regarding other specific conditions have been developed elsewhere [25-27].

Health technology solutions such as chatbots are rarely implemented in health care after the initial pilot study phase [19]. Previous studies evaluating health chatbots have mostly used interviews or questionnaires and have not been based on quantitative analysis of chatbot logs [28]. Exploring chatbot dialogues may provide valuable information needed for further improvement [29]. In 2019, Dina the chatbot was integrated into the Norwegian official digital health platform and is thus an example of implementation of health technology solutions in clinical care.

Our study aim is to provide a basis for improvement and further development of Dina the chatbot by exploring log data on what type of information the users' seek, with the research question being as follows: What type of information do users seek in a health chatbot providing support on GDM? Further specific aims are to explore how many questions each dialogue contains and the time of day the chatbot is used. We subcategorized questions that led to a fallback message from the chatbot to obtain a deeper understanding of which type of questions the chatbot was unable to answer. This knowledge may provide insight into the use of health chatbots and potentially establish more general theoretical knowledge on this type of chatbot.

Methods

Background and Settings for Developing the Chatbot

In 2016, a pilot study for the project revealed an incoherent follow-up and lack of personally adapted information provided to women with GDM. Contrary to current practice when promoting health technology solutions [30], Dina the chatbot was developed after an observed and expressed need from both women with GDM and involved clinicians. Dina the chatbot was developed at Haukeland University Hospital in cooperation with Bergen municipality and Western Norway University of Applied Sciences. User involvement throughout development and evaluation of health technology is important [19], and a user-centered design [31] was applied throughout the development process. User representatives were involved from idea conception to evaluation [32,33] as was an interdisciplinary team of gynecologists, midwives, psychologists, nutritionists, endocrinologists, and information technology developers [34]. Initially, the chatbot was launched at its own website and was made available to all pregnant women in the country, but promotion was limited to Haukeland University Hospital and surrounding municipalities. In 2019, Dina the chatbot was implemented in the official Norwegian digital health platform, presented with an improved user interface (Dina 2.0), and hence made more available to all pregnant women in Norway. Of the 54,407 women who gave birth in Norway in 2019, the target population represented 2769 pregnant women diagnosed with GDM although a portion of these women might have had difficulty using the chatbot due to language barriers. The chatbot offers low-threshold access to quality-checked information, as login or a registered user account is not required. The overall goal for developing the chatbot was to provide reliable information to women with GDM, strengthen women's knowledge about their own health, and improve their daily coping with the condition. Dina is intended as an addition to established care and was developed as an informational chatbot. Pregnant women frequently seek information online and from apps [35] and expect modern health service to provide integrated digital solutions in treatment and follow-up [36]. This chatbot could be an important supplement for pregnant women with GDM [35]. However, evaluation of its use based on objective data from the chatbot's log is needed for further development. The results may also be beneficial in future development of similar informational chatbots created for other specific medical conditions. An observational study analyzing user data from Dina the chatbot was designed. Dialogues were collected from

the chatbot's log and platform over 20 weeks (from week 41 to 48 in 2018 and from week 47 in 2019 to week 6 in 2020). The management team of Dina added "test dialogues" to the chatbot for training and further development. However, these test dialogues were excluded from the collected data because they were not raised by the target population of Dina the chatbot and would have biased the results. A manual log review of the collected dialogues was performed. All data were anonymous, and the identification of users was not permitted. Thus, it was impossible to identify unique users or to determine if they visited the chatbot once or several times. Each dialogue served as the unit of analysis, and we prefer using the term "users of the chatbot" rather than "women with GDM."

Variables

Questions from users to the chatbot were categorized (see Figure 1), and all categories were mutually exclusive [37].

We identified the time of day that dialogues took place and the number of questions in each dialogue.

Table 1 presents the variables in Dina the chatbot with explanations and categories.

The time of day the dialogue took place was grouped into day (8 AM-3:59 PM), afternoon (4 PM-11:59 PM), and night (midnight-7:59AM), while the number of questions in each dialogue was categorized into 1-3, 4-6, 7-9, and ≥10 questions. We registered the frequency of questions the chatbot was unable to answer that resulted in a fallback message from the chatbot (eg, "I´m sorry, I cannot answer that at this point, could you rephrase the question?"). Questions resulting in a fallback message were subcategorized and counted numerically (see Figure 1) to explore which categories of questions the chatbot was unable to answer.

Figure 1. Categorization of questions for Dina the chatbot. HbA_{1c}: hemoglobin A_{1c}.

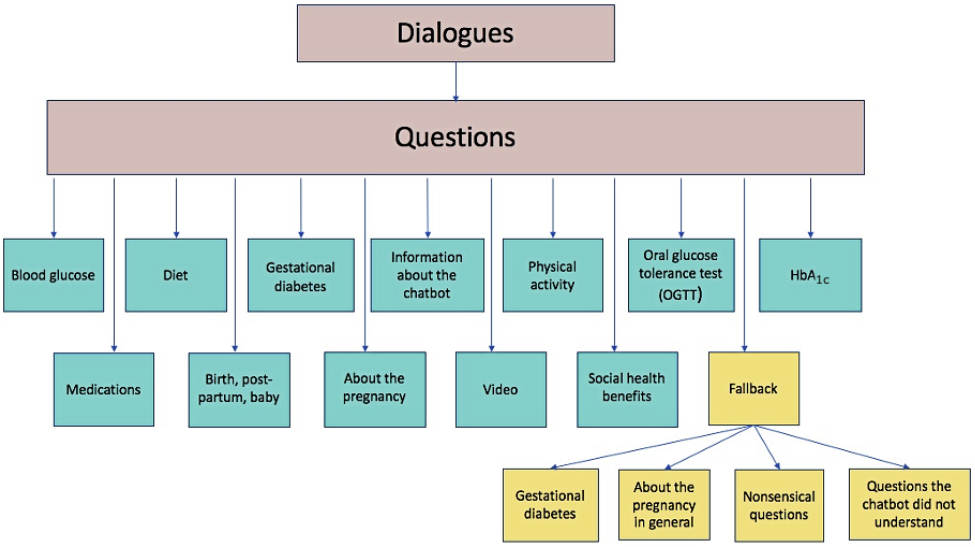


Table 1. Variables with explanations for Dina the chatbot.

Variable	Explanation	Categorization
Dialogue (the unit of analysis)	Question sequence between the user and the chatbot	N/A[a]
Period	Data collection period	Period 1: week 41 to 48 in 2018 Period 2: week 47 in 2019 to week 6 in 2020
Week number	Week the dialogue took place	Weeks 41 to 48 in 2018 Week 47 in 2019 to week 6 in 2020
Day of the week	Day of the week the dialogue took place	Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Sunday
Date	Date the dialogue took place	Day, month, year
Time of day	Time of day the dialogue took place	8 AM-3:59 PM 4 PM-11:59 PM Midnight-7:59AM
Total number of questions in each dialogue	Number of questions from the user to the chatbot in each dialogue	1-3, 4-6, 7-9, ≥10
Blood glucose	Number of questions from the user regarding blood glucose	Numerical
Diet	Number of questions from the user regarding diet and nutrition	Numerical
GDM[b]	Number of questions from the user regarding the GDM diagnosis	Numerical
Information about the chatbot	Number of maneuvers to "navigate" in the chatbot (theme button, general information about the chatbot, privacy in use, greetings)	Numerical
Physical activity	Number of questions from the user regarding physical activity	Numerical
HbA_{1c}[c] (average blood glucose levels)	Number of questions from the user regarding HbA_{1c} (specific test used to diagnose pre-existing diabetes before the 16th week of pregnancy)	Numerical
OGTT[d]	Number of questions from the user regarding OGTT	Numerical
Medications	Number of questions from the user regarding medications used in the treatment of GDM	Numerical
Birth/postpartum/baby	Number of questions from the user regarding birth, postpartum period, and/or the baby	Numerical
About the pregnancy	Number of questions from the user regarding the pregnancy in general	Numerical
Video	Link to informational videos	Numerical
Social health benefits	Number of questions from the user regarding sick leave and appointments with midwife or doctor	Numerical
Fallback	Number of questions in free text from the user the chatbot failed to answer that resulted in a fallback message from the chatbot (eg, "I'm sorry, I cannot answer that at the time, please contact your physician or midwife for further information.")	Numerical 1. Questions about GDM 2. Questions about the pregnancy in general 3. Questions the chatbot did not understand (eg, questions with several spelling errors, questions asked in a foreign language) 4. Nonsensical questions (eg, "Who is the king of Denmark?", "When does my bus leave?")

[a]N/A: not applicable.

[b]GDM: gestational diabetes mellitus.

[c]HbA_{1c}: hemoglobin A_{1c}.

[d]OGTT: oral glucose tolerance test.

Data Analyses

The unit of analysis was the individual dialogue. Dialogues were manually registered and thoroughly read by the first author (MHS). In dialogues, users could either type their questions in free text or click theme buttons. Dialogues could therefore consist of free-text questions, theme button questions, or a mix of the 2. All dialogues are displayed the same way in the chatbots log, making it impossible to distinguish between the predefined questions and free-text questions. Therefore, it was not possible to determine if a user chose to spell "blood sugar" in free text or if they pressed the theme button "blood sugar." Both free-text questions and predefined questions were counted as a whole, but questions that led to fallback would naturally be free-text questions, as the chatbot offers answers to the questions that are predefined. Differentiation between free-text and theme button questions will be considered in the future development of the chatbot. Variables were coded as nominal or interval. We used descriptive statistics: frequencies, proportions, and percentages. For continuous variables, we have reported mean as the central tendency with SD. Normal distribution was tested by Q-Q plot. Chi-square tests were performed to explore associations between variables, and independent *t* tests were used for comparisons of means. Results are presented visually in charts [37]. IBM SPSS Statistics (version 26) was used for all analyses. The significance level was set at 5%.

Ethical Considerations

This study was conducted as a collaboration between Haukeland University Hospital, Western Norway University of Applied Sciences, and Bergen municipality. The chatbot's platform and technological design have been validated in a risk and vulnerability analysis by the technical department at Haukeland University Hospital, and users' data are protected according to the General Data Protection Regulation [38]. Data are stored at a secure server, and access to data are limited to authorized personnel only. Users were informed by the chatbot about anonymity, asked not to leave any personal information, and told about potential future use of data for scientific purposes. This study was presented to the regional ethics committee of Western Norway (approval #167012, 12.08.2020) and found exempt from extended application, as all data are completely anonymous. The data protection officer of Haukeland University Hospital approved the study on August 25, 2020 (ID 1555).

Results

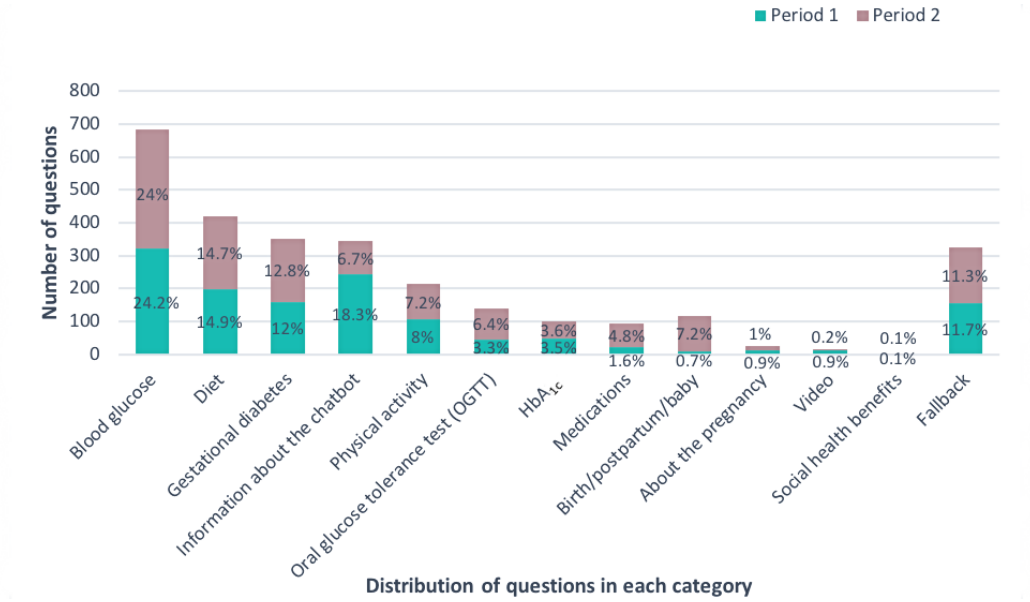
A total of 610 dialogues containing 2838 questions were registered during data collection. In the first period, 288 dialogues were registered, containing 1329 questions, while in the in the second period, 322 dialogues were registered, containing 1509 questions.

The Users' Informational Needs

Questions by category and period are presented in Figure 2.

Questions on blood glucose, diet, the GDM diagnosis, and physical activity accounted for 58.81% (1669/2838) of all questions, with little variation by period. The most frequent single category was questions on blood glucose levels, accounting for 24.07% (683/2838) of all questions. Questions on maneuvering and orienting in the chatbot (information about the chatbot) decreased from 18.28% (243/1329) in the first period, to 6.69% (101/1509) in the second period (P<.001). The remaining categories involving screening for GDM (oral glucose tolerance test and hemoglobin A_{1c}), birth and postpartum period, treatment (medications), general information concerning the pregnancy, informational videos, and questions on social health benefits represented 17.58% (499/2838) of questions.

Figure 2. Number of questions by category and period (period 1: weeks 41 to 48 in 2018 with 1329 questions; period 2: week 47 in 2019 to week 6 in 2020 with 1509 questions) for Dina the chatbot.



When and How the Chatbot Was Used

The number of dialogues per week ranged from 5 to 92 across the 20 weeks of registration, with a mean value of 36 (SD 19.26) and 26.8 (SD 24.34) for the first and second period, respectively. The dialogues by day of the week and time of day for the 2 periods combined are presented in Figure 3.

In total, 90.7% (553/610) of all dialogues took place Monday through Friday, and 58% (354/610) took place during the daytime (8 AM-3:59 PM). The dialogues registered during the afternoon accounted for 28.2% (172/610) of dialogues Monday through Friday. There was little registered activity during weekends.

The number of questions in each dialogue ranged from 1 to 38, with a mean value of 4.65 for the 20 weeks of registration. Short dialogues (1-3 questions) were most frequent, both in the first (153/288, 53.1%) and second period (187/322, 58.1%; see Figure 4).

There was a decrease in number of dialogues containing 4-6 questions from the first period (75/288, 26.0%) to the second period (57/322, 17.7%; *P*=.013). Long dialogues of >7 questions were stable across the 2 periods.

Figure 3. Number and percentage of dialogues in Dina the chatbot (n=610) by weekday and time of day for period 1 and period 2 combined.

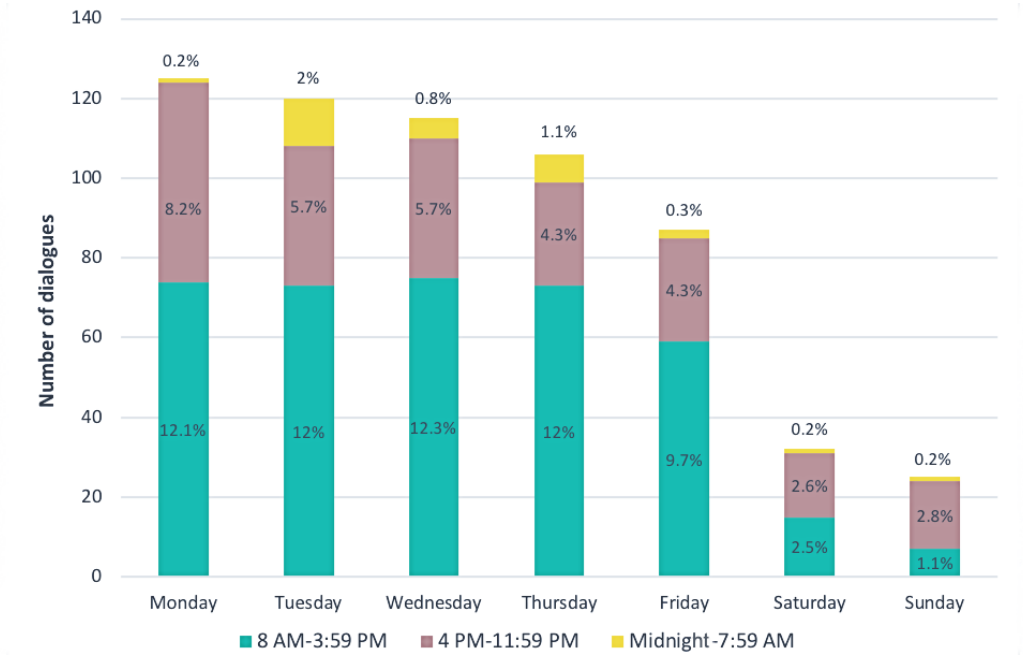
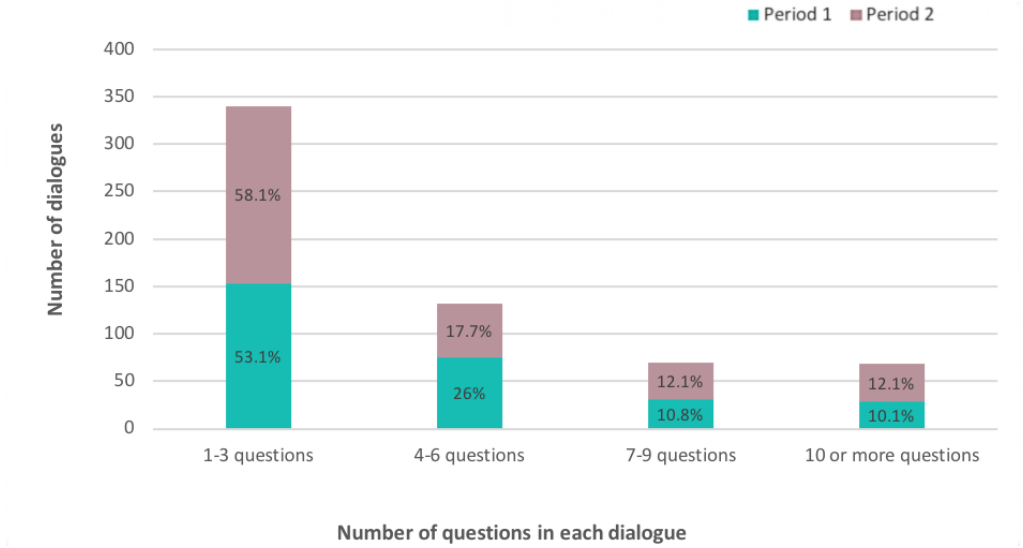


Figure 4. Dialogues by number of questions and period (period 1: weeks 41 to 48 in 2018, 288 dialogues; period 2: week 47 in 2019 to week 6 in 2020, 322 dialogues) for Dina the chatbot.

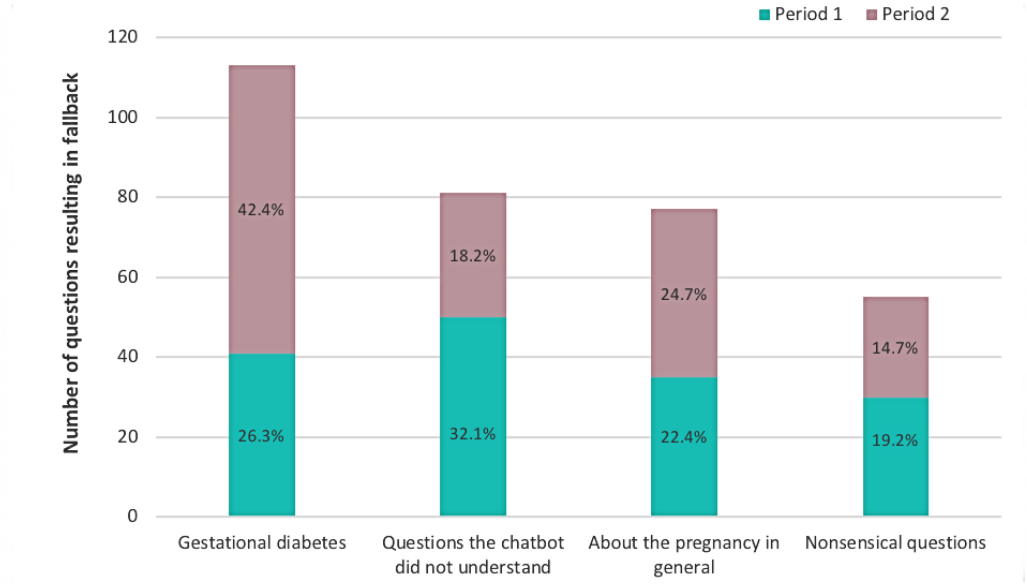


Ability To Answer Questions and Fallback by the Chatbot

Overall, Dina the chatbot was able to answer 88.15% (2512/2838) of all questions asked by users. Figure 5 shows the types of fallback questions by period.

Fallback questions on GDM increased from 26.3% (41/156) to 42.4% (72/170) from the first to the second period (P=.002), while the fallback questions the chatbot did not understand decreased from 32.1% (50/156) to 18.2% (31/170; P=.004). Fallback questions about pregnancy in general and nonsensical questions showed small variations between the 2 periods.

Figure 5. Types of fallback question by period (period 1: weeks 41 to 48 in 2018, n=156; period 2: week 47 in 2019 to week 6 in 2020, n=170) for Dina the chatbot.



Discussion

Principal Findings

Nearly 60% (1669/2838) of all questions from users were on blood glucose, diet, GDM, and physical activity, and the chatbot was able to answer 88.51% (2512/2838) of all posed questions. The chatbot was most frequently used during the daytime, Monday through Friday, and most dialogues were short, containing 1-3 questions. However, the mean number of dialogues per week was 36 in the first period and 26.83 in the second period.

Most Frequently Asked Questions to Dina the Chatbot

Few prior studies have evaluated health chatbots based on log reviews [28]. Inkster et al [27] explored log data on self-reported symptoms of depression, using questionnaires integrated in their chatbot, Wysa, but with a different focus than ours. To the extent of our knowledge, our study is the first study aiming to explore what users ask a health chatbot integrated into a national health service platform by categorizing incoming questions. Dina the chatbot provides the opportunity to click on related themes and questions, “guiding” the user through the conversation. This might have increased conversation efficiency and influenced findings in this study by making some information more available for the users than other topics. Our results indicate that users mainly seek information with high relevance for their currently experienced issues related to GDM (questions regarding blood glucose levels and diet) as opposed to relevant information on future events like the postpartum period or contextual factors such as social health benefits. The information sought also seems to overlap with information available through the established antenatal health care program in Norway, as distribution of the most frequent questions mirrors the cornerstones in the treatment of GDM [14,15]. This indicates that the chatbot could serve as a low-threshold addition to the already-established health care service. The chatbot may enhance the treatment of GDM, promote stable blood glucose, and thereby prevent the development of adverse outcomes for the mother and the fetus. Qualitative studies have shown that women diagnosed with GDM may perceive a lack of personally adapted information, contributing to a feeling of insecurity [17,33] in which managing blood glucose measurements and changing diets are the main challenges [18]. Information provided from a chatbot can thus serve as a reminder or a confirmation for the user on already-received information from medical professionals [33] and not as a substitute for the traditional face-to-face consultation [39]. For users, adding technology like informational chatbots to the standard patient care may reduce insecurities [33,40] and potentially contribute to increased self-efficacy [19].

What Can User Behavior in the Chatbot Tell Us?

Despite some unanswered questions, we found that exploring user behavior in the chatbot will provide useful information for planning and organizing future antenatal care. A previous study on a comparable supportive chatbot developed for patients with breast cancer explored user behavior by asking a weekly question and by observing the retention rate among users [25]. As all data in our study were anonymous, we were unable to explore retention rate, and we treated each dialogue as the unit of analysis. We anticipated a higher frequency of use out of office hours, when medical professionals are less available. Surprisingly, the chatbot was most frequently used during the

daytime, Monday through Friday. Even though a great advantage of chatbots is their 24-7 availability, frequent daytime use provides valuable insight for planning future antenatal care. To our knowledge, prior studies on health chatbots have not explored this issue before. The frequent use during the daytime may be a result of the users needing to quickly access information already provided for them by the health care service. With the timeframe of consultations often being limited [41], questions may arise before or after consultations [33]. The chatbot may provide reassurance for managing the condition of variable validity as an alternative to Google or other internet sources [33]. A chatbot may also provide answers to questions that appear too insignificant or embarrassing to ask health personnel directly [33], potentially reducing the barriers for contacting the health care service [33,42,43].

As there is currently a lack of a standardized methods for evaluating health chatbots, a comparison of chatbots performances may be challenging [25,28]. In general, metrics used to measure chatbot performance depend on which purpose the chatbot is designed to serve; still, most developers aim to keep the conversations short and effective [44]. Keeping this in mind, our results may prove an effective change in user interface in Dina version 2.0, as findings indicate that this version requires fewer conversational steps from the user, evidenced by both fewer questions from users on maneuvering in the chatbot and a decrease in dialogues containing 4-6 questions. This is supported by findings from a previous qualitative study, in which participants stated that they perceived Dina version 2.0 to be effective in providing answers [33]. However, short dialogues could also be an indication of users "giving up" and leaving the conservation; nonetheless, efficiency and the ability to provide a fast answer are important for the intention to use a chatbot [33].

Despite the fact that Dina the chatbot was integrated into the Norwegian digital health platform and made available for all pregnant Norwegian women between the 2 periods of registration, we found that the weekly mean number of dialogues was 36 in the first period and 26.83 in the second period. Although this change was not significant, it could be explained by a possible insufficient promotion of the chatbot among both pregnant women and health care personnel [33]. Previous studies have described several obstacles like organizational, economic, and knowledge barriers when implementing new technology in the health care service [45]. It is our view that the promotion of the chatbot should be a priority going forward to increase the chance of implementation of the chatbot in Norwegian antenatal care.

The Chatbot´s Ability To Answer and Need for Further Development

As the chatbot currently does not provide users with the opportunity to express if they are satisfied with the answer, we used the percentage of questions that the chatbot was unable to answer (fallback) as a measure of how well it operates. Our findings showed that a fallback message was given in 11.49% (326/2838) of all questions asked to Dina the chatbot. The goal is to keep the percentage of fallback as low as possible in order to meet user satisfaction [46]. In a previous study on conversational repair in a chatbot developed for customer service, the fallback percentage was reported to be 15% [47]. However, we did not consider "false positive" responses, where the chatbot seemingly provided an answer but not the answer the user sought. This would have provided more insight into the chatbots ability to answer and will be important to consider in future analyses. We categorized questions resulting in a fallback message to discover problem areas that need further development [48] and to satisfy our specific aim of determining what type of questions the chatbot is unable to answer. Our results (Figure 5) suggested an increase in the fallback category "GDM" between the 2 periods of registration. These are questions the chatbot should be able to answer, and calls for further training and development of content regarding information on GDM are warranted. Notably, we found that that number of questions that the chatbot did not understand decreased in the second period, which may be an indication of increased functionality in Dina version 2.0, as the chatbot may provide more options to click on related themes, thereby guiding the user in a more efficient way. Nearly 1 in 4 questions resulting in a fallback message were related to pregnancy in general, and this may be viewed as an expression of an interest from users and possibly serve as an idea for future development. Nonsensical questions represented 16.9% (55/326) of the overall questions resulting in a fallback message from the chatbot, and one could therefore consider the real fallback rate for the chatbot to be lower than 11.5% if one disregarded these questions.

There are several challenges when it comes to integrating this type of new technology into the established health care [39]. Studies outline several reasons as to why users of health technology tools such as chatbots can lose interest, among them being frustrations with the technology and losing the in-person contact with the caregiver [49,50]. A chatbot is not a finished product once it is deployed, and it is important to continuously monitor and add information to improve the chatbot's ability to function optimally [51]. By highlighting areas in Dina the chatbot that need improvement, we hope this study may serve as a contribution for further improvement and implementation.

Strength and Limitations

The strengths of this study are its use of the chatbot log data from 2 different periods during the course of continuous development and maintenance of the chatbot [52]. Utilization of user data is a cost-effective approach, providing important insight needed for further development. This study also has some limitations. We were unable to assess if users were women with GDM; however, the chatbot could also be a resource for health personnel or partners or next of kin. As all questions to the chatbot are displayed as dialogues in the chatbot's log, we were not able to stratify our analysis according to which method the user decide upon (ie, free text, theme buttons, or a mix of the 2). A registration of users' preferred way of asking questions should be considered in the future development of the chatbot. Furthermore, we could not identify if the user visited the chatbot once or several times. There is currently no way for the users to express whether they received the answer to their question in the dialogue, and obtaining this information would have been a useful addition to the fallback percentage acquired in analyses. Moreover, it would be useful to explore "false positive"

responses by the chatbot (the chatbot provides an answer but not the answer the user is seeking). This would have provided more insight into the functionality of the chatbot and will be considered in future studies. The chatbot is currently only available in Norwegian language, limiting the external validity of the knowledge. In addition, not all women may feel comfortable trusting a chatbot on health issues, which might have potentially excluded some women and introduced selection bias into our study.

Implications

Our findings indicate that users seek information on topics relevant to them at the time, such as blood glucose, diet, and physical activity, and that the most frequently asked questions mirror the cornerstones of GDM treatment. This may indicate that the chatbot is used to quickly access information already provided to users by the health care service, but the chatbot offers a low-threshold way to access that information.

Furthermore, results indicate that Dina version 2.0 guides the user in a more efficient way. However, the low mean number of dialogues per week in the second period (26.83) suggests further efforts should be put into promoting and integrating the chatbot into Norwegian antenatal care. We view our findings as potentially relevant to future development of informational and supportive health chatbots. The authors finds a low-threshold design is an advantage, as this will provide easy access to information the user is also provided through other channels in the health service to further support self-efficacy. As our society quickly becomes more digital, there is a call for the health care service to keep up with the rapid development [36]. We see the need for an informational tool like Dina the chatbot to contribute to increased self-efficacy and coping with GDM, considering the rising prevalence of the condition [2,4,5]. The next step for us with Dina the chatbot would be to continue the ongoing work of further development and to improve promotion to increase its use. We believe that when chatbots are a more integrated part of the health care service, they may serve as a positive contribution to antenatal care.

Conclusions

The majority of posed questions pertained to blood glucose, diet, the GDM diagnosis, and physical activity, and the chatbot was able to answer about 9 out of 10 of all questions from the users. The most frequent use was during the daytime, Monday through Friday, and the majority of dialogues were short, containing 1-3 questions. However, the mean number of dialogues per week was 36 in the first period and 26.83 in the second period.

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Authors' Contributions

The study was designed by MHS, NHM, AL, LJD, ABVN, and LMS. AL further obtained access to the data. MHS and LJD performed the data collection, and LJD especially contributed to the background material for this manuscript. MHS and LJD performed the statistical analysis with support from LMS and ABVN, and MHS drafted the first version of this manuscript. LMS contributed to project administration, and NHM provided important insight regarding the methodology and statistical analysis. MHS, NHM, AL, LJD, ABVN, and LMS all contributed to the interpretation of the data and the visualization of tables and figures and have critically revised the manuscript throughout the process and approved the final manuscript. The first author, MHS confirms that all listed authors meet authorship criteria.

Conflicts of Interest

Contributing author AL is the founder and concept developer of Dina the chatbot. The other authors have no conflicts of interest to declare.

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Abbreviations

GDM: gestational diabetes mellitus

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Original Paper

Videoconferencing in Pressure Injury: Randomized Controlled Telemedicine Trial in Patients With Spinal Cord Injury

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Abstract

Background: Geographical, financial and travel-related barriers may impact access to necessary health care for people in need of long-term follow-up.

Objective: The goal of the research was to perform a nonblinded, randomized, controlled trial on health-related quality of life (HRQoL), healing, interaction, and satisfaction of patients with spinal cord injury (SCI) and PI receiving multidisciplinary videoconference consultations from a wound clinic to the participant's home versus regular outpatient care. The multidisciplinary team consisted of a medical doctor, a wound nurse, and an occupational therapist. In both groups, district nurses attended the consultations at the participant's home.

Methods: A total of 56 participants, 28 in each group, were randomized to a videoconference group (VCG) or a regular care group (RCG). Validated questionnaires were used to measure and compare the follow-up effect on HRQoL. Percentage reduction of wound volume was measured at end of the follow-up. A Likert scale was used to measure the satisfaction of the patients and district nurses regarding the interaction between different modalities of care in the 2 groups.

Results: The HRQoL did not show significant differences between the 2 groups (P values ranging from .09 to .88) or the rate of PI healing, experienced interaction, and satisfaction in the groups. A total of 67% (37/55) of all PIs healed, 64% (18/28) in the VCG and 70% (19/27) in the RCG. Mean reduction in ulcer volume was 79% in the VCG and 85% in the RCG (P=.32). A Kaplan-Meier plot with a logrank test regarding time to healing did not show any significant difference between the 2 groups.

Conclusions: Videoconference-based care seems to be a safe and efficient way to manage PIs in terms of HRQoL, healing, interaction, and satisfaction compared to conventional care for people with SCI. This should be considered when planning for future care. SCI has a huge impact on the individual, the family, and the health care system. There is an urgent need to improve systems of care so that individuals who live far from specialists and require long-term follow-up for conditions such as PI can get optimal treatment.

Trial Registration: ClinicalTrials.gov NCT02800915; https://clinicaltrials.gov/ct2/show/NCT02800915 and Current Research Information System in Norway (CRISTIN) 545284; https://app.cristin.no/projects/show.jsf?id=545284

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KEYWORDS

telemedicine; telecommunication; videoconference; outpatient follow-up; spinal cord injury; pressure injury; healing; participant satisfaction; participant interaction; health-related quality of life

Introduction

Background

For people living in rural or medically underserved areas, treatment access may be limited or even nonexistent [1]. Financial situation, travel and treatment costs, ability to take paid time off from work to visit a clinic or hospital, health insurance issues, pandemics, climate change, and unpredictable weather conditions may all impact access to necessary health care [1,2]. Transportation to hospitals and outpatient clinics may be a barrier because of length and duration of the transportation, discomfort, stress, and risks related to the transport [3]. People with spinal cord injury (SCI) are at particular risk of developing pressure injury (PI) due to paralysis, reduced skin sensitivity, and skin exposure to moisture for extended periods of time [4]. They are often hospitalized for long periods of time and need frequent outpatient care for treatment and to monitor the treatment [5]. However, long transport can cause new wounds to develop [6]. This may cause people not to attend to needed appointments [7]. Telecommunication could help to overcome such limitations [2,8]. Telecommunication between hospital and home is a potential way to offer effective health services, regardless of the geographical location of the patient and health care professional [9,10]. Telecommunication in health care covers a broad range of digital remote care services, all with the aim to provide investigation, monitoring, and management of patients and education for patients and staff using technology, allowing access to expert advice and patient information, no matter where the patient or relevant information is located [11]. Different solutions are in use, depending on the health service offered, technology needed, and performance of the service. There are real-time services like videoconferencing, videophone solutions and phone calls, store-and-forward services like text messages and electronic data collection and transmission, and web-based interactive platforms [7,12]. Services can be used to deliver education, consultation, therapy, social support, data collection and monitoring, and clinical care delivery [7,12]. Real-time video consultations allow health care professionals to perform remote visits to the patients' homes with the possibility to communicate and interact directly with each other [10,11]. Moreover, local care providers, like district nurses, can be included in the consultation. Thus, this system of care delivery increases the possibility of interaction between members at different health care levels and the patient.

Prior Work

Today there are telecommunication services available for many different health care issues. Teleradiology, telepathology, teledermatology, and telepsychiatry are popular and established areas all with the purpose of transmitting images, test results and medical information, as well as performing evaluations and consultations. The transmitting is via digitalized solutions, video and telephony [7,12-18]. Some services, like cardiology, electrocardiography, ultrasonography and mammography, are available at several hospitals and in different countries, while some services, like emergency medicine, immunology, hematology and speech therapy, are only performed in individual countries or individuals hospitals [7,16,18,19]. As in rehabilitation, research into long-term follow-up has shown mixed evidence of feasibility and efficacy regarding use of telecommunication solutions [15-18,20,21].

The Sunnaas model of telerehabilitation [22] has been used to provide videoconferencing as part of inpatient and outpatient rehabilitation services at a Norwegian rehabilitation hospital. A feasibility study evaluated videoconference as a possible alternative method for outpatient follow-up for patients with SCI and PI [4].

Goal of the Study

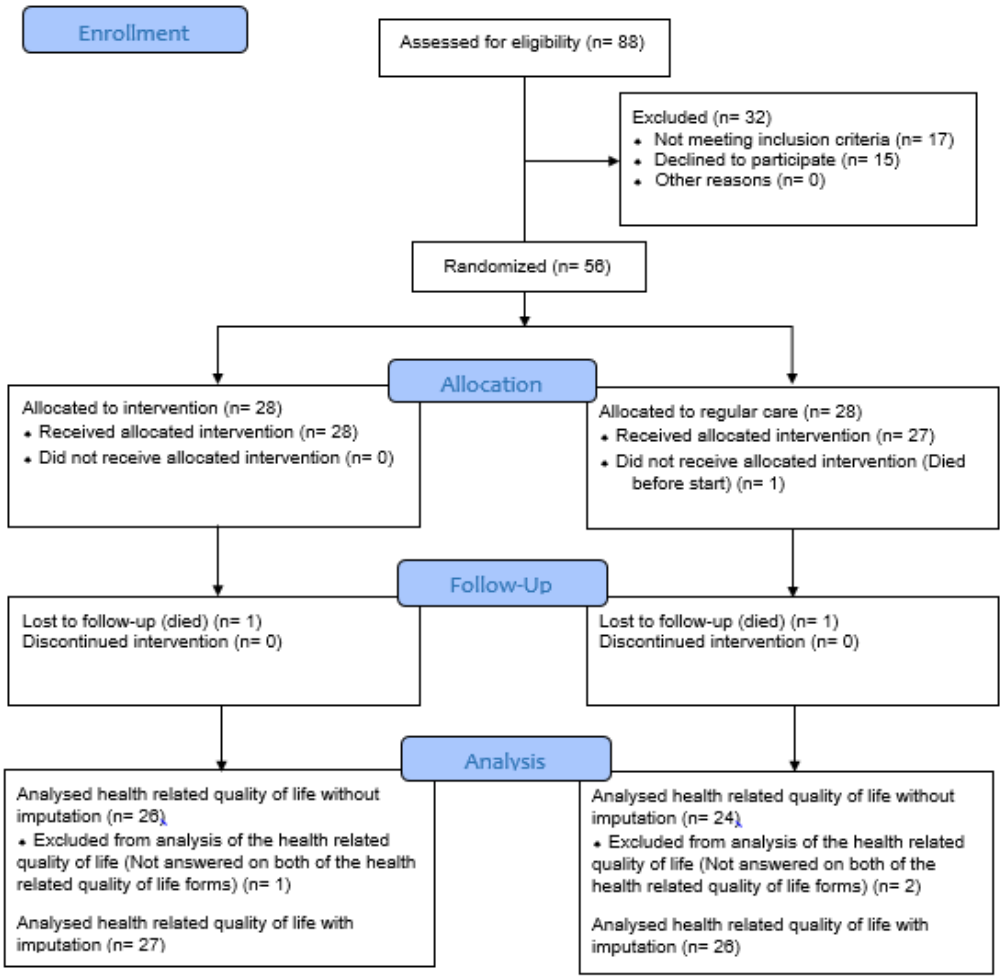
The primary aim of this study was to investigate if videoconference consultations could increase health-related quality of life (HRQoL) in people with SCI and PI. Secondarily, we wanted to determine whether PI healing, perceived interaction, and satisfaction could be considered as good and efficient as conventional follow-up [11].

Methods

Recruitment

People with SCI and ongoing PI were invited to participate in a nonblinded, national, randomized controlled study at 2 spinal cord units in Norway, located at Haukeland University Hospital in western Norway and Sunnaas Rehabilitation Hospital in southeastern Norway. Participants were invited based on response to a questionnaire [11] and from referrals to the outpatient wound clinic at the units. Inclusion criteria were traumatic or nontraumatic SCI, ongoing PI, aged over 18 years, and consent to participate. Individuals were included regardless of concomitant medical concerns. Exclusion criteria were not living in Norway and unable to give their consent due to cognitive impairments. Eligible participants were provided with written and oral information and signed a written consent before inclusion. The study took place between March 6, 2016, and October 19, 2019. The study flowchart is shown in Figure 1.

Figure 1. CONSORT 2010 (Consolidated Standards of Reporting Trials 2010) flow diagram of the trial.

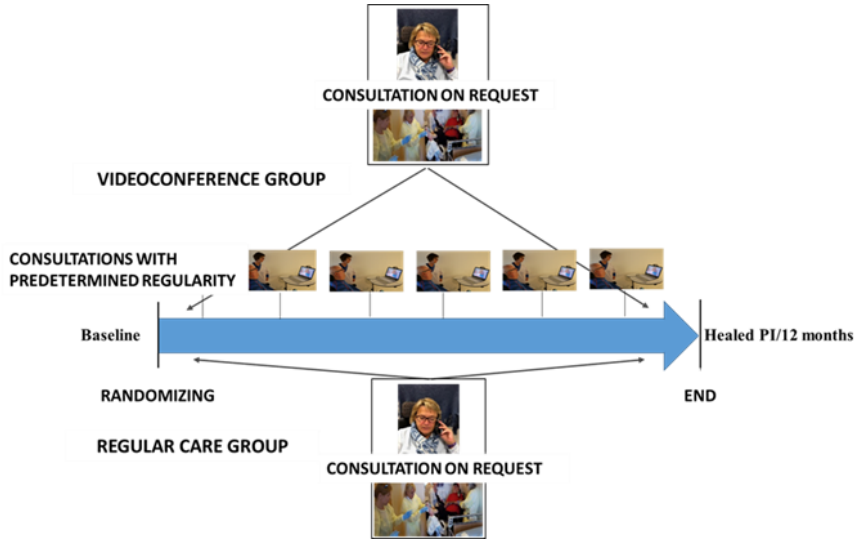


Study Design

Once the written consent was given, baseline data were collected and participants were randomized to a videoconference group (VCG) and a regular care group (RCG) by use of the random number generator in the statistical software SPSS (version 25, IBM Corp). The group allocations were then told to the participants. For both groups, a multidisciplinary wound team conducted the follow-up from the outpatient clinic. The team consisted of a medical doctor with several years of experience in PI treatment, a certified wound care nurse, and an occupational therapist with specialized skills regarding pressure measurements and PI follow-up. For both groups, district nurses were present with the participant at the participant's home during the consultations. The district nurses performed the wound treatment supported by remote guidance from the multidisciplinary wound team at the outpatient clinic. The participants in the RCG received treatment and guidance based on existing routines (ie, by telephone or outpatient consultations at the hospital, if requested). The participants in the VCG were offered treatment and guidance via predetermined videoconference consultations and regular care similar to the RCG. Both groups were followed until healing of the PI or for a maximum of 52 weeks. Figure 2 shows the organization of the follow-up in the 2 groups.

The timeline for study enrollment, intervention, and assessment is described in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [23]. The Template for Intervention Description and Replication (TIDieR) [24] checklist and guide were used to record and describe the intervention. The study conforms to the Consolidated Standards of Reporting Trials (CONSORT) guidelines extension for randomized pilot and feasibility trials [25].

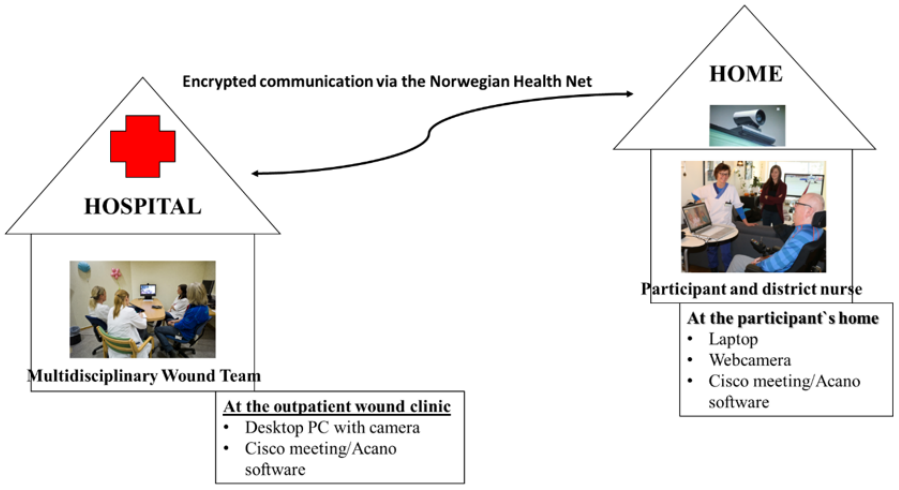
Figure 2. Organization of follow-up for the videoconference and regular care groups.



Technical Logistics

In both groups, the district nurses used their work phone or the participant's cell phones for telephone consultations. For participants in the VCG, arrangements for installation of encrypted software and rehearsal in the use of the program and equipment were addressed immediately after randomization. All participants in the VCG had available broadband or mobile broadband connection. Most of them used their private laptops in the consultations or they borrowed laptops from the hospital's storage. All of them borrowed mobile webcams from the hospital's storage. The consultations were performed as synchronous live, videoconferencing in real time, using a Cisco TelePresence System EX90 PC with camera at the wound clinic and a laptop with a mobile webcam at the participant's location. Encrypted communication channels via the Norwegian Health Net were used to protect privacy of the participants [26]. The wound care nurse at the outpatient wound clinic tested the equipment with the participant and the district nurses before start of the follow-up. Each participant was given a unique subscription number. The wound care nurse at the outpatient wound clinic addressed the participant at each session, and the participant had to accept the call before the consultation could start. Figure 3 shows the organization of the videoconference consultations.

Figure 3. Organization of the videoconference consultations.



Information and Guidance

For both groups, the participants gave their consent to send medical records to the general practitioner and their district nurses after each consultation, no matter the kind of consultation. For both groups, all treatment and guiding were conducted in accordance with evidence-based wound therapy guidelines [27] and individualized in accordance with each participant's needs. The district nurses in both groups were guided in treatment principles according to their knowledge needs. Clinical guidelines, online education programs, and e-learning programs were accessible for the district nurses in both groups.

Study Variables

Demographic information included gender, date of birth, age at SCI, time since SCI, etiology (traumatic, nontraumatic), level and grade of the SCI, and SCI associated problems. SCI was described according to the International Standards for Neurological Classification of SCI recommendations including clinical findings standardized by the American Spinal Injury

Association (ASIA) Impairment Scale (AIS) [28]. Any use of alcohol or tobacco or abuse of drugs was recorded. In addition, information regarding any previous PIs and PI recurrence was recorded, together with the number of present PIs, as well as the category and volume of the present PIs. All PIs were categorized and numbered according to the joint 2019 guideline prepared by the 3 collaborating PI organizations: National Pressure Injury Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance [27]. According to this guideline, the categorization of PIs varies with size and severity of the tissue affected, ranging from reddening of the skin (category 1) to damage to muscle and underlying bone (category 4). In category 1 and 2, the injury is partially going through the skin, while in category 3 and 4, there is a full thickness skin wound. In a suspected deep tissue injury, the depth and severity of the wound is unknown. In an unstageable PI, the wound cannot be categorized due to sloughing/scarring [27]. The PI categorization and volume, (length × width × depth) was measured at baseline by the medical doctor and wound care nurse and at the end of the follow-up by either the medical doctor and wound care nurse at the outpatient wound clinic or by the district nurses guided by the wound team. A ruler adapted for PI measurement was used. The district nurses gained access to the rulers via the multidisciplinary wound team. Difference in volume was calculated as percentage change. Time to healing was measured as days from baseline to healing. Changes in HRQoL in the 2 groups were compared using the Norwegian versions of the 36-item Short Form Health Survey (SF-36) [29] and the Five-Dimension European Quality of Life (EQ-5D) scale [30]. In case of lack of an available Norwegian index version of the EQ-5D scale, the validated UK index is recommended to be used in analyses regarding Norwegian subpopulations [30]. We also used the International Spinal Cord Injury Quality of Life Basic Data Set (ISCI-QoL-BDS) questionnaire [31] to measure the HRQoL among the participants. The form used is similar to the version used by the Norwegian Spinal Cord Injury Registry [32].

The participants reported subjective ratings regarding satisfaction, safety, and level of interaction during the follow-up using a Likert scale with 1 being completely dissatisfied and 5 being totally satisfied. Moreover, as an ad hoc analysis, we wanted to gain knowledge about the district nurses' experience, and thus we invited them to report their ratings as well.

Ethics

The research project was carried out in accordance with ethical guidelines and privacy rights for health services in Norway [26] based on the code of ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Established routines to secure confidentiality and ethical guidelines for conducting consultations involving examinations related to intimate body areas, which may be visible on the screen, were established before the study was initiated [22]. Knowledge and expertise achieved through a previous feasibility study [4] was applied in this study. Communication occurred through the Norwegian Health Network's encrypted video channels. The study was performed in compliance with Norwegian data security and privacy standards [26]. The study was approved by the regional committees for medical and health research (2014/684/REK-Nord) [33] and registered with ClinicalTrials.gov (NCT02800915). All participants were insured through the Norwegian health care system and the hospitals' insurance programs for adverse effects.

Statistical Analyses

Demographic variables were descriptively analyzed. Continuous variables are presented as mean with standard deviation whereas categorical variables are presented as counts and percentages. For the HRQoL scores, missing data were handled by multiple imputation. Each missing data point was replaced by m=20 imputed values based on the predictive mean matching technique before analysis. The imputation models include age, gender, AIS grade, and HRQoL scores.

Mean HRQoL scores with corresponding 95% confidence interval are presented for each of the 2 treatment groups at baseline and end of follow-up, and the groups were compared using linear regression analysis with adjustment for baseline. This analysis was repeated without imputation for missing values as well, for comparison. The mean percentage reduction in PI size was calculated with corresponding 95% confidence interval for each of the 2 groups and compared using a Mann-Whitney test. Time to healing was analyzed by the logrank test and is presented by a Kaplan-Meier plot.

$P<.05$ is considered significant. Independent *t* tests were used to analyze the mean difference in participant satisfaction scores. Corresponding 95% confidence intervals were calculated. All statistical analyses were performed using SPSS statistical software.

Sample Size

We based our sample size calculation on investigation of HRQoL and the group comparison at the end of follow-up. Our hypothesis was that HRQoL would increase in the VCG as compared to the RCG, and the sample size calculation was based on an expectation of a standardized difference of at least 0.8 (typically considered a large effect). With 80% power, we would need 25 patients in each of the 2 groups.

Results

Demographics

A total of 56 participants were included, with 28 in each group. One participant in the RCG died of acute illness prior to start of the follow-up, and the participant's data were excluded from the analyses. Furthermore, 2 participants, 1 in each group, did not complete any of the HRQoL questionnaires and were removed from the analysis of the primary outcome. Two participants, 1 in each group, died during the follow-up. They are included in the analysis of wound healing as not healed PIs. All deceased participants were male and causes of death were reported to be cardiovascular disease (2) and pneumonia (1). Of the 55 participants included in the analysis, the majority were male, 86% (24/28) in the VCG and 78% (21/27) in the RCG. The mean age was 58 years in both groups. Baseline data of the included participants are shown in Table 1.

Table 1. Baseline data of the participants in the 2 groups.

Characteristics	Videoconference group (n=28)	Regular care group (n=27)
Gender, n (%)		
Male	24 (86)	21 (78)
Female	4 (14)	6 (22)
Age (years), mean (SD)	57.50 (14.2)	57.96 (12.81)
Age group (years), n (%)		
15-29	0 (0)	1 (4)
30-44	6 (21)	3 (11)
45-59	8 (29)	12 (44)
60-74	12 (43)	9 (33)
75+	2 (7)	2 (7)
Years since SCI[a], mean (SD)	16.30 (12.7)	18.90 (15.0)
Etiology of injury, n (%)		
TSCI[b]	22 (79)	24 (89)
NTSCI[c]	6 (21)	3 (11)
Level of injury[d], n (%)		
C1-C4	4 (14)	5 (19)
C5-C8	5 (18)	6 (22)
T1-S3	19 (68)	16 (59)
AIS grade[e], n (%)		
A	18 (64)	18 (67)
B	3 (11)	0 (0)
C	6 (21)	8 (30)
D	1 (4)	1 (4)
SCI-associated problems, n (%)		
Incontinence	25 (89)	23 (85)
Pain (all types)	8 (29)	9 (33)
Spasticity	9 (32)	8 (30)
PI[f] category, mean (SD)	2.90 (0.86)	2.82 (0.98)
Other PIs/PI recurrence, n (%)		
No	3 (11)	7 (26)
Yes, other PI	11 (39)	9 (33)
Yes, recurrence	13 (46)	10 (37)
Yes, both	1 (4)	1 (4)
Comorbidity, n (%)		
DM1[g]	1 (4)	1 (4)
DM2[h]	6 (21)	2 (7)
Hypertension	10 (36)	4 (15)
CV disease[i]	4 (14)	7 (26)
TE disease[j]	6 (21)	6 (22)
Depression/low mood	2 (7)	3 (11)

Characteristics	Videoconference group (n=28)	Regular care group (n=27)
Regular use/abuse, n (%)		
None	9 (32)	9 (33)
Tobacco	14 (50)	15 (56)
Alcohol	13 (46)	11 (41)
Illegal drugs	0 (0)	1 (4)

[a]SCI: spinal cord injury.

[b]TSCI: traumatic spinal cord injury.

[c]NTSCI: nontraumatic spinal cord injury.

[d]Level of injury: location of the injury in the spinal cord (C: cervical, T: thoracic, and S: sacrum).

[e]AIS grade: completeness/severity of the injury.

[f]PI: pressure injury.

[g]DM1: diabetes mellitus type 1.

[h]DM2: diabetes mellitus type 2.

[i]CV disease: cardiovascular disease.

[j]TE disease: thromboembolic disease.

Pressure Injuries at Baseline

In the VCG, 32% (9/28) of the PIs were category 2, 50% (14/28) category 3, 11% (3/28) category 4, and 7% (2/28) could not be categorized at the time of inclusion. The distribution in the RCG was 52% (14/27) were category 2, 22% (6/27) category 3, 19% (5/27) category 4, and 7% (2/27) were unstageable.

Most of the PIs were located at the ischial tuberosities: 50% (14/28) in the VCG and 33% (9/27) in the RCG. At the sacrum-gluteal cleft, PIs occurred in 32% (9/28) of the participants in the VCG and 48% (13/27) in the RCG.

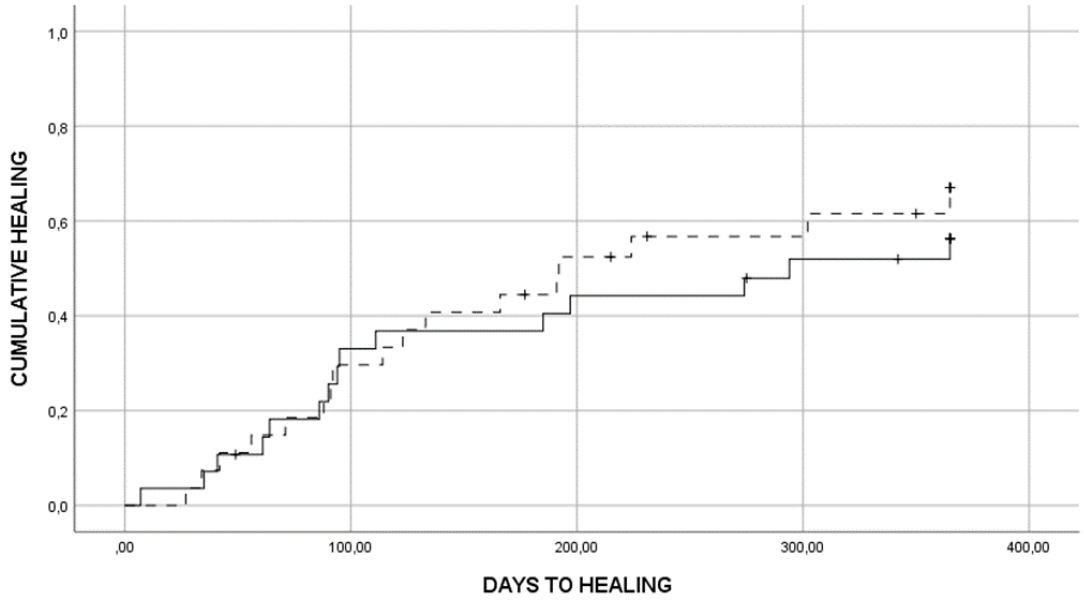
Health-Related Quality of Life

The SF-36 scale, the UK version of the EQ-5D scale, and the ISCI-QoL-BDS basic data set were used to measure and compare changes in HRQoL. Performing a linear regression analysis, comparing the 2 groups with adjustment for baseline, did not yield any significant differences regarding HRQoL, as shown in Multimedia Appendix 1 (imputed data). Multimedia Appendix 2 shows the complete data.

Healing

A total of 67% (37/55) of all PIs healed completely during follow-up: 64% (18/28) in the VCG versus 70% (19/27) in the RCG. Mean reduction in ulcer volume in the VCG was 79% versus 85% in the RCG. No significant difference in the 2 groups were found (P=.32). The median time to healing in the VCG was 275 days (95% CI 111.18-438.83) versus 192 days (95% CI 113.71-270.29) in the RCG. A Kaplan-Meier plot (Figure 4) with a logrank test regarding time to healing did not show any significant difference between the 2 groups (P=.56). Figure 4 displays time to healing in both groups.

Figure 4. Kaplan-Meier plot showing time to healing in the two groups (videoconference: solid line; regular care group: dotted line).



Interaction, Satisfaction, and Safety

A total of 85% (47/55) of the included participants responded to the feedback form, 86% (24/28) in the VCG and 85% (23/27) in the RCG. No significant differences were found in interaction, satisfaction or safety, and the estimated mean differences were minor. Table 2 shows the mean difference between the RCG and VCG, with corresponding confidence intervals and P values. The district nurses were also asked to report their experienced interaction, satisfaction, and safety with the follow-up. A total of 45% (24/55) of the nurses responded, 52% (14/28) in the VCG and 38% (10/27) in the RCG. No significant differences were found in the 2 groups.

Table 2. Comparison of interaction, satisfaction, and safety experienced by participants and district nurses as reported at follow-up.

	Mean difference[a]	95% CI	P value[b]
Participants			
Planning	–0.08	–0.78 to 0.62	0.82
Implementation	–0.04	–0.73 to 0.81	0.91
Interaction	0.14	–0.59 to 0.87	0.70
Participation	–0.13	–0.67 to 0.94	0.74
Safety	–0.01	–0.77 to 0.76	0.99
Usefulness	–0.19	0.97 to 0.60	0.63
Overall satisfaction	0.11	0.66 to 0.88	0.78
District nurses			
Planning	0.21	–0.41 to 0.82	0.49
Implementation	0.04	–0.55 to 0.63	0.88
Interaction	0.33	–0.32 to 0.99	0.30
Participation	0.00	–0.60 to 0.60	1.00
Safety	0.16	0.41 to 0.74	0.56
Usefulness	–0.15	0.87 to 0.56	0.65
Overall satisfaction	–0.16	–0.68 to 0.36	0.52

[a]Mean difference: difference in mean values (regular care group minus videoconference group).

[b]Based on an independent *t* test.

Discussion

Principal Findings

SCI has a huge impact on the individual, the family, and the health care system. Regular contact with specialized health care is required for the condition itself as well as the frequent related complications such as PI. Thus, there is an urgent need to secure availability of high-quality services for patients who live far from specialists and require long-term follow-up [5,34]. Individuals with SCI and PI require frequent outpatient care to monitor their wounds [34]. Long travel distances to receive treatment, resulting in time-consuming transport, can attribute to greater morbidity [6]. To our knowledge, this is the first randomized controlled study using videoconferencing to provide long-term treatment to persons with PI. The results from our study indicate that regular home-based videoconferences are as safe for patients and their district nurses as conventional care with in-person attendance.

According to our study, the HRQoL was not dependent of the type of health service offered. We still find it relevant to mention that the estimated mean difference was in favor of the VCG for 12 out of 13 HRQoL scores. There were no substantial differences between the analyses based on the imputed data (Multimedia Appendix 1) and the complete case analysis (Multimedia Appendix 2).

In this study, the 2 groups were evenly distributed by gender, age, PI occurrence, and PI location. There were no significant differences regarding healing between the 2 groups. Looking at the Kaplan-Meier plot (Figure 4), the 2 curves follow each other very closely, at least for the first 200 days, indicating that the videoconference service was as efficient as the conventional follow-up. All participants and their district nurses were given similar guidance regarding nutrition, skin care, PI prevention, position change, and pressure relieving mattresses and cushions, and an individual treatment plan was established for each participant in both groups [27].

We also investigated the association between potential risk factors and time to healing as a post hoc analysis. Interestingly, overall comorbidities did not show any association regarding time to heal. Due to low number of concomitant diseases among the participants in our study (Table 1), further substudies could not be performed.

Participants in both groups and their district nurses reported acceptable levels of experienced interaction and satisfaction, with no significant differences regarding the follow-up. This indicates videoconference consultations offer satisfactory remote

interaction with the district nurses as compared to regular follow-up. However, we believe a larger study with a noninferiority design would be warranted to establish this.

There is a lack of studies regarding PI and long-term follow-up in the literature. Based on the number of nonhealing PIs in our study, a longer follow-up period may be an interesting topic for future research. We also think that the issue of nonhealing PI should be further explored, no matter the mode of follow-up intervention.

Telemedicine has been widely adapted in many fields of medicine, especially in recent years. We believe that this should also be the case for rehabilitation and that individualized follow-up where a hybrid solution of video communication and conventional consultations is used, may be a promising path for the future.

Limitations

When the present study was designed, we based our sample size calculation on an investigation of HRQoL. However, we do not have sufficient statistical power to provide conclusive evidence regarding the rest of the comparisons we performed in this study.

Comparison With Prior Work

This study is the first randomized, controlled, multidisciplinary long-term study using videoconference as mode of administration of treatment to provide care to persons with SCI and PI [15]. Videoconference consultations seem to be an acceptable solution concerning treatment and follow-up. Our study shows feasibility and efficacy in the examined population. However, the heterogeneity regarding participants, modalities, and the level of mixed evidence in previous research makes it difficult to compare with prior work [15,35]. This is also in line with previous research [13,15,17,20,21,36].

Conclusion

Videoconference in a patient's home ensures safe and efficient quality of care without any reduction in HRQoL, PI healing, or satisfaction as compared to conventional outpatient care at the hospital. Long-term videoconference at home under these circumstances ensures interaction with patients and district nurses and assures they receive relevant information on-site. Further research should assess and compare the value of videoconference for routine long-term care, such as managing spasticity, urinary tract and bowel needs, and chronic pain.

Data Archiving

The dataset is stored in a locked and fireproof research cabinet at the research department, Sunnaas Rehabilitation Hospital, Norway, and can be made available on request according to the Norwegian Data and Telecommunications Authority's requirements for safe information flow [26].

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Authors' Contributions

II and TR designed the protocol of the study. JMH, RJ, MT, and JKS coauthored the protocol, in particular regarding the methodology and design of the custom-made forms and scales. II collected and entered the data. II and MT performed data analysis. II was the main author of the article, and JMH, RJ, MA, JKS, MT, and TR coauthored the manuscript and supervised during the writing. The main author and all coauthors critically read and approved the final manuscript before submission and publishing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Differences in health-related quality of life between the two groups from baseline to end of follow-up, based on imputed data.
[DOCX File , 19 KB - formative_v6i4e27692_app1.docx]

Multimedia Appendix 2
Differences in health-related quality of life between the two groups from baseline to end of follow-up, based on actual data.
[DOCX File , 21 KB - formative_v6i4e27692_app2.docx]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 96 KB - formative_v6i4e27692_app3.pdf]

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Abbreviations

AIS: American Spinal Injury Association (ASIA) Impairment Scale
ASIA: American Spinal Injury Association
CONSORT: Consolidated Standards of Reporting Trials
EQ-5D: Five Dimensions European Quality of Life scale
HRQoL: health-related quality of life
ISCI-QoL-BDS: International Spinal Cord Injury Quality of Life Basic Data Set
PI: pressure injury
RCG: regular care group
SCI: spinal cord injury
SF-36: 36-item Short Form Health Survey
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
TIDieR: Template for Intervention Description and Replication
VCG: videoconference group

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Original Paper

The Cost-effectiveness of a Mass Media Campaign to Promote Smartphone Apps for Weight Loss: Updated Modeling Study

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Abstract

Background: Evidence suggests that smartphone apps can be effective in the self-management of weight. Given the low cost, broad reach, and apparent effectiveness of weight loss apps, governments may seek to encourage their uptake as a tool to reduce excess weight in the population. Mass media campaigns are 1 mechanism for promoting app use. However, the cost and potential cost-effectiveness are important considerations.

Objective: The aim of our study was to use modeling to assess the health impacts, health system costs, cost-effectiveness, and health equity of a mass media campaign to promote high-quality smartphone apps for weight loss in New Zealand.

Methods: We used an established proportional multistate life table model that simulates the 2011 New Zealand adult population over the lifetime, subgrouped by age, sex, and ethnicity (Māori [Indigenous] or non-Māori). The risk factor was BMI. The model compared business as usual to a one-off mass media campaign intervention, which included the pooled effect size from a recent meta-analysis of smartphone weight loss apps. The resulting impact on BMI and BMI-related diseases was captured through changes in health gain (quality-adjusted life years) and in health system costs. The difference in total health system costs was the net sum of intervention costs and downstream cost offsets because of altered disease rates. An annual discount rate of 3% was applied to health gains and health system costs. Multiple scenarios and sensitivity analyses were conducted, including an equity adjustment.

Results: Across the remaining lifetime of the modeled 2011 New Zealand population, the mass media campaign to promote weight loss app use had an estimated overall health gain of 181 (95% uncertainty interval 113-270) quality-adjusted life years and health care costs of –NZ $606,000 (–US $408,000; 95% uncertainty interval –NZ $2,540,000 [–US $1,709,000] to NZ $907,000 [US $610,000]). The mean health care costs were negative, representing overall savings to the health system. Across the outcomes examined in this study, the modeled mass media campaign to promote weight loss apps among the general population would be expected to provide higher per capita health gain for Māori and hence reduce health inequities arising from high BMI, assuming that the intervention would be as effective for Māori as it is for non-Māori.

Conclusions: A modeled mass media campaign to encourage the adoption of smartphone apps to promote weight loss among the New Zealand adult population is expected to yield an overall gain in health and to be cost-saving to the health system. Although other interventions in the nutrition and physical activity space are even more beneficial to health and produce larger cost savings (eg, fiscal policies and food reformulation), governments may choose to include strategies to promote health app use as complementary measures.

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KEYWORDS

mass media; smartphone apps; weight loss; cost-effectiveness; simulation modeling; health equity; mobile phone

Introduction

Background

The obesogenic food environment and unhealthy dietary patterns have led to overweight and obesity becoming a critical public health problem [1,2]. These risk factors result in numerous health conditions, including diabetes, cardiovascular disease, and certain forms of cancer [1,2]. Overweight and obesity are the fifth highest risk factor for global mortality, corresponding to at least 2.8 million deaths each year [1]. Elevated BMI levels also pose a substantial economic burden, with obesity alone directly accounting for an estimated 0.7% to 2.8% of national health care expenditures among a wide range of countries [3].

Although modifying the food and physical activity environment is critical, addressing unhealthy dietary patterns and insufficient physical activity (and therefore overweight and obesity [4]) in individuals is also important. Even modest weight loss can yield substantial health benefits [5,6], especially when distributed across the population level. There has been an increase in the use of mobile health (mHealth) tools for addressing weight loss goals [7,8]. The widespread use of mobile phones makes mHealth interventions easily scalable to a broader population [9,10], and as a result, mHealth interventions are increasingly considered tools for weight loss in individuals. Although there are numerous types of mHealth tools (eg, PDAs, iPods, and MP3 players) and services (eg, health call centers, appointment reminders, health surveys and data collection, and mobile patient records [11]), smartphone apps have been identified as particularly popular among the general population and potentially effective at supporting weight management [7,9,12].

The use of health apps is increasing, with a reported 50% of smartphone users having ever downloaded a health app [13,14]. The most popular health apps are typically for diet and physical activity tracking, weight management, and adherence to medication [13,15]. Weight loss apps may be especially useful for circumstances where face-to-face weight loss treatments are not possible or not preferred [16]. Smartphone apps are generally considered easy to use and to be helpful in pursuing weight loss goals by many patients [7], even for older participants [12].

Reviews have found that mHealth interventions can be more effective than non-mHealth interventions at inducing weight loss and improving diet and physical activity [17]; mHealth interventions also promote adherence to weight loss behaviors [9]. Even when mHealth apps produce outcomes equivalent to those of traditional interventions, their broad accessibility makes them a valuable tool [7]. However, there are limitations to the effectiveness of app use. For instance, engagement with apps declines over time [7,18], especially for dietary tracking [19,20]. Researchers estimate that a quarter of mHealth apps are only used once after download, and most individuals stop using mHealth tools before the fifth interaction [21,22]. However, other evidence suggests that apps are most effective for weight loss management when certain characteristics are incorporated [7], such as self-monitoring of physical activity and diet, reminders for app use, and social interaction with peers [7,23,24]. Generally, higher adherence to self-monitoring is associated with improved weight loss outcomes [10,25].

Given the low cost, broad reach, and apparent effectiveness of apps at promoting weight loss, governments may seek to encourage the uptake of such apps as an opportunity for reducing excess weight among the population. For example, in the United Kingdom, the National Health Service has developed a free 12-week diet and exercise plan that is available as an app [26] that incorporates a mass media campaign to promote use [27]. Such campaigns may be an important intervention component to increase the use of effective weight loss apps among the population and stimulate reductions in BMI. Evidence indicates that health mass media interventions can effectively encourage the use of health support resources [28,29] and influence public dietary behaviors [30-35].

The cost and potential cost-effectiveness are important considerations when governments are selecting among obesity reduction interventions, including the use of mass media campaigns. Research by Cleghorn et al [36] used health economic simulation modeling to assess the cost-effectiveness of a hypothetical mass media campaign in New Zealand that promotes the uptake of weight loss mHealth technologies. Along with numerous other parameters, the authors used the results of a 2014 meta-analysis of mobile device interventions to quantify how much weight loss could occur [17]. The authors found that such a campaign was not cost-effective in the base case analysis [36]. Another study using similar methods assessed the potential of a mass media campaign to promote smartphone apps for physical activity and found that it was unlikely to be cost-effective at the population level, although the health impact and cost-effectiveness estimates were highly sensitive to assumptions around long-term adherence [37]. The evidence on the cost-effectiveness of mass media campaigns is primarily from tobacco control [29], and previous research indicates that a mass media campaign for promoting smoking cessation apps is likely to be cost saving [38].

Updated Estimates

Since the modeling conducted by Cleghorn et al [36] on the weight loss mHealth mass media campaign, there has been rapid growth in the literature on the effectiveness of weight loss apps, as well as changes in app technology and a higher uptake of smartphones. In this study, we use updated parameters that reflect these developments and recent data on app use over time, thereby providing updated estimates that reflect the current context. The setting for this study is New Zealand, a typical high-income country with high rates of overweight and obesity [39]. Our study uses a multistate life table modeling approach to assess the health impacts, health system costs, cost-effectiveness, and health equity of a mass media campaign to promote high-quality smartphone apps for weight loss in New Zealand.

Methods

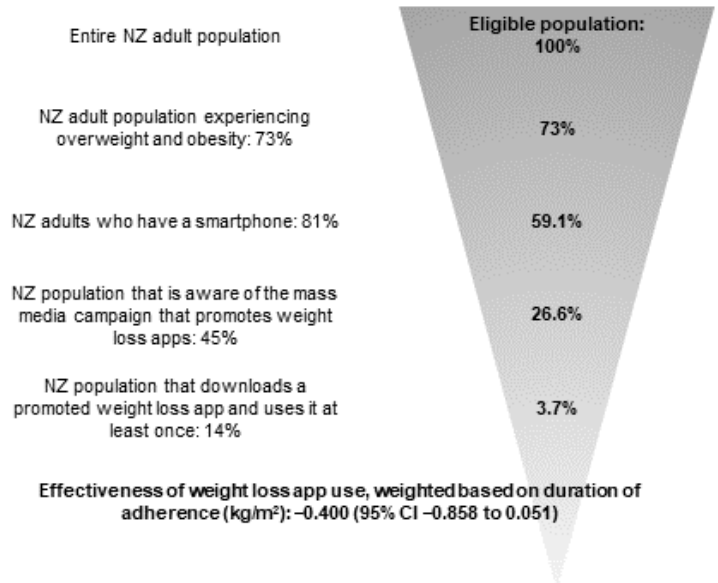
Overview

We used an established proportional multistate life table model [40] that was parameterized with health data for the 2011 New Zealand adult population and simulates this population until death. The risk factor of interest was BMI; the simulation model designates the proportion of New Zealand adults with overweight or obesity (overweight: BMI 25 kg/m^2 to <30 kg/m^2; obesity: BMI ≥30 kg/m^2). We compared a business-as-usual baseline analysis to an intervention base case analysis. The resulting impact on BMI and BMI-related diseases was captured through changes in health gain (as measured by quality-adjusted life years [QALYs]) and in health system costs (net sum of intervention costs and downstream cost offsets because of altered disease rates). The study used a health system perspective that focused on costs and benefits within the health system [41]. An annual discount rate of 3% was applied to health gains and health system costs, consistent with established New Zealand modeling protocols [41] and health economic expert recommendations [42]. Discounting is a standard practice in economic evaluation to account for preferences toward present benefits over future benefits [41]. Full details on the model are documented elsewhere [40].

Intervention Pathway

The modeled intervention was a one-off mass media campaign among the New Zealand population stimulating the uptake and use of a smartphone app for weight loss that effectively promotes weight loss. The pathway from the intervention's implementation to impact is detailed in Figure 1. The proportion of the New Zealand population that would experience weight loss was calculated as follows: out of the New Zealand adult population, the intervention was applicable to only New Zealand adults aged >18 years with overweight or obesity (73% of the total adult population). Using recent metrics on New Zealand smartphone ownership, 81% of New Zealand adults own a smartphone [43] (eligible population reduced to 59.1%). To model the reach of the mass media campaign, we used the results reported by Kite et al [44] of an obesity-prevention mass media campaign called Make Healthy Normal that was run over 1 year by the New South Wales (NSW) government in Australia. Recognition of the campaign was 45% among sampled adults aged ≥18 years after completion of the campaign, which consisted of television commercials, community events, press, out-of-home (eg, billboards) and web-based advertising, public relations, a website, and social media [44]. We identified other studies that evaluated recognition of mass media campaigns [30,32]. However, the NSW study by Kite et al [44] was preferred because it evaluated a health campaign that we could verify was resourced similarly to the high level of costs associated with our modeled mass media campaign: Make Healthy Normal campaign NZ $0.37 (US $0.25) per capita of the NSW population [44] and modeled campaign NZ $0.66 (US $0.44) per capita of the New Zealand population. As the New Zealand modeled campaign involved a higher cost per capita than the NSW campaign, in sensitivity analysis we modeled a scenario where this greater resourcing produced an enhanced mass media campaign that achieved wider recognition than the NSW campaign. On the basis of the rate of campaign recognition, the eligible population reduced to 26.6% of the total adult population. We found limited published research on the degree to which government-led mass media campaigns can stimulate health app use. After a search of academic and gray literature, we identified only 1 study that quantified a relationship between a mass media campaign to promote health app use and subsequent health app use [45]. In the study, the authors found that 14% of the surveyed respondents reported *taking an action* after a UK-based mass media campaign to promote an uptake of a health app [45]. Assuming that this *action* was to download and use the app at least once, we modeled app downloads and use as 14% of the New Zealand adult population. The final eligible population that would use the app and experience weight loss was 3.7% of the New Zealand adult population.

Figure 1. Flowchart of intervention conceptualization. NZ: New Zealand.



Weight Loss App Effectiveness

We quantified the effectiveness of weight loss apps using the results of a recent meta-analysis by Islam et al [46]. The review's authors examined randomized controlled trials and case-control studies published from 2000 to mid-2019 on mobile phone app interventions for reducing body weight (including BMI) and increasing physical activity among children and adults. We preferentially selected this meta-analysis for modeling over other reviews [9,47-53] because of the focus on mobile apps (over other mHealth or mobile phone–based interventions), selection of studies with control groups that received minimal or no interventions, preferred outcome (ie, BMI), meta-analyzed results, and recent publication date with latest available studies. In the 10 included studies that examined BMI, the proportion of male participants ranged from 0% to 15%. The mean age of the participants ranged from 12.7 years to 44.9 years. For the outcome of weight, Islam et al [46] reported finding that longer trials (>3 months) were associated with significantly greater weight loss than shorter trials (≤3 months), suggesting that greater app adherence (ie, longer use) is associated with greater weight loss than shorter app adherence. For the outcome of BMI, Islam et al [46] conducted an analysis of all included trials (pooled effect size –0.454, 95% CI –0.787 to –0.121) and did not conduct meta-analyses by trial duration subgroup (ie, ≤3 months vs >3 months). We calculated these pooled effect sizes using the study's reported data (≤3 months –0.219, 95% CI –0.672 to 0.223; >3 months –0.609, 95% CI –1.072 to –0.146) [46]. In the >3-month subgroup, the maximum trial length was 9 months. We consulted evidence on weight loss app adherence from the UK study by Carter et al [54], which measured the proportion of users who adhered to app use for ≤3 months (53% of the users) and >3 months (47% of the users). We multiplied each pooled effect size by the proportion of users and summed to produce a weighted effect size of app effectiveness that accounted for variations in duration of app use:

$$E_{weighted} = (E_{\leq 3\ months} \times >P_{\leq 3\ months}) + (E_{>3\ months} \times P_{>3\ months})$$

where E is the effect size and P is the proportion of users. The resulting weighted estimate of weight loss app effectiveness was –0.400 kg/m^2 (95% CI –0.858 to 0.051 kg/m^2). Additional details on these decisions and steps are reported in Multimedia Appendix 1 [19,46,54].

Intervention Modeling Approach

In our modeling, the business-as-usual baseline encapsulated the existing levels of dietary health promotion in New Zealand, including current promotion of weight loss apps, and the continuation of the current low or no app promotion environment. The costs of implementing the intervention are reported in Table 1, with further details regarding the methods used to scope these costs reported by Cleghorn et al [36].

Table 1 provides further detail on the inputs used to conceptualize the intervention pathway, along with the type of distribution modeled for each of these inputs. For the effectiveness of the weight loss app, CIs quantified the range of plausible values. As no measures of variance were available for the remaining inputs, we applied our established protocol and estimated an SD of either 5%, 10%, or 20% of the central value [56]. A value of 20% was used when there was deemed to be a high degree of uncertainty that could influence effectiveness and cost-effectiveness outcomes from the modeled intervention.

Table 1. Intervention parameters and uncertainty distributions.

Parameter	Value	Distribution	Source
Adult New Zealand population who own a smartphone, % (SD)	81 (5)	Beta	As reported by DataReportal based on Google Consumer Barometer data [43]
Adult New Zealand population who are assumed to be aware of a relevant mass media campaign, % (SD)	45 (20)	Beta	On the basis of an evaluation of an Australian obesity-prevention mass media campaign that measured the proportion of survey respondents who recognized the campaign [44]
Adult New Zealand population who were assumed to download and use a promoted weight loss app, % (SD)	14 (20)	Beta	On the basis of the proportion of survey respondents who reported *taking an action* after a UK-based mass media campaign to promote use of a health app [45]
Intervention BMI reduction for those who used the app (kg/m^2; 95% CI)	–0.400 (–0.858 to 0.051)	Normal	The weighted results of studies included in the Islam et al [46] meta-analysis of smartphone app weight loss trials whereby the pooled effect sizes for interventions ≤3 months and interventions >3 months were weighted based on adherence rates at 3 months, obtained from Carter et al [54]
Assumed weight regain after delivery of the intervention (kg/m^2 per month; SD %)	0.03 (20)	Log-normal	Meta-analysis of weight loss decay evidence from Dansinger et al [55], as used in the previous published work by Cleghorn et al [36]
Estimated cost of one-off 1-year national-level mass media campaign, NZ $ (US $; SD %)	2,883,000 (1,940,000; 20)	Gamma	As used in the previous published work by Cleghorn et al [36]. New Zealand data on the costs consist of identifying high-quality apps and a national mass media campaign across multiple media

Multistate Life Table Model Overview

The multistate life table model consists of a main life table organized by age, sex (male or female), and ethnicity (Māori or non-Māori) and populated with all-cause mortality and morbidity rates for the 2011 New Zealand adult population. Parallel to this are life tables for each BMI-related disease where proportions of the simulated population are also modeled. Although the model includes a wide array of diet-related diseases [40], our intervention focused on weight loss and used only the disease tables for 14 BMI-related diseases: coronary heart disease, stroke, type 2 diabetes, osteoarthritis, and cancers (endometrial, kidney, liver, esophageal, pancreatic, thyroid, colorectal, breast, ovarian, and gallbladder).

Mortality and Morbidity Modeling

Within the model, the proportions of the population in each disease table are a function of past and current rates of disease incidence, case fatality, and, for cancers only, remission, which are calculated at each annual time step. The model is populated with mean BMI values according to age, sex, and self-identified ethnicity measured in person during New Zealand's most recent available national nutrition survey (New Zealand Adult Nutrition Survey 2008-2009) [57]. The mass media campaign intervention induces changes in BMI for a proportion of the New Zealand population. The effect of these BMI changes is combined with relative risks that capture the association between BMI and BMI-related disease outcomes to produce modified population impact fractions [40]. As the risk of BMI-related diseases decreases after implementation of the intervention, the population impact fractions modify disease incidence rates, resulting in changes to all-cause mortality and morbidity rates. Time lags to simulate the delay between when BMI change occurs and when changes in disease incidence across the population-risk distribution occur were built in for all conditions. Specifically, the change on disease rates was distributed over 0 to 5 years for cardiovascular diseases, diabetes, and osteoarthritis and over 10 to 30 years for cancers, with probabilistic uncertainty added in around these lag periods. Although there is evidence that mHealth interventions can result in changes in dietary intake beyond reduced weight loss, such as increased fruit and vegetable intake and decreased takeout meals [7], our intervention modeling focused on the effects of the app on BMI and assumed no other impacts on diet or physical activity.

Our model included the health system costs associated with changing disease prevalence and population longevity, which were calculated using an established protocol [40]. These costs were specific to the condition, age, and sex and were based on the timing of health events (first year of illness, subsequent years of illness, and the last 6 months of life). The change in the proportions of the population in each disease state resulted in proportional changes in health system costs and unrelated health system costs from people living longer. The intervention's overall results reflect projected health gains and health system cost impacts over the remainder of the modeled population's life course.

Equity, Scenario, and Sensitivity Analyses

In addition to the main base case intervention, we conducted an equity analysis where an *equity adjustment* was applied in the model to eliminate differences in life expectancy between Māori (Indigenous) and non-Māori. Other scenario and sensitivity analyses were conducted to examine the potential impact of alternative modeling parameters and decisions. These consisted of the following: (1) the mass media campaign's design is enhanced, leading to wider recognition of the campaign's key message (68% recognition rather than 45%, using evidence from an evaluation of New Zealand's Health Promotion Agency *Small Steps* campaign [58]); (2) improved weight loss apps that have been developed since the meta-analysis we used, leading to a hypothetical 50% improvement in app effectiveness (modeled by increasing the mean BMI reduction by 50%); (3) all app users use the app for more time to test impact if there is good long-term engagement (modeled using the pooled effect size for trial lengths of >3-9 months); (4a) weight regain is delayed by 1 year; (4b) weight regain is delayed by 5 years; (4c) no weight regain occurs throughout the remaining life of the modeled population (ie, a highly hypothetical scenario that quantifies the envelope of potential benefit that could be obtained if weight regain was avoided); (5) the effect size for weight loss app effectiveness that was used in the previous modeling by Cleghorn et al [36] is applied in this study's updated model and intervention pathway; and (6) alternative discount rates of 0% and 6% are applied to health gains and healthy system costs to illustrate the impact of discount rates. This variation of discount rates is consistent with established health economic evaluation practices [41].

Simulation Analysis

The model was built in Microsoft Excel and run using Ersatz (version 1.34; EpiGear International). Uncertainty around health gains and cost-effectiveness was quantified using a Monte Carlo analysis. The parameters were sampled independently 2000 times from each of their respective probability distributions. The presented results are the mean values, with 95% uncertainty intervals (UIs). The exception to this is the expected values in the scenario and sensitivity analyses, which did not include uncertainty analysis.

Results

Health Gain and Cost Savings

Across the remaining lifetime of the modeled 2011 New Zealand population, the mass media campaign to promote weight loss app use in the base case analysis had an estimated overall health gain of 181 (95% UI 113-270) QALYs and health care costs of –NZ $606,000 (–US $408,000; 95% UI –NZ $2,540,000 [–US $1,709,000] to NZ $907,000 [US $610,000]). The mean of the health care costs is negative, representing an overall savings to the health system and a cost-saving intervention. However, the 95% UI spans positive values, indicating that there remains a possibility that the intervention is not cost saving, albeit still cost-effective (ie, below the threshold of NZ $45,000 [US $30,000] per QALY gained, approximately the gross domestic

product per capita for New Zealand that we use in our modeling [36]).

In the first 10 years after the intervention was implemented (2011-20), the mean health gain was 56 QALYs and net health system expenditures averaged NZ $850,000 (US $572,000) because of the cost of implementing that mass media campaign and few savings to the health system (although still below the cost-effective threshold of NZ $45,000 (US $30,000) per QALY gained). After 20 years (2011-30), the total health gain was 112 QALYs and the mass media campaign became cost-saving (–NZ $176,000 [–US $118,000]) for the health care system. Most of the health gain (62%) occurred between the years 2011 and 2030 (first 20 years after implementation), whereas most of the health system savings (71%) occurred after 2030 (ie, 20 years after implementation). The delayed health system savings was due to the initial up-front cost of implementing the intervention, which was also relatively high compared with the eventual reductions in downstream cost offsets because of altered disease rates.

Table 2 presents the results overall and by subpopulations over the remaining lifetime of the modeled population. The total health gains for non-Māori and Māori were 148 QALYs and 33 QALYs, respectively. Per 1000 population, this equated to 0.040 QALYS for non-Māori and 0.049 QALYS for Māori. When ethnicity was examined by sex and age group, the mean values consistently suggested greater per capita health gains for Māori. These mean values also suggest that the greatest health gain occurs among the age group 45-64 years and that, on average, the health gain was greater for men than for women. The exception to this was Māori women aged ≥65 years; this subgroup had a similar health gain to Māori men (0.079 QALYS per 1000 and 0.078 QALYS per 1000, respectively). Similar patterns were reflected in the health system cost estimates, which are, on average, savings to the health system. When the equity adjustment for Māori was applied (Table 3), the health gains for Māori increased to 40 QALYs and 0.060 QALYs per 1000. On the basis of the outcomes examined in this study, the modeled mass media campaign to promote weight loss apps among the general population would be expected to reduce health inequities arising from high BMI for Māori. However, the absolute reduction in health inequities would be small. In addition, this analysis assumed that the intervention would be as effective for Māori as it is for non-Māori (ie, the mass media campaign was culturally appropriate in design).

Table 2. Health gains and cost-effectiveness of a mass media campaign to promote smartphone apps for weight loss in New Zealand by age, sex, and ethnicity (lifetime impacts and 3% discount rate).

Sex, ethnicity, and age group (years)	Health gain in QALYs[a] (95% UI[b])	Health gain in QALYs per 1000 population (95% UI)	Health system costs[c], NZ $ (US $; 95% UI)
All	181 (113 to 270)	0.041 (0.026 to 0.061)	–606,000 (2,540,000 to –907,000); 408,000 (–1,709,000 to 610,000)
Non-Māori, all ages	148 (85 to 231)	0.040 (0.023 to 0.062)	–491,000 (2,310,000 to 921,000); –330,000 (–1,555,000 to 620,000)
Māori, all ages	33 (18 to 53)	0.049 (0.027 to 0.079)	–115,000 (–494,000 to 158,000); –77,400 (–332,000 to 106,000)
Men, all ages	97 (48 to 170)	0.045 (0.022 to 0.079)	–436,000 (–1,872,000 to 554,000); –293,000 (–1,260,000 to 373,000)
Non-Māori[d]			
25-44	19	0.038	–85,000 (–57,200)
45-64	46	0.094	–556,000 (–374,000)
≥65	16	0.063	–127,000 (–85,500)
Māori[d]			
25-44	6	0.080	–51,000 (–34,300)
45-64	9	0.171	–118,000 (–79,400)
≥65	1	0.078	–13,000 (–8750)
Women, all ages	84 (44 to 141)	0.037 (0.020 to 0.063)	–170,000 (–1,370,000 to 698,000); –114,000 (–922,000 to 470,000)
Non-Māori[d]			
25-44	16	0.031	–45,000 (–30,000)
45-64	35	0.069	–369,000 (–248,000)
≥65	17	0.055	–77,000 (–52,000)
Māori[d]			
25-44	6	0.066	–49,000 (–33,000)
45-64	9	0.143	–106,000 (–71,000)
≥65	1	0.079	–11,000 (–7000)

[a]QALY: quality-adjusted life year.

[b]UI: uncertainty interval.

[c]A negative cost indicates that the intervention is cost-saving to the health system.

[d]The 95% uncertainty intervals for QALY and health system costs were not calculated for these subgroups.

Table 3. Results for Māori with equity adjustment applied (lifetime gains and 3% discount rate).

Population	Health gain in QALYs[a] (95% UI[b])	Health gain in QALYs per 1000 population (95% UI)	Health system costs[c], NZ $ (US $; 95% UI)
All	40 (23 to 65)	0.060 (0.034 to 0.097)	–132,000 (–513,000 to 152,000); –89,000 (–345,000 to 102,000)
Men	20 (9 to 39)	0.062 (0.026 to 0.118)	–67,000 (–341,000 to 115,000); –45,000 (–229,000 to 77,000)
Women	20 (9 to 37)	0.058 (0.025 to 0.109)	–65,000 (–331,000 to 111,000); –44,000 (–223,000 to 75,000)

[a]QALY: quality-adjusted life year.

[b]UI: uncertainty interval.

[c]A negative cost indicates that the intervention is cost saving to the health system.

The modeled lifetime health gains among adults experiencing overweight or obesity were 0.065 (95% UI 0.041-0.097) QALYs per 1000 target population. By ethnicity, the gains for non-Māori were 0.064 (95% UI 0.037-0.100) QALYs and for Māori 0.070 (95% UI 0.038-0.113) QALYs.

Scenario and Sensitivity Analyses

A range of results for scenario and sensitivity analyses are presented in Table 4. The modifications to the intervention pathway scenarios of either a more effective mass media campaign (eg, with better reach and targeting; scenario 1), more effective apps (scenario 2), or greater adherence to app use (scenario 3) all resulted in higher health gains and greater savings to the health system. When the model was altered to delay weight regain by 1 year (scenario 4a), 5 years (scenario 4b), or a highly hypothetical scenario of eliminating weight regain altogether (scenario 4c), the improved health gains and cost savings went from modest (eg, absolute increase in 20 QALYs for weight regain by 1 year) to markedly greater (eg, absolute increase in 14,544 QALYs for no weight regain). This highlights the substantial further health and economic benefits if weight regain was prevented across the remaining life course. The meta-analysis value [17] used in the previous modeling of mass media campaigns to promote weight loss [36] (scenario 5) yielded lower health gains and cost the health system, suggesting that apps have become increasingly more effective in weight management. The varied discount rates yielded results in the expected directions (scenarios 6a and 6b).

Table 4. Sensitivity and scenario analyses for a mass media campaign to promote weight loss smartphone apps by age, sex, and ethnicity (expected value analysis, lifetime perspective, and 3% discount rate, unless otherwise stated).

Sensitivity and scenario analyses[a]	Health gain in QALYs[b]	Difference in QALYs from base case, %	Health system costs[c], NZ $ (US $)	Difference in health system costs from base case, %
Base case analysis	183	—[d]	–625,000 (–421,000)	—
1. Mass media campaign: higher recognition at 68%	276	51	–2,414,000 (–1,620,000)	286
2. Increase effect size of app use by 50%	274	50	–2,375,000 (–1,600,000)	280
3. 100% of population use the app for more time	278	52	–2,454,000 (–1,650,000)	293
4a. Delaying weight regain by 1 year	203	11	–2,400,000 (–1,620,000)	284
4b. Delaying weight regain by 5 years	1,261	589	–21,271,000 (–14,300,000)	3305
4c. No weight regain	14,727	7948	–286,465,000 (–193,000,000)	45,762
5. Value from the previous Cleghorn et al [36] mobile health modeling study	69	–62	1,549,000 (–1,040,000)	–348
6a. 0% discount rate	334	83	–1,892,000 (–1,270,000)	203
6b. 6% discount rate	114	–38	186,000 (–125,000)	–130

[a]Expected values given for all scenarios.

[b]QALY: quality-adjusted life year.

[c]A negative cost indicates that the intervention is cost saving to the health system.

[d]Base case is the reference with which scenarios are compared.

Discussion

Principal Findings and Interpretation

The results from this updated health economic simulation modeling suggest that a hypothetical government-initiated mass media campaign to promote use of smartphone weight loss apps would result in modest health gains over the remaining lifetime of the New Zealand adult population. There was an estimated net saving to the health care system because of reductions in BMI-related diseases, although the UIs included estimates that were cost-effective (rather than cost saving). The intervention would be expected to generate greater per capita health gain for Māori and therefore potentially reduce health inequities attributable to BMI differences between Māori and non-Māori, assuming that the intervention would be as effective for Māori as it is for non-Māori.

Several key characteristics contributed to this modeled mass media intervention being cost-effective. First, and perhaps most importantly for this study, recent evidence from a meta-analysis of randomized controlled trials and case-control studies shows that the use of smartphone weight loss apps largely results in some degree of weight loss, even when accounting for variations in the duration of app use [46]. Several different behavioral theories suggest that self-monitoring progress toward a goal is a critical step between setting a goal and achieving a goal [59]. Apps can be a useful tool for self-monitoring dietary behaviors [9]. Monitoring progress helps to ensure that goals are translated into action, and the effect of an intervention on goal attainment is mediated by the frequency of monitoring [59]. Second, there was a sizable target population for this intervention: adults with excess weight who own a smartphone make up approximately 60% of the population. Accordingly, even small reductions in weight can achieve wide-reaching benefits in health [1]. Third, government-initiated mass media campaigns are relatively low

cost, especially in comparison with measures such as health service provision [60]. When designed well, mass media campaigns are effective at reaching a substantial proportion of the population with key health messages that can lead to modifications in behavior [29]. The World Health Organization has identified mass media as playing an important role in coherent national strategies for obesity prevention and management [61].

We found that there was very limited research examining whether mass media campaigns stimulate the specific action of adopting use of a smartphone app. Therefore, we relied on a UK evaluation of a mass media campaign that encouraged the use of a physical activity app [45]. A mass media campaign to promote a weight loss app would have been more appropriate. The tobacco control literature reports that media campaigns are associated with increased downloads of health apps (eg, smoking cessation apps) [62] and behavior changes further downstream (ie, attempts to quit smoking) [63]. There may be ways of making the mass media campaign more effective by targeting specific population groups in the messaging. For instance, there is evidence that mass media campaigns can better reach ethnic minorities using highly feasible social media or mass media that have reach to particular audiences [64] (eg, iwi radio and Māori Television in the New Zealand context).

Comparison With Prior Work

This paper provides new evidence using updated parameters on the potential health gain and cost-effectiveness of this health intervention. The previous Cleghorn et al [36] modeling conducted by some of our team found that there was very minimal health gain from the mass media campaign to promote mHealth interventions and that the intervention was not cost-effective [36]. However, there are 3 notable differences between the methods used in this study and the previous modeling by Cleghorn et al [36]. Most importantly, in this study, we used the results of a very recent meta-analysis of studies of smartphone weight loss apps showing a meaningful decrease in BMI (–0.454 kg/m^2, 95% CI –0.787 to –0.121 kg/m^2) [46]. The previous modeling used the best available evidence at the time, which was a meta-analysis of mobile device interventions that included apps as well as tools such as SMS text messaging [36]. The pooled effect size, which is measured in kilograms rather than BMI units, showed a comparatively smaller reduction in weight (–0.430, 95% CI –0.609 to –0.252 kg); this smaller effect size was the main contributor to the difference between the 2 studies. For some intervention pathway steps that were the same between the 2 modeling studies, we used different, more recent data. Specifically, smartphone ownership was higher than previously modeled and the reach of the mass media campaign was lower. We also conceptualized some of the pathway between the initial intervention (ie, the mass media campaign) to the effect size (ie, the effect of weight loss app use on BMI) based on new evidence that was incorporated into other modeling on mass media campaigns [37]. In our sensitivity analyses, we used the previously modeled effect size to isolate how much of a difference was due to the revised pathway versus the effect size. We found that most of the improved outcomes in our modeling were due to greater effectiveness of the apps, with only a small proportion of the gain due to the different conceptualization of the pathway. Our study adds to the very limited simulation modeling evidence on the cost-effectiveness of health apps [36-38].

Strengths and Limitations

A strength of this research is that it builds upon an established model [40], uses an effect size from a recent meta-analysis [46], and uses high-quality disease data that includes ethnicity-specific data [40]. There are a number of other ways that the mass media campaign could have been modeled, including alternative pathways that reflect numerous theories used to inform the development of mass media campaigns [29]. To account for a degree of uncertainty in input parameters and stochastic uncertainty, we modeled distributions of these inputs and quantified this variation using UIs. Parallel pathways for achieving impacts could be part of this intervention. For instance, we did not model that app uptake may also be by people who did not see the campaign but whose family members or friends saw it, started to use the app, and encouraged them to use it. In addition, the modeling might have underestimated the health benefits, given that there is evidence that mHealth interventions can result in changes in dietary intake beyond reduced weight loss, such as increased fruit and vegetable intake and decreased takeout meals [7] (which are typically high in sodium, sugar, and saturated fats). Some of these apps can also promote physical activity, which provides benefits to health beyond just a BMI pathway (eg, to mental health and cardiovascular health). It is unclear what proportion of the New Zealand population is already using a weight loss app and thus would not take up this intervention. However, despite the relatively high availability of mHealth apps, the level of awareness of such apps by individuals may be relatively low [65] and the apps being used may not be on the high-quality end of the spectrum. Our modeling did not account for differential impacts of either different apps or individual characteristics that could influence the adoption and engagement of apps, including the duration of this engagement and the quality of this engagement. Such differential impacts are too complex for inclusion in models of this design and also require highly detailed data for accurate measures. There is also no consistent definition for measuring constructs such as adherence to app use, which can encompass characteristics such as frequency, consistency, and detail of dietary monitoring [66].

Potential Policy Implications

As part of a wide range of interventions to address the obesogenic environment and unhealthy dietary patterns, governments should consider investing in promoting such weight loss apps, along with funding research that improves their effectiveness and uptake in the community. But all such interventions should also be well evaluated, particularly given the large potential for scalability. Laws and taxes can create a less obesogenic environment (and have been shown to be more cost-effective than nutrition mass media campaigns [60]). However, such actions can take time, and there is political and food industry resistance [67]. Hence, there is a role for tools (such as smartphone apps) that support using dietary changes that improve weight management as complementary measures.

Smartphone apps can also be combined with traditional interventions (eg, face-to-face counseling) [68], can form a component of a broader national social marketing health strategy [69], or they can be used as stand-alone treatments [54]. There may be further benefit from smartphone apps when face-to-face contact with patients must be limited [9], as in the case of the COVID-19 pandemic.

Conclusions

Using recent evidence on the effectiveness of smartphone weight loss apps, a modeled mass media campaign to encourage the adoption of smartphone apps to promote weight loss among the New Zealand adult population is expected to yield an overall gain in health and to be cost saving to the health system. This is an update of previous modeling that showed a smaller health gain and that the intervention was not cost-effective. Although other interventions in the nutrition and physical activity space are even more beneficial to health and cost savings (eg, pricing policies and food reformulation [60]), governments may choose to include strategies to promote health app use as a feasible complementary measure.

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Authors' Contributions

ACJ led the conceptualization of the intervention, modeled the intervention, and wrote the first draft of the paper (excluding the introduction). LG wrote the first draft of the introduction. NW contributed to the study and intervention conceptualization and led the research grant that funded the study. NN provided foundational work in the costing of the modeled intervention. CC led the development of the diet model, contributed to the study and intervention conceptualization, and provided modeling expertise. All authors contributed to drafts of the manuscript and read and approved the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Calculating the weighted pooled intervention effect size.
[DOCX File , 50 KB - formative_v6i4e29291_app1.docx]

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Abbreviations

mHealth: mobile health
NSW: New South Wales
QALY: quality-adjusted life year
UI: uncertainty interval

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Original Paper

Toward Research-Informed Design Implications for Interventions Limiting Smartphone Use: Functionalities Review of Digital Well-being Apps

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Abstract

Background: Much research in human-computer interaction has focused on well-being and how it can be better supported through a range of technologies, from affective interfaces to mindfulness systems. At the same time, we have seen a growing number of commercial digital well-being apps. However, there has been limited scholarly work reviewing these apps.

Objective: This paper aims to report on an autoethnographic study and functionality review of the 39 most popular commercial digital well-being apps on Google Play Store and 17 apps described in academic papers.

Methods: From 1250 apps on Google Play Store, we selected 39 (3.12%) digital well-being apps, and from Google Scholar, we identified 17 papers describing academic apps. Both sets of digital well-being apps were analyzed through a review of their functionalities based on their descriptions. The commercial apps were also analyzed through autoethnography, wherein the first author interacted with them to understand how these functionalities work and how they may be experienced by users in their daily lives.

Results: Our findings indicate that these apps focus mostly on limiting screen time, and we advanced a richer conversation about such apps, articulating the distinctions among monitoring use, tracking use against set limits, and 4 specific interventions supporting limited use.

Conclusions: We conclude with 6 implications for designing digital well-being apps, namely calling to move beyond screen time and support the broader focus of digital well-being; supporting meaningful use rather than limiting meaningless use; leveraging (digital) navigation in design for friction; supporting collaborative interaction to limit phone overuse; supporting explicit, time-based visualizations for monitoring functionality; and supporting the ethical design of digital well-being apps.

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KEYWORDS

digital well-being; smartphone apps; tracking use; monitoring against set use limits; interventions for limiting use; barriers; design for friction; screen time; attention; self-regulation; mobile phone

Introduction

Background

A significant growth of research in well-being [1] and affective health [2] has taken place in the last decade across a range of disciplines, from human-computer interaction (HCI) and science and technology studies to clinical psychology and psychiatry. This range reflects the interdisciplinary work in this space, and we argue the unique position of the HCI discipline to articulate the design knowledge required for digital well-being interventions. Such work includes novel affective interfaces

intended to support real-time awareness of emotions or their regulation [3-7], novel design approaches emphasizing the importance of the human body such as soma design [8], novel technologies supporting reflection and meaning making [9], and those intended to train meditation or mindfulness skills [10] or to conceptualize meaning [11]. Other strands of HCI work have focused on ill-health, such as mobile apps for cognitive behavioral therapy [12] and empirical studies exploring ways to support vulnerable users; such as those living with depression [13], dementia [14], addiction, or the compulsive use of technology; including screen time research [15,16]. Much of such work frames mental well-being as "positive emotional, psychological and social health" [17], whereas digital well-being is broadly seen as the result of being able to use technologies in productive and healthy ways without the negative consequences of dependency, distraction, or risks to users' privacy [18].

A specific body of work has focused on interventions supporting smartphone nonuse, for instance, by increasing interaction cost to discourage smartphone app use [19]. Both limiting phone use and increasing interaction cost can be conceptualized within the slow movement, where technology is reframed with the aim of pausing and reflecting on its use [20]. Other examples of interventions of smartphone nonuse include apps such as MyTime to make users aware of their tracked use data, which in turn prompt them to reflect upon their use and especially the problematic use [21]. In addition, Roffarello and De Russis [22] argued that current digital well-being apps' focus on self-monitoring may not be a sufficient mechanism to change users' behavior with smartphones. Moreover, Roffarello and De Russis [22] also pointed out the limited exploration of the effectiveness and theoretical underpinning of digital well-being apps, whereas van Velthoven et al [23] highlighted also the insufficient investigation of the positive effects of regulating problematic smartphone use with digital interventions. The nascent research exploring the effectiveness of digital well-being apps has been limited, with only 1 study focusing on the analysis of users' qualitative reviews of commercial apps [22]. Their findings indicate that such apps are liked, especially in studying, working, sleeping, parental control, and free time contexts, albeit limited in supporting behavior change and habit formation toward more conscious smartphone use.

In addition, the theoretical underpinning of digital well-being apps has also received limited attention. In this respect, most work has looked at their adoption [24,25], leveraging, for instance, technology acceptance theories [26,27], including the more recent technology acceptance life cycle model [28]; although these models are rather generic, they are leveraged for personal or domestic technologies. Scholars such as Douglas et al [25], Lukoff et al [29], Lyngs et al [30], Kim et al [31], or Colombo et al [3] have also identified other theories more relevant to digital well-being apps, such as the uses and gratification theory [19,31], theory of planned behavior [32], dual system theory [33], nudge theory [34], framework for behavior change [35], or theories for regulation [36]. However, it is less explored how such theories could actually inform the developing of commercial well-being apps.

Given the limited research on the theoretical and evidence-based aspects of digital well-being apps [23,25], we argue that unpacking the functionalities of the most used commercial apps is an important initial step toward better designing them. The exploration of functionalities and features of mobile apps is an emerging research area, with initial HCI work focusing on digital interventions and especially development of apps for specific conditions such as depressions [37,38] or for supporting, for instance, mindfulness [39,40] or physical activity [41]. In contrast, the functionalities of digital well-being apps have been less investigated. A noticeable exception is the exploration by Roffarello and De Russis [22] of 42 digital well-being apps and their descriptions on Google Play, whose findings indicate the following as key features: (1) tracking user behavior through phone unlocks, phone and app time, and app checking; (2) data presentation through phone and app summary, charts, daily or widget recap, and social comparison; (3) phone interventions through timers and blockers; (4) app interventions through timers, blockers, and notification blockers; and (5) extra features such as motivational quotes or rewards. However, given the brevity of apps' descriptions available on marketplaces, a richer source to identify their key functionalities is the actual use of the apps, with authors, as HCI experts, adopting the role of the user by directly interacting with the apps—a method previously used for app reviews [38,42,43].

Specific functionalities of digital well-being apps have been also explored through research prototypes usually implementing tracking and notifications [44,45], whereas others included also specific interventions for limiting use [21,46]. For instance, the Socialize [22,47] app integrates the most common functionalities of tracking, data presentation, real-time notifications, and blocking use, which were evaluated in the wild with 38 young people over 3 weeks. Findings indicate improvements in terms of problematic use, measured through the phone addiction scale, and self-regulation, measured through the general self-efficacy scale. Although this is one of the few studies involving measures to explore the effectiveness of a digital well-being app, the Socialize app itself does not appear to be novel, borrowing common functionalities of commercial apps, whose theoretical grounding is limitedly unpacked. The Focus app [48] is another research prototype that leverages Nielsen's heuristics to support tracking phone use and the blocking of any app, indeterminately or for a limited time set by the user, with the option to unblock them at any time, and provision of educational content on digital addiction. To mitigate overuse from a broader perspective, another research prototype, the FeelHabits app [49], tracks and notifies users about their use of specific apps; albeit rather than on a smartphone alone, this apps tracks use across devices and blocks them if limits set by the user are exceeded.

Another strand of scholarly work with richer theoretical underpinning has focused on restrictive and coercive interventions intended to be stronger than persuasive interventions by supporting users to commit to self-impose limits of use while the phone is blocked [31]. The framework for influencing behavior change [35] suggests the following four types of influence: persuasive (explicit and weak); coercive (explicit and strong); seductive (implicit and weak) and decisive (implicit and strong), which are based on the influencing force

(strong and weak); and salience (explicit and implicit). Inspired by this framework, Kim et al [31] designed and evaluated GoalKeeper, a smartphone app featuring both a *weak lockout*, that is, the phone is locked increasingly longer (eg, 1, 5, 15, 30 and 60 minutes) each time the user exceeds the time they have previously set for use, with each lockout being mitigated by a temporary 15-minute allowance time, and a *strong lockout*, that is, the phone is locked until midnight without any allowance. Their findings indicate that both mechanisms were more effective than mere notifications of use, with the strong lockout being the most effective, as users set longer limits for not using their phones. Although in the latter case users experienced also more frustration, this was mitigated by the flexibility of setting their own limits and one-time opportunity to modify it.

Objectives

Despite this growing academic interest in digital well-being, the commercial apps far outweigh the research prototypes in terms of uptake. Thus, the increased adoption of commercial well-being apps offers an opportunity to explore their potentially richer set of functionalities, and the aim of this paper is to articulate these functionalities as well as the novel design implications informed by them to better inspire the design of technologies for well-being. To address this aim, we focused on the following research questions:

1. What are the key functionalities of the top-rated digital well-being apps?
2. What theoretical underpinning supports these functionalities?
3. What design guidelines for digital well-being apps can be informed by these functionalities?

Our contributions are 3-fold. First, we unpacked richer insights about tracking and monitoring functionalities in terms of user profiling and understanding of monitoring as a *complete, location-based, and flexible practice* that can benefit from tailored, time-based visualizations. Second, we identified 4 interventions for limiting use including richer understanding of different types of obstacles for limiting use and specific features for less explored functionalities such as supporting awareness for reaching use limits, focused attention, and motivation to keep within set use limits. Third, grounded in our findings, we generated 6 design implications for digital well-being apps.

Methods

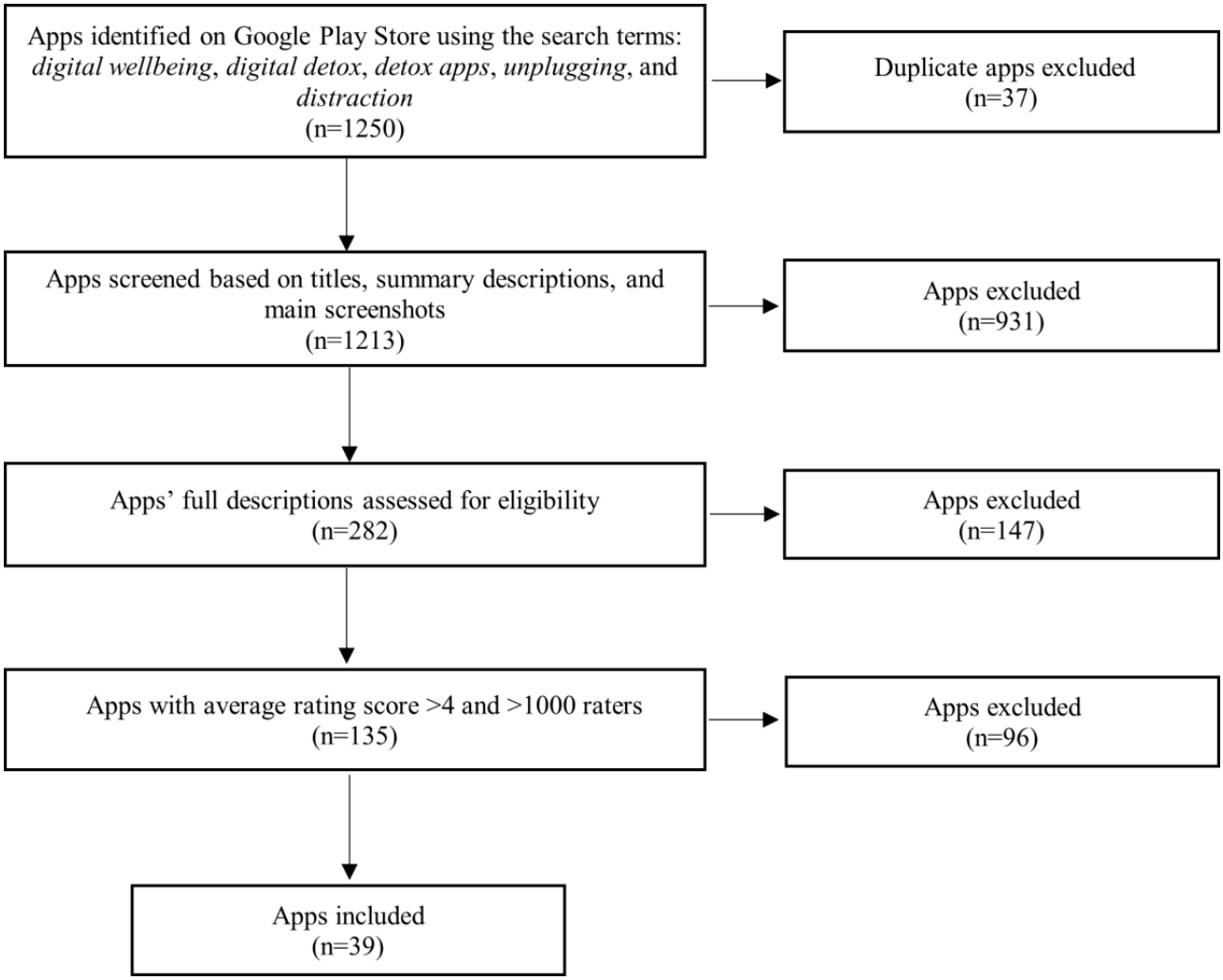
App Selection

To identify the digital well-being apps, in winter 2019, we searched for free apps in Google Play Store using the following search terms: *digital wellbeing*, *digital detox*, *detox apps*, *unplugging*, and *distraction*, which is a new direction given that extensive previous work on such apps has prioritized addiction and screen time [22]. We have focused on Google Play because its apps represent the largest global market share, >2.5 greater than iOS apps [50], whereas the latter is also more restrictive in terms of available information [22]. However, future work could extend this exploration to other platforms.

For each search term, the top 250 most relevant apps returned on Google Play were retained, totaling 1250 apps, with 37 duplicates. At the screening stage, after reading their titles, summary descriptions, and main screenshots, we excluded 931 less relevant apps such as fitness, activity planner, or nondigital detox apps. The eligibility of the remaining 282 apps was assesses based on their full descriptions, with further 147 apps being excluded such as utility apps, games, and general well-being and meditation practice apps. From the remaining 135 apps, we further excluded those with less than 1000 raters and with average rating score <4, leading to 39 apps to be included in our review. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram for the searching and screening process for digital well-being apps is shown in Figure 1. We also note that of our 39 apps, 12 (31%) are also available on the Apple Store, with 7 (58%) of them having user rating >4.2.

Our final set consisted of 39 digital well-being apps (Multimedia Appendix 1 [19,21,22,31,34,44-46,48,49,51-57]), which were analyzed through two complementary methods: first, a review of their functionalities based on their descriptions from Google Play and, second, an autoethnography with the authors (SA and CS), as HCI experts directly interacting with them in order to viscerally understand how these functionalities work and are experienced by potentially users in their daily lives. Such interactions were iterated, involving at least two sessions for each app, lasting for at least 30 minutes. For the autoethnography, we used a Samsung Galaxy Note 9 phone with an Android mobile operating system.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram for the searching and screening of digital well-being apps.



App Analysis

The first author (SA) evaluated all 39 digital well-being apps, whereas the second author (CS) evaluated 21% (8/39) of the apps. Through the use of both methods, the authors (SA and CS) iteratively revised the coding scheme over several months, a process that has followed a hybrid approach. This integrated deductive codes, informed by prior work on functionalities [22] such as tracking, data presentation, and interventions (Table 1). The inductive coding was informed the distinction between tracking and monitoring, the revision of intervention functionalities such as tracking phone or app use by setting limits and of data presentation or visualization and its subcategories such as numerical and diagrammatic format through charts, round diagrams, metaphors, heat maps, or reports. Particularly important are the new functionalities capturing 4 interventions for limiting use.

To better contextualize our review in scholarly work, we subsequently extended the list of apps with 17 digital well-being apps designed in academia, which we found through search on Google Scholar using the following keywords: *digital wellbeing application* or *digital wellbeing app*. This search returned 42 papers, which after reading their abstracts, led to 17 papers describing such apps [3,8,12,18,26,32,37,49,51,58-65]. The remaining 25 papers do not included digital well-being apps and for this reason they were excluded. We have explored the functionalities of the apps described in the 17 papers by applying the above coding system to their description, as not all of them were available to download from app marketplaces. All the tables provided in Multimedia Appendices 1-7 [19,21,22,31,34,44-46,48,49,51-57] include information on both commercial and academic apps.

Table 1. The main codes and subcodes from the app analysis.

Functionality codes and subcodes	Definitions
Tracking	
Recording phone or app use	The tracking functionality supports the recording of phone or app uses.
Visualizing tracked use data	The tracking functionality supports the visualization of tracked data.
Profiling users	The tracking functionality supports profiling users based on tracked data.
Monitoring	
Setting time limits of phone and app use, their scope and place	The monitoring functionality provides use time limits or supports users to customize them in terms of scope and place.
Visualizing monitored data	The monitoring functionality supports the visualization of monitored data against set time limits of use.
Providing flexibility for limiting monitoring	The monitoring functionality supports flexibility for limiting monitoring through allowances to extend use beyond the set time limit, excluding apps from being monitored, or discontinuing the monitoring.
Interventions for limiting use	
Creating obstacles to limit phone and app use	This intervention supports creating different types of obstacles to limit phone or app overuse.
Supporting awareness of reaching the set use limits of phone and app use	This intervention supports users' awareness of reaching the set use limits through different types of notifications varying in content and form.
Supporting focused attention away from phones and apps	This intervention supports users' focused attention on main task and away from habitual phone and app use through training or white noise.
Supporting motivation to keep within limited use	This intervention supports motivation to keep within limited phone and app use through rewards and penalties, motivational quotes or education, and social motivation.

Results

This section starts with a brief overview of the descriptive characteristics and ethical aspects of the 39 apps, continues with the identified main functionalities of top-rated digital well-being apps and how they compare with the apps developed in academia.

Descriptive Characteristics of Digital Well-being Apps: Ethics

The descriptive characteristics captured by our analysis include app category, target users, scientific underpinning and evidence base, and cost. Findings indicate that the top-rated digital well-being apps belong to 6 categories, albeit feature predominantly in the Productivity category (27/39, 69% apps), followed by fewer apps in the Tools (4/39, 10%), Personalization (3/39, 8%), Health and fitness (2/39, 5%), Parenting (2/39, 5%), and Lifestyle (1/39, 3%) categories. Together with their main aim of limiting phone overuse, this is an interesting outcome that can be linked to the ethical principle *of nonmaleficence* [2] to protect users from the negative impact of phone overuse. These can also be aligned with the ethical principle of *beneficence*, particularly the predominant instrumental value of digital well-being apps supporting increased productivity rather than their eudemonic value for supporting meaningful goals [66]. Arguably, the latter would further strengthen their beneficence potential.

Another important outcome, which can potentially hinder their beneficence is the limited science base of digital well-being apps, with 97% (38/39) of the apps not specifying if they are backed up by research, the only exception being the Focus To-Do app described as a *science-based app*. This indicates the importance of these apps unpacking in their descriptions the scientific underpinnings informing their design and any available outcomes from evaluation studies. This, in turn, will support users make more informed choices regarding their beneficence.

The target users of digital well-being apps appear to be unrestricted, with most of them available to users of all ages, which reflects the principle of *justice*. Indeed, all but 4 apps are rated on Google Play as "PGEI 3," which stands for "Pan European Game Information." The remaining four apps do not specify any age: Brain Focus Productivity Timer, Lock Me Out, SleepTown, and Sma-Phospital. Interestingly, the design of the apps does not vary with age, as we see the same functionalities for both children and adults. We also examined whether the target users include the clinical population. Findings indicate that of the 39 apps, 38 (97%) do not specify clinical user groups, whereas 1 (3%) app, that is, AppBlock, mentions its suitability for children or adults with attention deficit hyperactivity disorder. This suggests that digital well-being apps predominantly target users without specific conditions or health concerns. However, given their value for supporting attention, some of these apps may be beneficial for users with attention deficit. Future work should further explore this.

Also related to justice, the cost of the digital well-being apps is an important aspect that can increase or limit diverse users accessing them. Regarding cost, an important outcome is that although all the 39 apps are free to download, only 11 (28%) are entirely free to use, whereas 28 (72%) offer in-app purchase mostly for removing adds, unlocking premium features, or subscribing to premium versions of the apps. This is an

important outcome indicating that most functionalities of these apps are freely available, making their use particularly inclusive.

Digital well-being apps have an interesting relationship with the ethical principle of autonomy. On the one hand, these apps tend to limit one's use of phone or apps; on the other hand, consistent findings have shown that autonomy is already impaired [67] when people live with some form of addiction such as phone overuse.

Functionalities of Digital Well-being Apps

Overview

We now turn our attention to the key functionalities of digital well-being apps. The iterative analysis led to specific functionalities that can be broadly grouped into the following six main functionalities: tracking use of the phone or apps, monitoring use against set limits, and the four functionalities that highlight interventions for limiting use, namely, creating obstacles for the phone or app use, supporting awareness of reaching the set use limits, supporting focused attention, and support motivation to keep within limits of use. Each of these functionalities is further detailed.

Tracking Overall Phone and App Use: User Profiling

Findings indicate that 28 digital well-being apps automatically track or record overall phone use, use of specific apps, or both (Multimedia Appendix 2 [19,21,22,31,34,44-46,48,49,51-57]). In particular, (1) the overall use of the time spent on the phone was captured by 11% (3/28) of the apps through overall screen time across all apps measured per minute, hour, day, or week or the number of times the phone unlocks per hour or day; (2) the use of specific apps that provide users the choice to select them to capture only their screen time was captured by 54% (15/28) of the apps; and (3) 21% (6/28) of the apps tracked both the overall use of the phone and the use of specific apps. Other digital well-being apps provide users with the choice to select the time when the tracking can occur, for instance, between 9 AM and 5 PM, but not outside of the specified time window. Tracking can also be contextualized, with three apps (AppBlock, Instant-Quantified Self, and Lock Me Out), allowing its coupling with physical locations specified by users.

Regarding visualization, the tracked use data tends to be provided in numerical and diagrammatic format through reports (27/28, 96%), charts (21/28, 75%), round diagrams (9/28, 32%), metaphors (4/28, 14%), or heat maps (1/28, 4%; Multimedia Appendix 2). The four apps providing metaphoric visualizations are Forest: Stay focused, Focus To-Do: Pomodoro Timer & To Do List, SPACE, and SleepTown, with the latter's visualization consisting of raising in-app towns when maintaining regular sleep hours. In addition, from the 27 of the apps including reports, 20 (74%) provided daily and weekly reports of screen time and 7 (26%) provided only daily such reports.

Findings also indicate that of the 39 apps, 10 (26%) extend the tracking functionality to also inform user profiling. Of these 10 apps, 4 (40%) use either the tracked data of app use (App Usage and Screen Time) to generate categories of used apps for broader purposes such as productivity and social, or ask users to identify these categories (SaveMyTime and Boosted). In addition, of the 10 apps, 3 (30%) provide users the option of creating different profiles for different settings that could be used to support different levels of limited use of the phone or apps, both with payment (HelpMeFocus) or without payment (Stay Focused), for instance, by allowing them to specify the location or specific Wi-Fi network where set limits are activated (AppBlock). This is important, as it indicates the flexibility of the interventions for limited use to the situatedness of users' different contexts such as homes or work. Finally, the YourHour app also aims to identify levels of phone addiction based on tracked data, whereas the Digital Detox app offers predefined levels of limited use that users can choose from. These 2 apps are interesting, as they attempt diagnosis of smartphone addiction and prediction of the intervention intensity. Although smartphone addiction is not yet a clinical condition featured in the *Diagnostic and Statistical Manual of Mental Disorders*, its problematic behaviors as diagnostic criteria have started to be explored [68]. In addition, several scales have been developed for measuring phone addiction [65,69] that meet the psychometric properties of validity and reliability. If digital well-being apps aim to identify users' level of addiction, which will allow for a better tailored intervention, these scales are useful to consider.

Interestingly, of the 39 apps, the remaining 11 (28%) that do not provide tracking functionalities include 8 (73%) apps supporting focused attention usually on offline activities (Forest, Boosted, Pomodoro Smart Timer, Brain Focus Timer, SleepTown, Engross, Visual Timer, and Hold), 2 (18%) launcher apps minimizing the number of apps being displayed (LessPhone Launcher and Before Launcher), and 1 (9%) app for turning off email notifications (Quite for Gmail).

Monitoring Phone and App Use Against Set Use Limits or Set Time Limits for Focused Attention

Apart from tracking, most digital well-being apps also allow setting use limits to track phone or app use against them (25/39, 64%); Multimedia Appendix 3 [19,21,22,31,34,44-46,48,49,51-57]). The distinction between tracking and monitoring is that monitoring is based on user intentions to self-limit their use, whereas tracking merely captures the time spent on apps or phone without any such limits. Thus, tracking becomes a prerequisite activity, performed first to explore one's use patterns, and based on this information, use limits can be set. Indeed, all apps supporting monitoring also support tracking; however, 33% (13/39) of the apps, although supporting tracking, do not support monitoring. This is an important outcome as arguably, monitoring is better positioned to support behavior change toward limiting use than mere tracking; however, approximately 36% (14/39) of the top-rated apps do not support monitoring.

Whereas most apps (25/39, 64%) support setting limits for using the phone or its apps, the remaining 36% (14/39) of the apps include 8 (57%) apps that allow people to focus attention by setting time for offline activities and therefore away from phones and apps; 3 (21%) apps providing only the tracking functionality (Smarter Time, Sma-Phospital, and Usage Analyzer); 2 (14%) launcher apps minimizing the number of apps being displayed; and 1 (7%) app for turning off email notifications (Quite for

Gmail). The prevalence of apps for focused attention on offline activities is an interesting and less explored monitoring aspect of digital well-being apps.

The monitoring functionality allows user setting of the scope and place of limited use, visualization of monitored content, and, interestingly, options for limiting monitoring. With respect to the scope of the limited use, more than half of the monitoring apps offer options to reduce the use of some of the installed apps (13/25, 52%). This means that while using these digital well-being apps, some apps' use remains unmonitored. In contrast, the remaining digital well-being apps extend this option to monitor use to all apps on the user's phone (6/25, 24%) or to the phone itself (7/25, 28%). Setting use limits can also be activated at specific locations, either specified through the phone GPS (3/25, 12% apps) or Wi-Fi network (1/25, 4% apps), although only a few apps offer these options.

Findings also indicate that 56% (22/39) of the digital well-being apps support a more forgiving or *flexible monitoring* by allowing users to limit their monitoring in 3 ways. This includes allowances to extend use beyond the set time limit (9/22, 41% apps) and the option to exclude specific apps from being monitored (19/22, 86% apps). Allowances are breaks during the set nonuse time limit so that users can continue to use the phone or the apps despite being during their set nonuse time limit, with or without (financial) penalties, although the number of breaks, and their duration is either capped or uncapped. This can also include terminating the nonuse time limit earlier than it is actually due (4/22, 18% apps). A total of 49% (19/39) of the digital well-being apps also offer the option of excluding specific apps from being monitored against time limits, especially apps such as App Usage–Manage/Track Usage, AntiSocial, and My Phone Time. In addition, 36% (14/39) of the apps allow users to discontinue monitoring when they reached the set use limit.

Regarding visualizations, monitoring function engulfs tracking one, so that it supports the visualization of tracked data. However, visualizations specific to the monitoring functionality are offered by less than half of the digital well-being apps (19/39, 49%). This is an important outcome, suggesting the value of considerably extending such visualizations within the monitoring functionality. These 19 apps provide monitoring-specific visualizations of (1) time unspent out of the use time limit, that is, count down (n=12, 63% apps), (2) time spent out of the use time limit (n=6, 32% apps), or (3) even time overspent as a percentage of the time limit (n=1, 5% apps). These are provided in either text form (12/19, 63% apps) and diagrammatic one as circles (4/19, 21% apps) or progress bars filled or unfilled gradually with colors (3/19, 16% apps) until the set time limit is reached. Interestingly, the monitoring of focused attention, usually during offline activities, can also be visualized, usually through time unspent out of the focus time (or time for not using the phones and apps), through countdown timers (3/19, 16% apps), or circle progressively unfilled with color (1/19, 5% apps).

Interventions for Limiting Use of Phones and Apps

Findings indicate four interventions for limiting the overall use of the phone or its installed apps, which include creating obstacles to limit use, supporting awareness of reaching the set limits, supporting focused attention, and supporting motivation for limiting use, which are further detailed.

Creating Obstacles to Limit Phone and App Use

The first intervention consists of creating obstacles for excessive phone or app use (21/39, 54% apps). Obstacles can be classified according to their force (strong or weak); saliency (explicit or implicit); temporal aspects such as being activated before, during, or after excessive use; and social aspects such as parental control or social commitment (Multimedia Appendix 4 [19,21,22,31,34,44-46,48,49,51-57]). Obstacles also differ with respect to their source (being generated by the digital well-being app or by users) and could be tailored to user profiles.

The identified strong obstacles feature predominantly in commercial apps (18/39, 46%). These obstacles that cannot be circumvented include the lockout of phones and apps beyond the set time limit of use (14/18, 78% apps), interrupting use while the set use time has been reached (12/18, 67% apps), and unchangeable time limits of phone and app use (6/18, 33% apps). In contrast, weak obstacles have features in much fewer apps (5/39, 13%), with only one app providing both strong and weak obstacles, that is, StayFree. Weak obstacles do not directly restrict use but make it more difficult through notifications from phones or apps after overuse (4/5, 80% apps), notifications inside the digital well-being app when reaching the time limit (4/5, 80% apps), and microboundary interactions that make it more difficult for users to access their apps targeted by limited use (2/5, 40% apps). Microboundary interactions are particularly interesting, as although theoretically explored in academic research, they have been limited, implemented through design. Such interactions feature in two apps (LessPhone Launcher and Before Launcher) and consist of *launchers* as substitute home screens for users' phones that display only a reduced number of apps so that accessing other apps requires additional clicks for navigating from the launcher to them.

According to their saliency, most obstacles are explicit such as lockout (8/39, 21% apps), set time limits for phone and app use (14/39, 36% apps), and textual or visual notifications (4/39, 10% apps), whereas others are implicit such as launchers (2/39, 5% apps) or activation of the dimming mode of the phone's screen when a set time limit was reached (1/39, 3% apps). This much lower number of implicit obstacles is interesting, suggesting a less explored design space and their potential value of complementing explicit obstacles.

With respect to the temporal aspect, most obstacles are created before the use of a phone or app and activated during the set limited time for using the phone or apps. The exception is flexible time limits, which can be changed not only during but also after the set time limit for use has ended.

The obstacles also have a social dimension, albeit only 13% (5/39) of the apps implemented them, in two forms: parental control (4/5, 80% apps) or social commitment (1/5, 20% apps). Regarding the latter, the Forest app leverages the feeling of failure to social commitment as a type of obstacle to prevent users from accessing apps while with friends.

Regarding the source, obstacles can be created by the digital well-being app or the user. The former leads to automatically generated obstacles, usually through user profiling (11/39, 28% apps), whereas the latter leads to customized obstacles (13/39, 33% apps). Apps allowing users to set use limits usually restrict this option to specific apps rather than all apps. Examples of the automatic setting of use limits feature in the YourHour app, which provides users short quizzes to identify if the app is used for work or entertainment. Another example is the SPACE app, supporting limited phone use through automatically suggested limits. Interestingly, two apps allow users to create multiple profiles, each profile with a particular setting to be assigned to different tasks (HelpMeFocus and Stay Focused). This is an interesting option, allowing users different modes of engaging with specific apps, which could, for instance, help with the context setting such as work or leisure, and different phone use for each.

Finally, different types of obstacles may be tailored to different user profiles for matching, for instance, the level of addition (1/39, 3% app) or users' preference for a specific level of digital detox (namely, easy, medium, and hard) that are proposed to users to choose from (Digital Detox app). Interestingly, no apps attempt to recommend interventions at different levels (weak or strong) based on tracked data. This is a less explored feature with potential to provide adaptive interventions better tailored to users' needs.

Supporting Awareness of Reaching the Set Use Limits of Phone and App Use

The second intervention is supporting awareness of reaching the set limits of use and is provided by 33% (13/39) of the apps (Multimedia Appendix 5 [19,21,22,31,34,44-46,48,49,51-57]). Such awareness is predominantly supported through explicit notifications of reaching the set time limits (12/13, 92% apps), usually in textual or diagrammatic form, with both push notifications that appear when the screen is both locked and unlocked, usually at the top in the status bar; (4/12, 33% apps) or pull notifications that appear suddenly in the middle of the screen as a small window alerting the user of something, sometimes these are big, covering most of the screen (7/12, 58% apps). Notifications can be provided both in the digital well-being apps about the use of the phone or its installed apps (13/39, 33% apps) and as embedded within a specific app when the time limit relates to that app (11/39, 28% apps). In contrast to explicit notifications, implicit ways to support awareness of reaching the time limit include screen dimming. Although less common (1/39, 3% apps), these are interesting, more subtle ways to notify users of reaching their use limits for specific apps or phones and to persuade disengagement. Although both notifications and screen dimming are provided in real time, daily reminders to review tracked data support a higher level of awareness beyond a specific instance of *in the moment* use and more about the historic user over the day (7/39, 18% apps).

Supporting Focused Attention on Primary Tasks and Away From Habitual Phone and App Use

The third intervention supports focused attention and features in >70% (29/39) of digital well-being apps (Multimedia Appendix 6 [19,21,22,31,34,44-46,48,49,51-57]). These include all apps that support monitoring (25/39, 64%) and four additional ones: Boosted, Pomodoro Smart Timers, Engross, and Hold. By aiming to limit phone and app overuse, digital well-being apps implementing the monitoring functionality implicitly support focused attention on the main task because they prevent the user's attention from being hijacked by habitual phone and app use.

Findings also indicate that, of the 39 apps, 8 (21%; four that support monitoring and four that do not: Boosted, Pomodoro Smart Timers, Hold, and Engross) explicitly target the training of focused attention. These apps encourage users to stay away from their phone to focus on specific offline tasks for a set time. This use of a time limit is different from that in the monitoring functionality, as people are supported to practice the adaptive behavior of maintaining attention for a set time away from the phone rather than resisting for a set time the temptation to use the phone.

In addition, of these 8 apps for training focused attention, 5 (63%) also provide users with white noise to better facilitate concentration. This is an interesting outcome, and although these apps provide limited evidence for its value, scholarly work indicates that white noise, defined as "task-irrelevant auditory input containing many frequencies of equal intensities" [8], has potential to improve cognitive performance in both healthy adults [17] and those with attention deficit [70]. Mechanisms that could explain the benefits of white noise include its ability to moderate brain arousal by inducing neural noise, which at specific dopamine-based thresholds could stimulate cognitive performance [58].

Supporting Motivation to Keep Within Limited Use of Phone or Apps

The fourth intervention supports motivation for limiting phone and app use (12/39, 31% apps; Multimedia Appendix 7 [19,21,22,31,34,44-46,48,49,51-57]). Findings indicate 3 mechanisms for supporting motivation. The first is the reward and penalty feedback usually implemented by those apps that support monitoring (7/12, 58% apps), with rewards being provided when users successfully kept within their set use limits of their phones and apps. The main types of rewards leverage gamification principles and consist of badges at different levels (2/7, 29% apps), points (2/7, 29% apps), in-app coins (1/7, 14% apps), building in-app trees (Forest) or towns (SleepTown), or motivational quotes (4/7, 57% apps). The main categories of penalty content are metaphoric and consist of in-app tree withers (Forest) or town-building collapses (SleepTown). Interestingly, however, most monitoring apps (20/29, 69%) do not support such motivation through rewards and penalties.

Second, in addition to the reward and penalty feedback provided on the basis of successful or unsuccessful keeping within set limits of phone or app use, other types of motivation are provided to support behavior regulation of limiting use, both during and even before the actual behavior of limiting use. This less common type of motivation consists of motivational quotes, either provided by the app (two apps: Stay Focused and HelpMeFocus) number and names or generated by the user (two apps: StayFree and App Usage–Manage/Track Usage); educational content about phone and life balance (one app:

SPACE); or motivational stories written by other users (one app: YourHour).

Third, social support is another form of motivation, whose role in facilitating behavior change has been much acknowledged [71]. An important outcome is the limited number of apps that encourage social support to limit phone or app use, through competition (5/39, 13% apps), collaboration (5/39, 13% apps), or both (3/39, 8% apps). This is distinct from the identified emphasis on competition [72]. For instance, the SPACE app allows comparing such progress of limited use. In contrast to this competition social motivator, our findings also show 13% (5/39) of the apps leveraging collaboration, in which family members, friends, or broader social networks are used. For instance, the SleepTown app allows sharing sleep time goals with friends and setting similar sleep goals with them. Another example is the Hold app, which provides different ways to share focus time through finding nearby Bluetooth-enabled devices to encourage focused attention in the group. The Hold app also integrates collaborative and competitive aspects, for instance, by ranking users according to the points they gained from their time spent on focusing tasks, most often offline ones. Apps leveraging competition can also integrate social recognition. For example, the Hold app rewards the top-ranked users according to their points with a crown icon next to their username, and the Focus app rewards the first three users with a trophy icon next to their usernames: gold, silver, and bronze.

Comparison of Commercial Digital Well-being Apps With Academic Ones

This section focuses on the comparison of the functionalities of the apps developed in academia with those of commercial apps, with a specific focus on how they differ. It is not surprising that most academic apps share the tracking and monitoring functionalities available in commercial apps. For example, the lockout mechanism that blocks the phone until midnight when reaching the use limit [31] is similar to blocking apps and phone when the user exceeds the defined time limit in some commercial apps (ie, Ubhind). Similarly, blocking and scheduling blocking in the academic app Forest [48] are comparable with those in the commercial app AppBlock. An interesting distinction concerning tracking and monitoring is the new form of visualization of tracked data in academic apps, namely, timelines.

In terms of interventions for limiting use, findings indicate additional key distinctions between commercial and academic apps for digital well-being. Regarding creating obstacles to limit phone or app use, important distinctions concern the force and saliency of the created obstacles and their temporal aspect and source. With respect to force, commercial apps predominantly use strong obstacles such as phone or app blocks (14/39, 35% apps) instead of weak obstacles such as notifications or microboundary interactions (5/39, 13% apps), with only 3% (1/39) of the apps providing both strong and weak obstacles. In contrast, academic apps take a more balanced approach, using equally both strong (10/17, 59%) and weak (11/17, 65%) obstacles, with 29% (5/17) of these apps using both strong and weak obstacles. Given the nascent research exploring the effectiveness of digital well-being apps, academic work is more likely to use both types of obstacles to compare their effectiveness.

With respect to the saliency of obstacles, almost half of the commercial apps (17/39, 44%) specify saliency, with all but 1 featuring explicit obstacles (which also tend to be strong), whereas the SPACE app features implicit obstacles. In contrast, almost all academic apps (16/17, 94%) involve explicit obstacles, that is, mostly notifications. What is interesting here is the innovative use in academic apps of a new type of obstacles for restricting use through design frictions. These could involve mandatory cognitive tasks such as entering several digits as users attempt to start interacting with apps targeted for limited use [57] or entering 30- or 10-digits try [19], which, when compared with merely pressing OK, indicates that the more complex the cognitive task, the more likely that users will restrain from engaging with those apps. Commercial apps present limited such cognitive tasks, with one exception being the MMGuardian app, which requires entering a password by parents to prevent the child from removing the app or modifying the set time limit of use.

Findings also indicate differences regarding the temporal aspects of obstacles to use. Although commercial apps use these obstacles predominantly after use of the targeted apps (15/39, 38%), as opposed to during use (4/39, 10%), academic apps take a more balanced approach using such obstacles equally during (8/17, 47%) and after the use of targeted apps (8/17, 47%), with 12% (2/17) of the apps using them both during and after use. This suggests not only the value of providing flexibility and users' choice but also the importance of real-time obstacles in limiting phone or app overuse in real time.

Regarding obstacles' source, commercial apps use mostly obstacles set and customized by users (15/39, 38%) rather than obstacles set automatically (6/39, 15%); in contrast, academic apps feature more automatically set obstacles (10/17, 59%) than those set by users (6/17, 35%).

Scholarly work on digital well-being apps has also focused on the types of apps that users are more willing to limit use. In this respect, empirical findings indicate that users were willing to restrict the use of specific apps such as messaging ones [56], as well as social media or games apps [21]. Academic work has also explored limited use not only beyond individual devices such as phones but also across multi-devices and their context of use [46,49]. Similar work has looked, for instance, at chatbots to notify users of their smartphone use [51] or video platforms supporting preschoolers to self-manage their phone and app consumption [52].

The second intervention, intended to increase users' awareness of reaching their limits of phone or app use, also shows differences. Although both sets of apps use mostly explicit notifications to support such awareness, academic apps do so more (8/17, 47%) than commercial apps (11/39, 28%). Interestingly, both sets of apps also used implicit notifications such as screen dimming featuring in the SPACE app and vibrations for notifying users when they exceeded their set time limit for phone use featuring in the Good Vibrations app [34].

The intervention targeting focused attention has been supported by both sets of apps through training for focused attention, with 21% (8/39) of commercial apps and 29% (5/17) of academic apps providing such training. Interestingly, commercial apps also feature white noise as a specific mechanism for supporting focused attention, whose effectiveness as part of digital well-being apps has been less explored, although a body of scholarly work has shown its value for relaxation [17,70].

Finally, the fourth intervention for supporting motivation to keep within set limits shows similar findings for the 2 sets of apps, with emphasis on rewarding user behavior when the goal of keeping within limits has been reached (9/39, 23% commercial apps; 3/17, 18% academic apps), albeit commercial apps show more diverse forms of rewarding content, usually leveraging gamification principles, as opposed to academic apps, which use merely points. In contrast, findings show much fewer apps leveraging punitive feedback when users fail to keep within set use limits for both commercial apps (4/39, 10%) and academic apps (1/17, 6%). In terms of social support, a small number of apps provide it to support cooperation (5/39, 13% commercial apps; 2/17, 12% academic apps), competition, and recognition (5/39, 13% commercial apps; 3/17, 18% academic apps).

Also unique to research on academic apps for digital well-being is the extended focus of their audience to include not only individual users as commercial apps but also groups of users. For example, such academic apps focused on enhancing self-regulation through groups of users collaborating or competing toward limiting their collective use of phones and apps [45,54], through limiting use as a family activity [45], or through providing in-app spaces for college students to restrict their phone use during class time [44].

Discussion

Principal Findings

We now revisit the research questions advanced in the *Introduction* section and articulate the novelty of our key findings. The first 2 research questions focused on identifying the key functionalities of the top-rated digital well-being apps and their theoretical underpinning. Our review of top-rated digital well-being apps indicates the following six main functionalities: tracking use; monitoring use against set limits; and four interventions for limiting use, namely, creating obstacles to limit use, supporting awareness of reaching the set limits, supporting focused attention, and supporting motivation for limiting use. In this section, we also theoretically position these functionalities and leverage them to articulate new implications for better designing digital well-being apps.

Findings indicate that >70% (29/39) of digital well-being apps provide tracking of use of phone or app data, visualized mostly through reports and charts. More than a third (11/29) of the apps providing the tracking functionality also support user profiling, either automatically from tracked data or through users' entered data. This aspect of tracking has been limitedly explored in previous work [22,23]. Another key finding is that almost 30% (11/39, 28%) of the digital well-being apps do not support tracking phone or app use but support instead focused attention or tracking of offline activities. This is a key outcome with important design implications that we will revisit later.

The second functionality is monitoring phone or app use against set time limits, which is key for limiting their use. This functionality features in 64% (25/39) of our reviewed commercial apps. Interestingly, however, the remaining almost 35% (14/39) of the digital well-being apps do not support this functionality directly, albeit they monitor the time spent on offline activities, away from the phone and its apps. From the former set of apps monitoring phone and app use, most tend to target some of the apps installed on the phone, with fewer digital well-being apps monitoring the use limits of all the apps. An important implication here is designing for *complete monitoring* of all the apps installed on the phone and providing users with the choice of selecting the ones to monitor, as well as *location-based monitoring* currently limitedly supported, albeit useful for situating the monitoring behavior in a spatiotemporal context. We also suggest supporting *flexible monitoring* allowing circumventing the set use time limit, which can support ongoing motivation for monitoring phone consumption and regulating phone overuse behavior. Findings also indicate interesting time-based, monitoring-specific visualizations featuring in approximately half (20/39) of our reviewed apps, which are useful to be extended to all digital well-being apps.

With respect to the first intervention, almost half (16/39) of our reviewed commercial apps implement strong and explicit obstacles, such as blocking to limit phone or app use, with much fewer apps featuring weak or implicit obstacles, usually in the form of notification. Even fewer apps attempt to implement microboundary interactions using launchers as substitute home screens. Such obstacles can be generated either automatically or by the users, with only few apps tailing them to user profiles and none mapping the force of obstacles (strong or weak) to such profiles. These approaches suggest the value of using both sources, so that digital well-being apps could benefit from the customization of users' set obstacles and potentially even more so from extending the use of automatically set obstacles. Although previous work suggested that strong obstacles, despite inducing frustration, can be preferred by users and are likely to be more effective than the less restrictive obstacles [22,46], the value of providing both strong and weak obstacles can be further explored, in terms of both effectiveness and user experience for more sustained and long-term change of one's relation with their mobile phones. Our findings from academic apps also highlighted new explicit obstacles for restricting use through design frictions such as cognitive tasks, which, unfortunately, have been limitedly explored. However, these innovative obstacles open up an interesting design space, as frictions support users to pause before compulsively re-engaging with their phones and apps, and thus a more mindful interaction.

From the 25 apps that support monitoring, 13 (52%) support users becoming aware when they reach the set use limits of their phone or apps, mostly through explicit notification and much less through implicit ones such as screen dimming, whereas daily reminders support a high-level awareness of use patterns exceeding set limits. Academic apps also started to explore implicit notification, albeit in tactile modality, through

vibrations. These implicit notifications open up a less explored design space for this intervention. Arguably, vibration-based notifications are weak obstacles, and illustrations of how nudge theory [34] can be leveraged in the design of digital well-being apps. Implicit notifications may be less intrusive and therefore more persuasive, although future work is needed to explore their specific benefits when compared with explicit ones.

An important outcome is the 2 ways of supported focused attention that digital well-being apps implement: The first is implicit support through the monitoring and limiting of phone or app overuse, and the second is the explicit training of attention by focusing on offline activities without phone use, including also exposure to white noise to support concentration, which has strong research underpinning [17,70].

A key functionality, less explored in previous research on digital well-being, is supporting motivation for keeping within limited use. For this functionality, we identified the following three mechanisms: reward and penalty leveraging gamification principles, educational and motivational content, and social support provided, however, by a limited number of apps and where cooperation among users is limited.

The theoretical underpinning of digital well-being apps has received limited attention. However, Roffarello and De Russis [22] suggested the value of grounding the design of well-being apps to support behavior change, habit formation, and self-regulation. As shown in the *Introduction* section, scholars have identified a range of theories that may inform the design of digital well-being apps, such as those of uses and gratification [19,31], planned behavior [32], dual system [33], nudge [34], framework for behavior change [35], or regulation [36]. However, it is less explored how such theories have been actually informing the developing of commercial well-being apps. However, the operationalization of these theories in this respect has been limited. In this section, we argue for the value of self-regulation theories.

Previous work has shown that tracking is a key functionality of digital well-being apps that captures the use of the phone and its apps [22]. However, this does not make the important distinction between the digital well-being app running in the background to collect such information and the user's active effort to minimize phone use. The former is usually important in the early stage of digital detox when people want to understand their consumption patterns, whereas the latter follows with setting up limits to phone or app use. For this, we called the former tracking, and the latter monitoring, which is a better term for capturing or tracking data against a specific target. Most behavior-changing apps use monitoring toward specific goals such as exercising ones [41]; therefore, the link between monitoring and goal setting is crucial. We note the important alignment of monitoring functionality to the three ingredients of self-regulation as reflected in self-regulation theories: setting target standards, monitoring the current state against these targets, and activating processes to reduce any identified distance between the current state and the targets [59]. Thus, we argue that designing for monitoring functionality can benefit from theoretical grounding in self-regulation theories.

Regarding the intervention of creating obstacles to limit use, we have seen the value of both strong restrictive mechanisms and weak ones, mostly explored in academic research rather than reflected in commercial apps. We argue that weak and particularly implicit obstacles are illustrations of nudges, which nudge theory describes as persuasive attempts for behavior change that do not limit users' choices [73,74]. Future work is needed to understand how nudge theory can be sensitively leveraged to rigorously inform such obstacles to use.

The intervention for supporting focused attention is particularly interesting, as it marks a shift away from limiting excessive use toward more mindful activities, either technologically mediated or offline, whose valuable side effect is limited use of the phone or apps. Rather than steering away from undesirable behavior, this intervention encourages engagement in meaningful and ideally desirable activities, subsequently supporting the most powerful appetitive rather than aversive motivation. We also highlight in this context the value of supporting users to understand and support their meaningful goals [66], which subsequently can address the phone overuse and the boredom often associated with it. However, goal theories have been limitedly discussed in relation to digital well-being apps.

The final intervention focuses on supporting motivation to keep within use limits. Although limitedly mentioned in relation to digital well-being apps, we suggest the value of broaden and build theory [75], where positive emotions are leveraged for increased self-awareness and behavior change. Illustrations of how this theory may be underpinning some of the identified functionalities include the provision of allowances for overruling the set use limits during monitoring. This is important for instrumental reasons both allowing the completion of some immediate tasks, and maintaining motivation in case of setbacks in meeting the set limits. In turn, this could broaden users' resilience and more flexibly support the acknowledged high demands of self-regulation [36]. Future work is needed to explore effective ways for managing the negative emotions associated with setbacks.

Design Implications for Digital Well-being Apps

Overview

The third research question focused on the design guidelines for digital well-being apps informed by our identified functionalities. For this, we articulate 6 implications for designing digital well-being apps including calling to move beyond screen time and support the broader focus of digital well-being; supporting meaningful use rather than limiting meaningless use; leveraging (digital) navigation in design for friction; supporting collaborative interaction phone overuse; supporting explicit, time-based visualizations for monitoring functionality; and supporting the ethical design of digital well-being apps. These implications open up a larger design space for digital well-being apps, going beyond the main tracking and monitoring functionalities [19,34,57].

Beyond Screen Time: Broader Focus of Digital Well-being

Although most of these functionalities focus on limiting screen time, echoing previous findings on addiction and phone overuse

[22], an important outcome is that about a third (13/39) of our apps support focus of attention either by limiting distractions or by supporting focused attention often on offline activities, including training of attention. We argue that this bias toward screen time fails to reflect the larger body of HCI research on well-being that can inspire novel apps that may better support users' skills for more mindful use of technologies. We call for stronger engagement of HCI research in the design of digital well-being apps that addresses this limitation. Indeed, our findings could mark a shift away from addressing a problematic behavior by explicitly limiting it but rather by supporting a high-level function that can arguably better address the root of the problematic behavior. There is an extensive body of work on mitigating the impact of interruptions [62,63] and a growing interest in mindfulness technologies [39,40,64,76] that can support the design of these apps for digital well-being aiming to support focus of attention.

Supporting Meaningful Use Versus Limiting Meaningless Use

Findings also indicate an important limitation of digital well-being apps reviewed in this work and in particular their rather narrow view of limiting use. We argue that this overlooks the broader goals for using technology in the first place and users' different avoidance or approach motivations. For this, we can leverage goal theories and the distinction between hedonic and eudemonic or meaningful goals [66] and how the latter can be purposefully designed for. Emphasizing the meaningful use of technology [11] may be a better approach to avoid meaningless or habitual use leading to phone overuse, while accounting also for the scarcity of attention [77].

Leveraging (Digital) Navigation in Design for Friction

Findings highlight obstacles for preventing app use that can inform the design for friction [78] as a mechanism for slowing down interaction (such as information sessions at the start of using a mediation app), which we know little about. Our findings suggest harnessing the digital distance and navigation to the target app. This is supported by findings showing that navigation in the folder hierarchy and in the real world share the same neural correlates [61]. One can imagine that information architecture imposing additional digital navigation cost for reaching apps located deeper in the phone's information hierarchy, whose use is to be limited, may mitigate against their overuse. We can also think of leveraging physical navigation, for instance, by allowing access to some apps only in physical locations that the user has to purposefully travel to, supporting thus fitness goals. Kim et al [31] positioned their app and this family of restrictive and coercive interventions within the HCI work on uncomfortable interactions aimed at helping people toward important goals while tolerating discomfort [60] and on design frictions through microboundaries consisting of small barriers enforced before an interaction to prevent habitual phone use [57].

Supporting Collaborative Interaction for Limiting Phone and App Overuse

Much work has shown the value of social support for behavior change, and our findings confirm that this is also an important intervention for digital well-being apps. Our outcomes echo previous ones showing the benefit of social support for limiting smartphone use, albeit by leveraging competition. We argue that the value of cooperation can be better harnessed in the design of digital well-being apps, both for limiting overuse and for training focus of attention. Our findings indicate that only 16% (9/56) of the apps in our app review implement social support as a built-in feature. This supports the argument presented in a study by Czerwinski et al [62] that social support is a feature needed in digital well-being apps, as current apps do not seem to leverage social support as a mechanism to enhance self-regulation.

Supporting Time-Based, Explicit Visualizations Tailored to Monitoring Functionality

In terms of data visualization, findings indicate a richer range of formats available for the monitoring of phone or app use against set limits compared with their mere tracking. This makes sense because tracking aims primarily to support users' exploration and understanding, whereas monitoring aims mostly to support behavior change toward set goals [79,80]. Hence, although more ambiguous representations are useful to motivate and engage users during tracking, for the monitoring functionality, more specific formats and particularly those including timelines are more useful. However, we have seen that academic apps leverage timeline representations, whereas commercial apps do so to a lesser extent. The latter allow people to easily match on the timeline their behavior with the recorded data to not only understand the data but also use it for reaching the goals. These outcomes align with previous work on the value of the ambiguity of different types of captured data [4] to support users' engagement in understanding it, particularly relevant in the tracking stage. In contrast, although the rationale of timeline visualizations has been limitedly unpacked in scholarly work, it can be grounded in the growing HCI interest in temporality [24] and its value for reflection, both in and on action [81]. Future work can compare the value of different visualization forms for supporting such reflection on data.

Supporting Ethical Design of Digital Well-being Apps

Despite their potential for supporting users with their phone overuse, most digital well-being apps have limited scientific underpinning and evidence base. They tend to target users without health conditions and tend to be inclusive, as many of their functionalities appear to be free. However, we call for extending the efforts toward a more research-informed and evidence-based design of digital well-being apps. This is particularly important because their beneficence can be limited by the risk of harming users with mental health conditions, as well as those who experience phone addiction. Such recommendation can be addressed to app market places or policy makers for regulating the requirements for their research underpinning. The most ethical challenge pertaining to these apps is supporting autonomy of users experiencing smartphone addiction [67]. However, given the challenges of diagnosing phone addiction, increased ethical sensitivity is required in this respect. In addition, more work is needed to explore how the shift toward increased autonomy can be best supported and by what features of digital well-being apps.

Limitations and Future Work

We focused on Google Play, which limited our review of iOS apps not available on Google Play. Future work could extend this exploration to other platforms. Future work can also aim to further strengthen the scientific underpinning of the design principles of digital well-being apps, in terms of both their theoretical framing and evidence-based evaluation studies. Our findings indicate that despite the growing number of digital well-being apps, parts of their design space have been less explored, such as supporting awareness for reaching use limits, motivation to keep within set use limits, implicit obstacles rather than explicit ones, recommended interventions to determine the right type of obstacles according to the tracked data, and mechanisms for supporting focused attention. We encourage researchers and developers to focus on these aspects, and together with the key features identified in our study, they can significantly improve the design of digital well-being apps.

Conclusions

We report on a functionality review of 39 commercial and 17 academic digital well-being apps. Findings provide richer understanding of tracking and particularly monitoring functionalities, together with 4 interventions for limiting use. These provide new understanding of the different types of obstacles for limiting use, as well as of specific features for less explored functionalities such as supporting awareness for reaching use limits, focused attention, and motivation to keep within set use limits. We conclude with 6 design implications for digital well-being apps, namely, calling to move beyond screen time and support the broader focus of digital well-being; supporting meaningful use rather than limiting meaningless use; leveraging (digital) navigation in design for friction; supporting collaborative interaction to limit phone overuse; supporting explicit, time-based visualizations for monitoring functionality; and supporting ethical design of digital well-being apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The reviewed top-rated digital well-being apps and academic apps, their user rating scores from 1 to 5, and their numbers of raters.
[DOCX File , 21 KB - formative_v6i4e31730_app1.docx]

Multimedia Appendix 2
Tracking functionality for phone and app use, format for visualizing the tracked data, and user profiling based on tracked data.
[DOCX File , 23 KB - formative_v6i4e31730_app2.docx]

Multimedia Appendix 3
Monitoring functionality: setting use or focus time limits, scope and place of limited use, visualizing time limit, and flexibility through 3 options (use allowance beyond time limit, exclude apps from time limit, and discontinuing tracking when limit was reached).
[DOCX File , 30 KB - formative_v6i4e31730_app3.docx]

Multimedia Appendix 4
Interventions for limiting use: creating obstacles for limiting use differing in force, saliency, temporality, sociality, user profile, and source.
[DOCX File , 26 KB - formative_v6i4e31730_app4.docx]

Multimedia Appendix 5
Interventions for limiting use: supporting awareness for reaching the set limit of use through different notification types, screen diming, and daily reminders.
[DOCX File , 24 KB - formative_v6i4e31730_app5.docx]

Multimedia Appendix 6
Interventions for limiting use: supporting focused attention through training or white noise.
[DOCX File , 18 KB - formative_v6i4e31730_app6.docx]

Multimedia Appendix 7
Interventions for limiting use: supporting motivation to keep within limited use involving different types and content, as well as social support of different types involving cooperation, competition and associated social recognition.
[DOCX File , 27 KB - formative_v6i4e31730_app7.docx]

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Abbreviations

HCI: human-computer interaction
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Original Paper

Development of a Blended Learning Approach to Delivering HIV-Assisted Contact Tracing in Malawi: Applied Theory and Formative Research

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Abstract

Background: Despite progress toward the Joint United Nations Programme on HIV/AIDS “95-95-95” targets (95% of HIV-positive persons tested, 95% of tested persons on treatment, and 95% of treated persons virally suppressed), a gap remains in achieving the first 95% target. Assisted contact tracing (ACT), in which health workers support HIV-positive index clients to recruit their contacts (sexual partners and children) for HIV testing, efficiently identifies HIV-positive persons in need of treatment. Although many countries, including Malawi, began implementing ACT, testing outcomes in routine settings have been worse than those in trial settings.

Objective: The aim of this paper is to use formative research and frameworks to develop and digitize an implementation package to bridge the gap between ACT research and practice.

Methods: Semistructured qualitative research was conducted in 2019 in Malawi with key informants. Barriers and facilitators to intervention delivery were identified using the Consolidated Framework for Implementation Research. Approaches to digitization were examined using human-centered design principles.

Results: Limited clinic coordination and health worker capacity to address the complexities of ACT were identified as barriers. Ongoing individual training consisting of learning, observing, practicing, and receiving feedback, as well as group problem-solving were identified as facilitators. Important features of digitization included (1) culturally relevant visual content, (2) capability of offline use, and (3) simple designs and basic editing to keep costs low.

Conclusions: Formative research and frameworks played a key role in designing and digitizing an implementation package for ACT delivery in a low-income setting such as Malawi.

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KEYWORDS

HIV; e-learning; digitial learning; blended learning; digital; contact tracing; assisted partner services

Introduction

In 2014, the Joint United Nations Programme on HIV/AIDS set ambitious "95-95-95" global targets for 2030 [1]. These targets aim to have 95% of persons living with HIV aware of their HIV status, 95% of persons living with HIV on treatment, and 95% of treated persons virally suppressed. Although 81% of persons living with HIV in sub-Saharan Africa (SSA) are now aware of their HIV status, 4.89 million remain undiagnosed, and half a million HIV-exposed infants do not receive timely early infant diagnosis each year [2-5]. Furthermore, a large share of HIV-negative adults remains unaware of being in a relationship with a person living with HIV and are therefore less likely to use effective HIV-prevention strategies [6]. Index-based approaches, in which health workers support persons living with HIV "index clients" to recruit their "contacts" (sexual partners and children) for HIV testing, efficiently identify other persons living with HIV in need of HIV treatment and HIV-negative persons in need of HIV prevention [7]. Index-based approaches build on a fundamental tenet of infectious disease epidemiology: each HIV-positive index has one HIV-positive contact who transmitted HIV to them and other potential contacts who could acquire HIV from them. Index-based approaches have higher diagnostic yields than any other testing approach [7] and hold great promise for achieving the global target of 95% of persons living with HIV tested for HIV [8]. Nonetheless, index-based approaches have not been an integral part of HIV epidemic control in SSA until recently [9].

In 2016, the World Health Organization (WHO) revised its recommendations surrounding index testing from "passive" approaches, in which indexes recruit their own contacts, to voluntary "assisted" approaches, in which health workers support indexes with contact recruitment [10]. These assisted approaches are referred to as "assisted partner notification," when focused on sexual partners, or "assisted contact tracing (ACT)," when biological children and other household contacts are included. The WHO guidelines provide a "strong recommendation" that assisted contact tracing "should be offered as part of a comprehensive package of testing and care to people living with HIV" [10]. In the years since the WHO guidelines were issued, the President's Emergency Plan for AIDS Relief (PEPFAR) has promoted index-based approaches that include ACT options [11]. Dozens of countries, including Malawi, have adopted ACT policies and intensified ACT implementation [11,12]. However, real-world ACT testing outcomes have been inferior to those observed in ACT trials [12]. Implementation strategies, guided by theory and formative research, may support translation of ACT outcomes observed from trials into real-world settings.

In this paper, we seek to describe the process of developing an ACT implementation package. We explain the two phases that led its development, which are (1) design and (2) digitization. As qualitative formative research, we did not set out to test hypotheses, but rather to generate them.

Methods

Setting

This work was conducted in Malawi, a country in Southeastern Africa with 19 million people. Malawi has a 10.6% adult HIV prevalence and 1.1 million people living with HIV [13]. Malawi has a mature HIV program that is approaching the 95-95-95 targets [13]. Malawi has long had a passive index-based program, with the Department of HIV/AIDS promoting routine distribution of "family referral slips." In early 2018, through a PEPFAR-led demonstration project, implementing partners began introducing ACT in dozens of facilities, and in early 2019, voluntary assisted partner notification, Malawi's ACT approach, was adopted as part of Malawi's national HIV testing policy.

Malawi has a dire human resource shortage with less than 2 physicians, 0.02 psychiatrists, and 0.01 psychologists per 100,000 people, some of the lowest global rates [14,15]. To address its formidable HIV burden with limited human resources, Malawi has task shifted many HIV-related activities, especially counseling tasks, to lay cadres. In 2015, to respond to gaps in HIV testing, Malawi introduced a cadre of HIV diagnostic assistants to improve coverage of early infant diagnosis, viral load testing, and rapid HIV antibody testing [16]. HIV diagnostic assistants are lay persons with secondary education and 4 weeks of preservice training. In its first year, nearly 1200 HIV diagnostic assistants were deployed to 450 facilities, resulting in improved diagnostic indicators [16]. Community health workers hired by local nongovernmental organizations are another lay cadre responsible for a range of HIV-related tasks, including community tracing. HIV diagnostic assistants and community health workers conduct most ACT implementation [17]. HIV diagnostic assistants typically diagnose HIV-positive indexes and support contact elicitation and selection of ACT options, and community health workers typically conduct tracing.

Throughout Malawi's national program, nongovernmental organizations implementing partners play a critical role in hiring and supervising these lay cadres. Tingathe Program, one of the largest PEPFAR-implementing partners in Malawi, and the implementation lead on this research, was initiated by Baylor College of Medicine Children's Foundation-Malawi in partnership with the Malawi Ministry of Health. Tingathe takes a family-focused approach to the HIV epidemic by supporting the provision of high-quality, comprehensive HIV services. Tingathe has over 10 years of experience implementing HIV testing, care, and treatment programs in Malawi and currently provides support to Malawi's HIV care and treatment program with more than 1000 staff in 95 Malawi Ministry of Health facilities.

Research Procedures

As Malawi's National HIV testing program evolved from a client-led passive referral model to a provider-supported ACT model, we sought to understand the barriers and facilitators to ACT implementation. This process was guided by the Consolidated Framework for Implementation Research (CFIR) [18]. The CFIR is a determinants framework comprised of five

domains (intervention characteristics, individual characteristics, outer and inner organizational settings, and processes) and 39 constructs within these domains that interact with one another [18].

We were also interested in digitizing some or all of these implementation strategies. To facilitate meaningful and sustainable digital programs, technological, human, and cost features must be taken into consideration. We used human-centered design thinking to inform potential adaptations of our implementation strategies into a digital platform. Human-centered design thinking is an approach that integrates the possibilities of (1) technology, (2) the preferences of people, and (3) the requirements for business viability [19] in the process of product develpoment.

In October 2019, we conducted a series of in-person focus group discussions, each 2 hours long, on (1) barriers and facilitators to ACT implementation and (2) the potential role of digital modalities to enhance the program. Tingathe staff were considered key informants and were purposively selected if they held ACT training as well as supervisory and clinical mentorship roles within the organization (N=10). Thus, they had routine contact with hundreds of ACT implementers at dozens of facilities. We also conducted one 2-hour-long, semistructured in-depth interview with a key informant who was not available for the focus group discussions.

All participants provided informed consent to participate. The discussion was facilitated using a semistructured guide. Data were audiorecorded, summarized, and transcribed. Data were reduced into themes organized within the constructs of the CFIR and human-centered design.

Ethics Approval

The study was reviewed and approved by the National Health Science Research Committee (20/01/2467), the local ethics committee in Malawi, and the Baylor College of Medicine Institutional Review Board (H-47655). Informed consent was obtained from all participants.

Results

Population Characteristics

Of the 11 key informants, 3 (27%) were district-level supervisors, 4 (36%) were facility-level supervisors, 2 (18%) were health care workers who provided ACT services, and 2 (18%) were data collection supervisors; 5 (45%) were female, and 6 (55%) were male. All were employed by Tingathe program.

Themes Surrounding Implementation Package Design

Themes arose within the five following domains of CFIR, which guided our implementation package development process: (1) intervention characteristics, (2) individual characteristics, (3) outer organizational settings, (4) inner organizational settings, and (5) processes.

With respect to intervention characteristics, complexity of ACT implementation was identified as a formidable barrier. Complexities included sensitivities around discussing sexual behavior with indexes, multiple potential contacts for each index, multiple tracing options for each contact, challenges with obtaining correct locator information for sexual contacts, and concerns around index safety.

This level of complexity, along with the minimal preservice training of lay health workers delivering ACT [16], exposed a set of individual characteristics, which were low competence around basic training principles and poor self-efficacy among both health workers and supervisors. For example, Tingathe staff reported that health workers frequently were uncomfortable taking sexual histories, did not understand which partners needed to be tested, and did not know how to help indexes decide which tracing methods to select. Supervisors suggested that modeling these counseling behaviors would enhance skills.

In the outer setting**,** diverse patient needs of both indexes and contacts were not being met, as counseling was conducted generically in a non–client-centered manner and without sensitivity to potential stigma and intimate partner violence or abandonment.

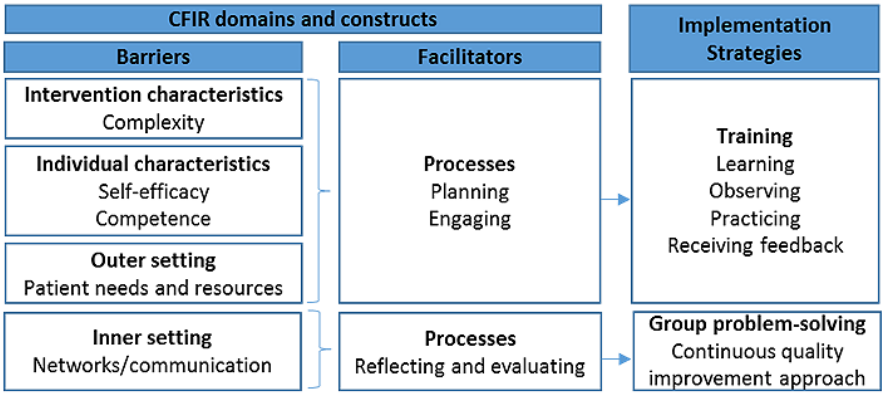
Networks and communication were identified as challenges in the inner setting: health workers in many sections of a single health facility (eg, antenatal care, pediatrics, and antiretroviral therapy) interacted with potential indexes and contacts, but responsibilities were not clearly delineated, and coordination between health workers was minimal.

To address these challenges, several processes were proposed: training that consisted of engaging strategies (role modeling) and planning strategies (practice and feedback) to address perceived intervention complexity, low health worker competence and self-efficacy, as well as patient needs. To address network and communication challenges, group problem-solving approaches that incorporated reflection and evaluation were suggested.

Resulting Implementation Strategies

Synthesizing these findings, we arrived at two sets of implementation strategies, which are as follows: (1) enhanced health worker training to improve ACT counseling sensitivity and competence; and (2) group problem-solving to facilitate ACT coordination (Figure 1). This set of strategies aligns with a seminal review showing the combination of training and group problem-solving to frequently improve health worker practices in low- and middle-income countries (LMIC) [20]. Our specific training and problem-solving approaches were guided by theory and evidence, which will be explained here in detail.

Figure 1. Application of Consolidated Framework for Implementation Research (CFIR).



Training

Training is the most common implementation strategy in LMICs; however, it is often conducted with suboptimal pedagogical practices and without any ongoing reinforcement [20]. We developed a training guided by the theory of expertise [21], an educational theory that considers deliberate practice and a core set of activities (learning, observing, practicing, and receiving feedback) as important for mastery of new skills [22,23]. Applying this theory to ACT, we developed a set of training activities consisting of the following: (1) explaining ACT counseling skills (learning); (2) modeling ACT counseling skills through vignettes (observing); (3) practicing counseling skills through role plays (practice); and (4) providing suggestions on improvement (feedback). This approach is supported by social cognitive theory, which posits that learning occurs in a social context with reciprocal interactions between the person, environment, and behavior [24]. Observation of modeled ACT vignettes facilitates social learning; practice solidifies behavioral skills and enhances self-efficacy; and feedback refines and reinforces behavioral skills. These activities have enhanced counseling skills across a range of behavioral interventions, including those related to HIV treatment, prevention, and psychosocial support [25-29].

Group Problem-solving

Group problem-solving draws on concepts from continuous quality improvement, which is a set of formal and systematic processes to identify and address health systems challenges [30,31]. The purpose is to identify challenges with ACT implementation and coordination, evaluate potential solutions, provide actionable recommendations, and revisit progress through a series of meetings. Similar processes have led to improvements in a range of implementation outcomes in several SSA contexts, including with lay cadres [32-37].

These sets of implementation strategies were combined into an "implementation package" with face-to-face health worker training and group problem-solving. In a previously published work, Tingathe delivered this package to nearly 500 health workers in 36 facilities in Mangochi, Malawi, and observed improvements in a range of ACT indicators: the number of sexual contacts elicited, the number tested, and the number newly identified as HIV-positive [17]. This work demonstrated the value of theory-driven training and problem-solving for improving ACT outcomes.

Themes Surrounding Implementation Package Digitization

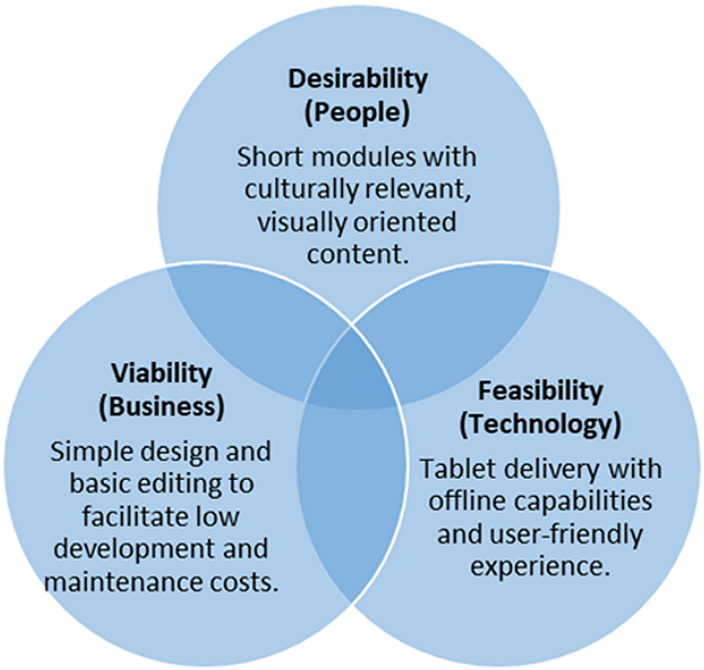
Themes were also categorized within human-centered design thinking domains, which guided the adaptation of these implementation strategies into a blended learning delivery platform (Figure 2). The results were organized around considerations of (1) technology, (2) desirability, and (3) the requirements for business viability [19].

Applied to rural Malawian health facilities, important technological challenges were discussed, including limited internet connectivity, limited computer literacy, and nonuniversal personal mobile devices, a theme observed in comparable studies in the region [38,39]. These considerations led us to deliberate on content that does not require continuous internet connectivity. They also suggested the importance of user-friendly applications, as has been observed in similar settings [40].

To address desirability for Malawian health workers, participants proposed content that was primarily audio- and video-based to ensure limited reading for this low literacy audience. Studies in similar low-resource environments also proposed similar multimedia elements to address challenges with computer literacy [41]. Participants suggested content be created with Malawian cultural and linguistic considerations in mind. Smaller segments were proposed to enable learning to occur in brief increments when workload permits.

With respect to business aspects, we selected tablets, which are less costly than laptops. We opted for simple visuals and basic editing to limit the budget. For digital learning packages to be cost-effective, it is important to minimize up front development costs, maximize the number of users, or, preferably, do both simultaneously.

Figure 2. Human-centered design framework.



Theme Synthesis: Final Implementation Package

We synthesized findings from the formative work to digitize the package. Based on the WHO's recommendation that digital modalities for training health workers in LMICs complement, rather than replace, face-to-face learning, we opted for a blended learning approach [42,43]. "Blended learning" combines the best features of digital learning (ie, quality, consistency, and convenience) with the best features of face-to-face learning (ie, interactivity and group engagement) [44,45]. Blended learning is typically more effective than either electronic or face-to-face learning alone for acquiring new knowledge and skills [25,46], and specifically for improving health worker counseling and communication [47-49].

The resulting blended learning implementation package translated our training plus group problem-solving approaches for the possibility of decentralized delivery. We included both individual asynchronous learning sessions and synchronous interactive small-group sessions. The individual learning sessions contain descriptions of ACT skills, video vignettes modeling these skills, and embedded questions assessing comprehension. The small-group learning session contains tablet-guided practice role plays, individual feedback, and facilitated group discussions. It was designed for facility-level conduct guided by ACT data. We developed a model where all health workers involved in ACT would meet to examine their facility's performance, identify gaps in performance, and propose actionable solutions. Each meeting would review progress toward proposed solutions, as well as their impact on ACT indicators.

Discussion

In this research trajectory, we used formative research, theory, and frameworks to guide the development of a novel implementation package. First, the consolidated framework for implementation research identified key barriers and facilitators to intervention delivery. Next, the theory of expertise, social cognitive theory, and principles of continuous quality improvement informed the development of an implementation package to address these barriers and facilitators. Finally, human-centered design principles guided the translation of the implementation package from in-person to digital delivery.

The facilitators we identified using the CFIR closely mirrored findings from successful ACT programs in SSA [50]. In 2017-2018, contacts form Kenya and Mozambique accounted for 51% of the 1.7 million contacts tested across 18 SSA PEPFAR countries, even though these countries only accounted for 14% of the population [12]. Similarly, several Cameroonian districts scaled and sustained ACT before the WHO guidelines were published [51]. In an analysis of ACT implementation in these three countries, the intensive ongoing nature of health worker capacity-building was essential [50]. Although the implementation contexts differed, the capacity-building processes were similar. Initial face-to-face trainings imparted ACT counseling skills through skill-based learning and practice role-plays. Ongoing on-the-job mentorship and refresher trainings reinforced and enhanced these skills, consistent with capacity-building best practices in the region [52,53].

Our contributions to ACT implementation science are novel, timely, and noteworthy. In the few years since the WHO issued its guidelines surrounding ACT, there has been widespread ACT implementation in SSA [11,12] and numerous descriptions of barriers, facilitators, and corresponding ACT indicators [50,51,54]. However, the role of theory and frameworks has been limited. Our research trajectory shows the key role that such approaches can play in the design of implementation strategies.

The final blended learning product was pilot tested with promising preliminary results regarding health worker fidelity and preliminary ACT effectiveness [55]. Our next step is to evaluate these ACT implementation strategies in a pragmatic cluster randomized trial to examine both implementation and effectiveness outcomes in a range of clinical settings. This design strength will allow for clear inferences about the impact of the blended learning ACT package on health worker behaviors, clinical indicators, and patient outcomes. This study will also contribute more broadly to the field of HIV implementation science, as only 14% of HIV studies involve implementation research and only 6% are cluster randomized [56].

Our work also represents an important innovation in health worker capacity-building in LMIC settings. A large-scale review of health worker practices in LMIC settings identified the combination of (1) health worker training and (2) group problem-solving as one of the few sets of strategies that routinely improves health worker practices across a range of countries and health conditions [20]. However, this promising combination of strategies has not been translated to a blended learning delivery modality and rigorously evaluated for patient outcomes in LMIC setting. Our research makes this innovative contribution.

Finally, to our knowledge, our planned research trajectory will be the first complete, rigorous evaluation of a blended learning package in a LMIC setting. Although there has been a proliferation of digital and blended learning tools for LMICs over the last decade, most evaluations have focused on proximal outcomes, such as adoption, health worker knowledge, and skills [46]. The WHO has highlighted the critical need for research assessing the impact of blended learning on health worker practices, patient outcomes, and cost-effectiveness in LMIC settings [43]. Our next step is to directly address this set of research questions in a cluster randomized controlled trial. If effective, this implementation strategy will provide an evidence-based solution for adaptation in settings with different characteristics and disease profiles. This research trajectory also represents an important contribution to digital and blended learning.

In recent years, digital learning has proliferated in the health sector, including in LMIC contexts, due to many enticing features, such as the following: (1) learning is not time- or place-dependent; (2) learning does not require an on-site instructor; (3) pace and degree of difficulty can be tailored to the learner; (4) progress and aptitude can be easily monitored; (5) high quality content can be delivered consistently; and (6) infrastructure needs are minimal [44-46]. For in-service training in LMIC contexts, these features are appealing. Digital learning can be delivered at the health facility, eliminating travel and lodging expenses associated with centralized face-to-face trainings. Individual sessions can be delivered asynchronously so all staff are not absent from the clinic simultaneously, minimizing understaffing. New staff can acquire necessary skills right away, rather than waiting for a scheduled training. Health workers can receive high quality instruction without relying on an on-site trainer. Finally, they can potentially be more easily adapted to new settings. Together, these features made digitizing our strategies enticing. Of note, this work was conceptualized in 2019, prior to the SARS-CoV-2 pandemic, but such digital approaches are also appealing for promoting physical distancing and minimizing SARS-CoV-2 exposures [57,58].

Our research has several important limitations. First, this formative study was small. Second, we focused on Tingathe staff (the target population for these implementation strategies), and not on other stakeholders, such as indexes, their contacts, and policy makers. Finally, it was conducted in a single country, and may not be generalizable to others, though these processes can be replicated elsewhere. Adaptation to new settings is an important potential future direction.

In conclusion, our research trajectory illustrates that theories, frameworks, and formative research can play an important role in designing and digitizing implementation strategies. The resulting implementation package provides a promising approach for enhancing ACT and ultimately achieving the 95-95-95 targets in Malawi and beyond.

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Disclaimer

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Conflicts of Interest

None declared.

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Abbreviations

ACT: assisted contact tracing
CFIR: Consolidated Framework for Implementation Research
LMIC: low- and middle-income countries
PEPFAR: President’s Emergency Plan for AIDS Relief
SSA: sub-Saharan Africa
WHO: World Health Organization

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Original Paper

A Tailored Web-Based Video Intervention (ParentCoach) to Support Parents With Children With Sleeping Problems: User-Centered Design Approach

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Abstract

Background: Many parents frequently struggle with undesirable or problematic behavior (ie, temper tantrums and whining) displayed by their child. To support parents in promoting positive parenting skills (ie, recognizing challenging situations and reacting appropriately), the interactive video e-learning tool *ParentCoach* was developed. The tool aims to teach parents generic behavioral responses by means of situational learning, tailoring, and problem solving. The first demonstration focused on sleeping problems.

Objective: The aim of this paper is to illustrate the user-centered development of ParentCoach.

Methods: We conducted usability, understandability, and acceptance tests among the target group (29 parents, 7 youth health care professionals, and 4 individuals with former lower health literacy) in different phases of the development process via focus groups, interviews, and surveys. This allowed for relevant insights on specifications and user requirements to guide the development and revision of the tool in each iteration.

Results: Iterative testing and development allowed for the final demonstration of ParentCoach to be experienced as a relevant and accessible parenting intervention that can be used as a stand-alone program or in combination with another program.

Conclusions: This paper elaborates on the iterative development process and its benefits for the final demonstration of ParentCoach.

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KEYWORDS

positive parenting; usability testing; lower health literacy; user-centered design; iterative development; eHealth; web-based intervention; mobile health; mHealth; parenting

Introduction

Background

Research has shown that 36% of parents with children living at home report concern regarding the upbringing of their children. Among this group, 60% look for help and advice outside their family, friends, and social environment [1]. In addition, an evaluation among users of the parental information platform GroeidGids (Growth Guide) in the Netherlands, a platform with >100,000 users yearly, showed that parents often have questions regarding diet, sleep, health, and parenting [2]. Hence, there is a substantial group of parents who do not know how to deal with common problems in their children, such as anxiety, stubbornness, disobedience, or temper tantrums, which may emerge in a certain developmental stage of the child [3]. It is important to provide early parenting education, advice, and support based on scientific knowledge about healthy and adaptive parenting. Effective parenting may prevent aggravation of relatively small and manageable problems, which could

otherwise result in more severe behavioral problems [4]. This might especially be true for vulnerable families (ie, lower-educated, lower-income, or migrant families) as these groups are more likely to experience problems that can negatively influence their parenting style (eg, less consistent or supportive parenting) [5].

The upbringing of children may affect various aspects early on, including social skills, brain development, self-control, emotional regulation, mental and physical health, and resilience [6]. According to Sandler [6], "effective parenting" consists of adequate discipline practices, advice, and guidance and a positive affective relationship between the parent and the child as well as instances to improve children's skills to adjust to environmental demands. A systematic meta-analysis by Kaminski et al [7] revealed several parenting strategies to be especially effective, such as consistently responding to one's child and using "time out" as a disciplinary strategy, with active acquisition of parenting skills revealing significantly large effects. In addition, improving parenting practices has been shown to benefit the well-being and overall development of both parents and children [8].

In the Netherlands, there are a number of effective parenting interventions available, but most focus on secondary or tertiary prevention; that is, the promotion of parenting skills for parents at high risk who already experience serious problems [9]. Moreover, most of these interventions are time-consuming; they consist of multiple individual or group meetings. This creates logistical difficulties for parents, such as inconvenience regarding location, transport challenges, limited flexibility in work schedules, and lack of childcare [10]. In addition, parents perceive stigma or concerns about confidentiality, which affects their willingness to participate in these interventions [10]. These interventions may also result in low program recruitment and retention as they require significant training- and supervision-related time and costs [11,12]. This poses a significant burden on participants and professionals, which potentially undermines their reach and impact [12]. The number of effective primary preventive parenting interventions is sparse [13]. There is a clear need for more easily accessible and effective primary preventive interventions that go beyond information provision [12,14].

Technology-assisted primary preventive parenting programs may be effective in overcoming some of the barriers of parenting programs. In a recent meta-analysis, the effectiveness of technology-assisted parenting interventions was examined, assessing the effects of 9 different programs among disadvantaged families [10], including programs such as Triple P Online [15], Parent-Child Interactions-Cellular [16], and Infant-Net [17]. This meta-analysis showed that such interventions can be effective in supporting positive parenting behavior and have a positive impact on parental well-being and child behavior. However, this study revealed considerable variation between programs. The difference between programs seemed related to programs that focused solely on information and demonstration of parenting principles and programs that also provided tailored feedback and advice (generally via phone or email). Programs without tailored advice and feedback proved far less effective than programs with tailored advice and feedback.

In this study, we describe the development of *ParentCoach*, a low-demand program that can be used depending on the experienced need of parents and to overcome potential taboos or reluctance to take part in parenting programs. Importantly, ParentCoach addresses some of the omissions of previous technology-assisted programs by not only providing information and demonstration of parenting practices but also providing a web-based environment to practice with common difficult parenting situations, in which parents receive personalized feedback and advice. Hence, we aim to make use of the advantages of technological possibilities and ensure tailored advice, which has been shown to improve the effectiveness of previous parenting programs, with the ultimate goal of enabling parents to practice adequate parenting skills to prevent more generally experienced parenting problems.

ParentCoach

ParentCoach is a web-based, tailored, interactive video e-learning tool [18]. A demonstration version of ParentCoach was developed to promote positive parenting skills with regard to children's healthy sleeping behaviors. This demonstration version provides a practice context with exercises and advice content, including tips and an explanation of how to apply the evidence-based principles. As sleep is a common concern for parents, ParentCoach was first developed with sleep in mind. The practice content addresses different aspects of getting children to bed by means of situated learning (ie, what to do when your child does not want to go to bed) and repeated rehearsal of (coping) skills (ie, how to cope with temper tantrums). Tips and resolutions are delivered through an animated female character as a relational agent.

ParentCoach consists of three scenarios in which parents can practice their parenting skills regarding the sleeping behaviors of their child (ie, *it's bedtime*, *putting on the pajama*, and *going to bed*). These scenarios depict a common situation that parents may experience to be difficult (ie, the child does not want to put on her pajama). Following short sequences in which a short dialogue between parent and child is shown, parents can choose between 2 options on how to react. In response to their choice, a relational agent provides instant feedback and reinforcement and offers further explanation of why a certain choice was (less) adequate. In each scenario, the child may act in different ways (ie, obedient, refusing, whining, or angry). Although the situation may be the same, as the child reacts differently, parents are expected to adapt their response (ie, reinforcing positive behavior or adequately responding to negative behavior). Thus, 12 practice situations can be completed. An overview of the scenarios can be found in the *Results* section. In these scenarios, parents can practice or are advised on how to deal with negative child behavior. In addition, they can receive advice on reinforcing positive child behavior. Therefore, parents can choose to receive a total of 6 tips regarding positive and negative behavior (eg, *reward your child*, *teach your child new things*, or *temper tantrums* and *refusal*). Upon opening the link, parents can decide whether to watch a short introduction or another segment. The intervention can be performed in one's own time

and repeated as many times as necessary as there are no time-bound restrictions. ParentCoach does not provide any additional human support as users interact with the animated web-based coach who provides tips and reacts to the users' choices on a 24/7 basis. Thus, the tool can be seen as an extension of other parenting programs.

ParentCoach was iteratively developed based on user-centered design principles, which means that the end user was closely involved in the developmental process to fine-tune the intervention as much as possible to their needs and preferences. Such a user-centered design approach is important as it enhances usability and user engagement and, hence, increases the likelihood of an intervention being effective and feasible [19,20]. Its multiple iterative cycles of concept generation, prototype design, and evaluation reveal important needs and preferences of the target group and result in enhanced usability and acceptability of the design by the end users [19,21]. Furthermore, early-stage prototype testing in terms of usability prevents the aggravation of use-related issues in later stages of the developmental process [19]. On the basis of early user acceptance testing, certain features are still flexible and can be further adapted or disregarded before a substantial amount of time, money, and effort has been invested without matching the users' requirements [22]. eHealth interventions often do not fit people with lower literacy skills and do not involve them in the intervention development [23]. This study also involved people with low literacy skills in the iterative user-centered design to examine and optimize the fit of the ParentCoach intervention to their needs and preferences.

In the following sections, we describe the phase-wise development and iterative testing of ParentCoach based on sleep problems in children.

Methods

Overview

ParentCoach was iteratively developed based on user-centered design principles. This process consisted of the following phases: (1) definition phase, (2) concept testing, (3) prototype testing, (4) usability testing, and (5) low-literacy testing. Potential end users (parents) and intermediate users (youth health care professionals [YHCPs]) were involved in the process by means of user-based assessments. An advisory board of professionals and parents provided feedback during the developmental process. First, the behavioral problem and program objectives were defined. Evidence-based methods were translated into behavioral strategies and included in ParentCoach. In the second phase, a concept version of ParentCoach was developed and tested among YHCPs in a focus group interview (n=3). The third phase consisted of incorporating the received feedback into the prototype of ParentCoach and testing this prototype among parents (n=3) and YHCPs in individual interviews (n=4). In the fourth phase, ParentCoach was tested among parents by means of a web-based survey (n=26). Finally, ParentCoach was evaluated among (former) people with low literacy skills (n=4) to ensure its acceptability and usability among vulnerable families. For each interview, a protocol was developed. All interviews (individual or group) were recorded. The input from the interviews was assessed using thematic analysis based on a topic list. The topic list consisted of topics such as relevance, usability, layout, and acceptability of the prototype intervention and was based upon the interview protocol. For each phase, a summary was made of the interviews by means of the topic list. The data from the web-based survey (phase 4) were processed using SPSS (version 25; IBM Corp), and descriptive statistics (frequencies, means, and SDs) were used to analyze the results. An overview of the different steps and sample characteristics can be found in Table 1.

Table 1. Overview of the iterative development steps and sample characteristics.

Step	Goal	Means	Sample
Definition phase	Definition of the behavioral problem and program objectives, translation of evidence-based methods into behavioral strategies	Literature study	N/A[a]
Concept testing	Storyboard development testing and testing of a concept version of ParentCoach: perceived relevance and user requirements	Focus group	3 female YHCPs,[b] mean age 38.7 (SD 4.5) years
Prototype testing	Early prototype development testing: exploring the acceptance and relevance of the script dialogue decision tree underlying ParentCoach	Individual interviews	3 mothers, mean age 34.3 (SD 2.1) years, and 4 female YHCPs, mean age 39 (SD 11.3) years
Usability testing	Refinement and usability (and acceptance) testing among the target group	Web-based survey	26 mothers, mean age 30.4 (SD 3.15) years
Low-literacy testing	Ensuring acceptability and usability of ParentCoach among vulnerable families	Individual interviews	4 parents with (former) low literacy skills

[a]N/A: not applicable.

[b]YHCP: youth health care professional.

To ensure the anonymity and privacy of the participants, data were processed in an anonymized way. Personal information

was not included in the reports of the interviews and surveys, and the contact information of the participants was deleted after they received a reward for participation.

Ethics Approval

ParentCoach was approved by the ethical board of the Netherlands Organisation for Applied Scientific Research (Institutional Review Board, 2018-068).

Results

Definition Phase

Sleep disturbances are strikingly common among preschool-aged and school-aged children (aged 2-6 years), with between 20% and 42% of these children experiencing sleep problems [24]. Sleep problems in children include bedtime resistance, night awakenings, short sleep duration, daytime sleepiness, and problems with falling asleep. These problems have been associated with behavioral, emotional, learning, memory, and health problems among children [25-28]. Sleep problems among young children also negatively affect parents and families; that is, parents may experience stress, sleep deprivation, health problems (including chronic fatigue), maternal depression, and irritability, whereas problems among families can be expressed as poor parenting strategies, family dissatisfaction, and relationship problems [29,30]. Thus, supporting parents to prevent sleeping problems among children is crucial for the health of both children and families.

Although it is essential for parents to learn how to deal with such problems, in the Netherlands, there are no proven effective programs to prevent sleeping problems among young children [31,32]. Providing preventive information alone is not sufficient; it has been shown that effective parenting is characterized by the ability to cope with difficult situations by implementing specific child interaction strategies. Moreover, repeated provision of problem situations in which parents can role-play and engage in situational learning activities (eg, calming, strategic ignoring, and consistent behavior) may enhance the effectiveness thereof [7,33]. Parents become more effective in interacting with their child or children when they are trained in positive behaviors (eg, enthusiasm, interest, and doing things together), are responsive to the emotional and psychological needs of their child, use time-outs efficiently, react to their child consistently, and learn which of their behaviors negatively and positively influence child (sleeping) behavior [6,7,34]. Situated learning and repeated rehearsal of (coping) skills are evidence-based methods to train parents in positive child interactions [7] and may help parents avoid child sleeping problems. Therefore, we formulated the following program objectives: to enable parents to (1) recognize challenging situations and (2) adequately react by training them in generic actions as suggested by the literature using evidence-based techniques, called *positive parenting principles*.

First, key elements and behavioral techniques were selected to match the goals of ParentCoach.

To realize the program objectives, ParentCoach will apply behavioral methods such as situational learning, tailoring, and problem solving. Possible applications identified were communication strategies such as narratives (also storytelling), video feedback in recognizable situations, or audiovisual materials to accomplish teaching generic behavioral options.

Situational learning of effective parenting practices could be stimulated by guiding a user through different scenarios in which the interaction between a parent and a child is observed so that they can interact, for example, by choosing an adequate reaction. Narrative communication has been shown to contribute to better recognition, relevance, realism, and active learning [35] and may increase active processing and understanding of the content [36]. In addition, narratives have been shown to improve comprehensibility in individuals with varying levels of health literacy [37] and, therefore, will be applied. Moreover, the use of audiovisual information (as opposed to textual information) can improve attention and comprehension in groups with lower socioeconomic status (SES) [38,39].

To improve information processing, active involvement, enhanced personal relevance, and positive effects on skills compared with universal interventions [40-42], tailoring could be an effective method to provide personalized feedback and scenarios depending on the user's choice. Tailoring (health) messages enhances the attractiveness, salience, and, thereby, effectiveness of the information [43], which may consequently lead to greater maintained behavior changes [44].

To facilitate the attainment of problem-solving skills, users may practice with a variety of potential problem scenarios that also integrate a range of different dialogues (eg, the child immediately listens to the parent vs a child who is reacting in a whiny manner). The application of various situations enhances the learning experience by providing the user with a greater number of practice situations as well as personalized feedback, which reinforces the learned content so that parents can practice different parenting strategies.

On the basis of the objectives and chosen methods stated above, a first concept was developed, which was consecutively tested in 4 iterative phases to be discussed in the following sections.

Storyboard Development and Testing

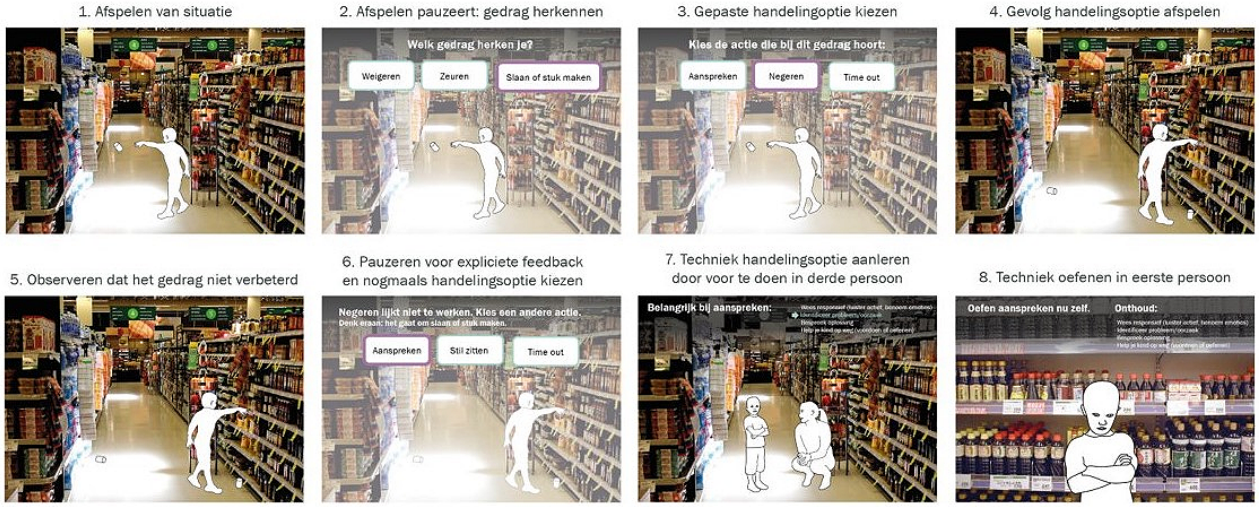
To test the idea of ParentCoach, a storyboard was developed. This test aimed to examine perceived relevance and user requirements. The concept scenario was tested by means of a focus group interview with 3 YHCPs in December 2017. Professionals were recruited via the child health center in Leiderdorp, the Netherlands. The interviewees were all female (3/3, 100%) with a mean age of 38.7 (SD 4.5) years and 10.5 (SD 6.1) years of work experience mostly with children aged between 0 and ≥7 years.

The first concept of ParentCoach incorporated a scripted 2D-based storyboard describing possible intervention features and functionalities. The storyboard as presented to the YHCPs offered various contexts (eg, at the beach or zoo) where parents could practice parenting skills in different situations that varied in degree of difficulty. In addition to personalization of the settings, including when to receive feedback and whether to suggest options on how to act, users were offered the possibility to personalize the child. A scoreboard sought to indicate the number of situations the user had already engaged in as well as

a *score* of correct answers given (Figure 1). A particular scenario was created (*supermarket scene*): while grocery shopping, the child is shown displaying rebellious behavior (throwing something; Figure 2). The user is then provided with a menu of options to indicate what kind of behavior they recognize in the situation (eg, refusal or whining), followed by the choice to react in a certain way (such as ignoring it or taking a time-out). Upon choosing a reaction, the scenario displays how the child reacts to the user's response.

Figure 1. Mock-up of the main menu of ParentCoach.

Figure 2. The scenario as depicted in the first iteration.



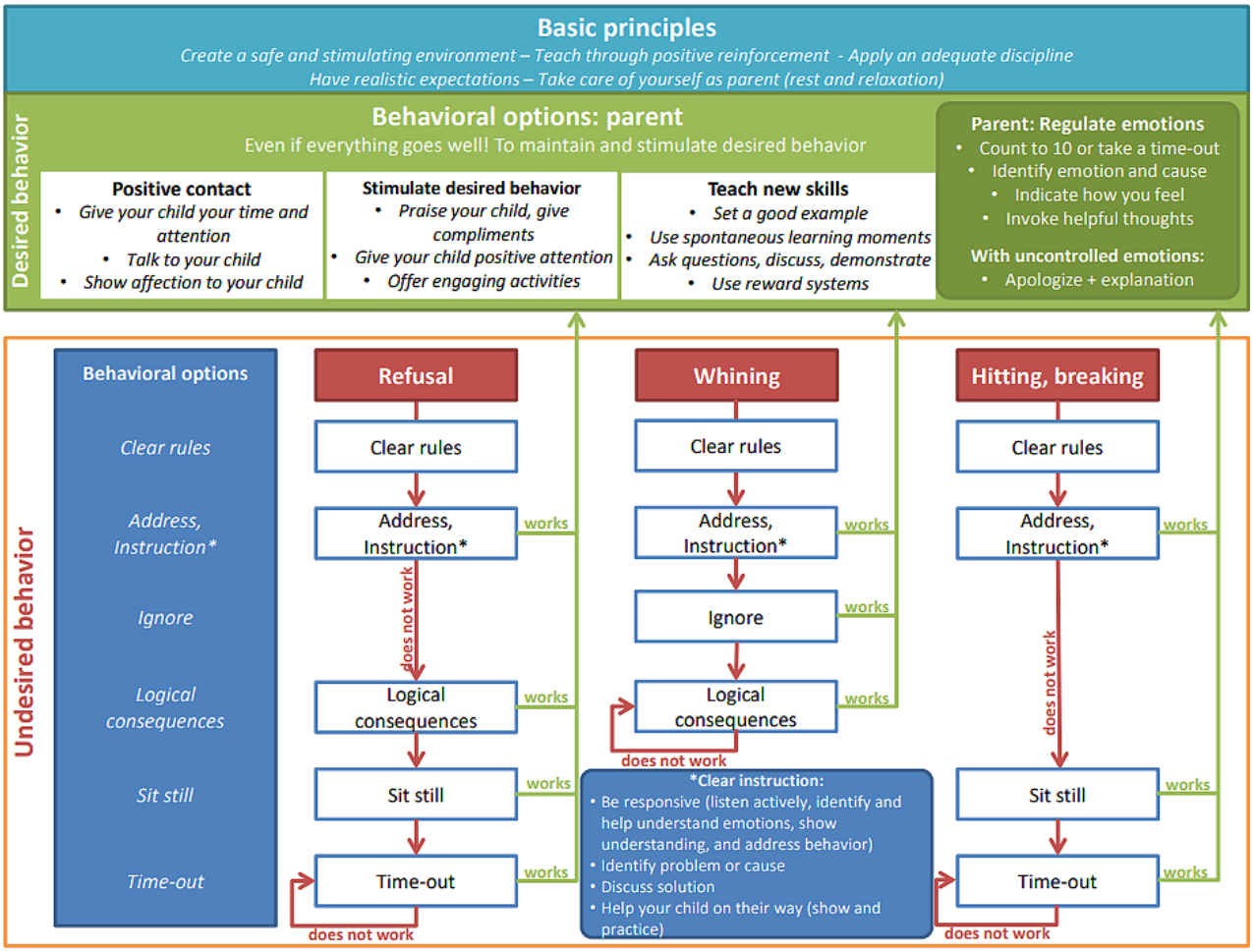
Regarding added value, all YHCPs (3/3, 100%) indicated that the scenario of ParentCoach was useful. The envisioned program was assessed to be "fun" in terms of enjoyment, and the mode of delivery was said to be innovative by all interviewees (3/3, 100%). Furthermore, the appearance was rated as attractive. Approximately 67% (2/3) of the health professionals reported that they would advise ParentCoach to all parents, whereas 33% (1/3) stated that they would rather advise the program to parents with parenting problems. The YHCPs found ParentCoach to be relevant, but certain points of improvement were shared. Although approving of the overall script and feedback provided to the user, the professionals indicated the concept to be relevant and realistic.

Hence, the evaluation strengthened the idea of the potential utility of ParentCoach. In addition, the YHCPs made improvement suggestions for further development of ParentCoach. Specifically, they pointed out that we should ensure that accessibility and the low literacy of potential users were taken into account, such as the use of simple language and starting off with the basic principles with potential for expansion on the topic.

Early Prototype Development and Testing

Next, a prototype was developed. First, a logical sequence of actions was defined (Figure 3).

Figure 3. Basic positive parenting principles underlying ParentCoach.



This model provides the user with instructions based on an operationalized problem. This consists of a stepwise instruction on how to (1) reinforce desired behavior and (2) discourage the undesirable behavior of a child. The scheme aims to offer users a structured approach to positive parenting and can be downloaded by the users.

Actions were then translated into scripts to mimic a dialogue between parent and child.

First, for the interactive videos, dialogues were scripted, and decision trees were defined to be able to tailor videos. The decision tree includes (1) type of situation, (2) type of child response, (3) type of options parents could choose, and (4) feedback from the relational agent, resulting in 24 potential situations. An example of such a decision is presented in Table 2.

The scenarios were integrated into an interactive video prototype and tested in the second iteration. This test explored the acceptance and relevance of the script dialogue decision tree underlying ParentCoach.

The updated prototype was assessed among 3 parents and 4 YHCPs by means of individual interviews in October 2018. Parents were recruited via flyers at the child health center in Leiderdorp, the Netherlands; via an advertisement at Kidsproof (a regional site for parents of young children with activities in the region of the Hague, the Netherlands); and via an email to parents of young children working at the Netherlands Organisation for Applied Scientific Research, Leiden, the Netherlands. All parents were female (3/3, 100%) with a mean age of 34.3 (SD 2.1) years. Their highest completed level of education was higher education, and they had 1 or 2 children aged between 2 and 5 years. YHCPs were recruited via the child health center in Leiderdorp, the Netherlands; via the Municipal Health Service in Leiden, the Netherlands; and via an email to a national network of YHCPs. All YHCPs were female (4/4, 100%) with a mean age of 39 (SD 11.3) years, had between 7 and 22 years of work experience, and worked with children in all age groups. This test focused, among other things, on attractiveness, utility, identification, and recognition. Questions elaborated, for example, on users' first impression of the program, the added value of the program according to the user, in which cases the user would want to use ParentCoach, and how they experienced the overall visualization.

Table 2. Extract from the decision tree indicating the possible dialogue between the user and coach in the case of the child (1) listening to the mother instantly and (2) showing refusal behavior within the scenario *It's bedtime*.

Type of situation and possible scenarios	Child response	Parent response options		Feedback from ParentCoach	
		Parent+	Parent–	Parent+	Parent–
"It's 6:45, bedtime. I want you to put on your pajama."					
Child listens	"Okay I will put on my pajama. Be right back."	"Great. How nice that you do this so quickly. I'll be right there."	"Hurry up hey."	Well done. This was positive behavior. In this case, you can indeed react with a compliment.	Look out. Your child shows positive behavior. Reward this; for example, by giving a compliment.
Child refuses	Child goes on playing	"I want you to put on your pajama."	"Okay, 5 more minutes then."	Well done, your child shows refusal behavior. Clear instructions are required here!	Look out. Your child displays refusal behavior. Do not reward this, but stick to your rules.

In general, the evaluation indicated that the examples were useful, and the scenarios were recognizable, short, and accessible. The relational agent was said to be pleasant. However, the options of parenting reactions that users could choose were declared to be too obvious, with the user experiencing a tendency toward the "right choice." This implied that the user did not have the full opportunity to learn from their mistakes as they were not provided with information on why a certain choice may be less adequate. Furthermore, concerning visualization, the mother in the scenario was said to be illustrated too much like a grandmother, and the explanation given by the coach was said to be too long and difficult to understand.

The professionals evaluated ParentCoach as relevant, especially for "short, simple problems." However, they suggested potential adaptations regarding the inclusion of lower-SES populations as well as taking cultural factors into account without stereotyping. Another suggestion to increase relevance comprised the provision of an explanation concerning the importance of the positive parenting principles.

Mothers experienced the scenarios in ParentCoach as recognizable. The child's voice and way of talking were said to be very realistic. Concerning the use of the program, the interviewees experienced ParentCoach as a short (ie, not too time-consuming), accessible program that could be used in one's own time. Both the fact that the coach was an independent character and the delivery format of ParentCoach as a whole were strong points according to the mothers. However, the amount and length of information and tips given by the coach were said to be too much as well as too scientific. The interviewees reported that they preferred alternations between explanations, short example movies, and exercises.

Both parties (parents and professionals) indicated a felt need to be able to get in contact with one another in case there was an indication of the need to provide or receive professional human support, which suggests embedding ParentCoach in the broader context of youth health care services (YHCSs). On the basis of the results of this test round, ParentCoach was further adapted taking into account the feedback received.

Refinement and Usability Testing

The third iteration comprised a survey evaluating usability and acceptance among the target group. This version incorporated adaptations and improvements based on the feedback and suggestions retrieved during the second iteration.

The participants evaluated the 3 animation figures that were shown in the videos (ie, the mother, child, and coach), the assignments and skill training, the design, and the idea of ParentCoach. Thereby, we assessed the third version of the web-based ParentCoach, which was complemented with a web-based survey among a convenience sample of 26 participants. Recruitment took place in March 2019 via Facebook advertisements targeting young mothers with children aged 2 to 6 years. The participants were female parents, each with 1 to 3 young children in the age range of 2 to 5 years. The mean age of the participants was 30.4 (SD 3.15) years. Most participants were higher educated (21/26, 81%) and had a Dutch background (23/26, 88%).

The survey consisted of close-ended and open-ended questions. Close-ended questions related, among other things, to the videos; for example, *I experienced practicing with the videos to be (i) certainly clear, (ii) certainly not educational, (iii) certainly not recognizable*, to be answered on a 7-point Likert scale, or *How did you experience the mother character?* regarding (1) recognizability, (2) trustworthiness, or (3) irritation, again to be answered on a 7-point Likert scale. Furthermore, the questions concerned the explanations given by the coach (eg, *I experienced the explanations of the coach to be (i) relevant, (ii) clear, (iii) educational, (iv) easy to follow*, to be answered on a 7-point Likert scale). Open-ended questions assessed what the users experienced as most and least pleasurable, what they missed, and tips and recommendations for further development.

Of the 26 participants, 24 (92%) reported having watched the practice videos, whereas 23 (88%) watched the explanation videos (referring to tips and basic parenting principles). Positive points taken from this usability test revealed that the situations were recognizable, and the overall program was accessible, concise, and clear. The relational agent was evaluated most positively (7.3 out of 10) of the animation figures, followed by the mother (7.0) and the child (6.9). In general, 46% (12/26) of the users reported that they would use ParentCoach themselves, whereas 81% (21/26) would recommend it to someone else. Table 3 shows the overall usability and acceptability scores of ParentCoach. The most positive ratings (all scores ≥4 on a 5-point scale) were for (1) ease of use, (2) accessibility, and (3)

recognizable situations. Nevertheless, *fit for personal purpose* was rated lower (3 on a 5-point scale).

Table 3. Usability and acceptability of ParentCoach (N=26).[a]

Item	Rating, mean (SD)
ParentCoach illustrates situations that I personally recognize.	4.12 (1.18)
ParentCoach teaches me what to do in challenging parenting situations.	3.62 (0.75)
ParentCoach includes practical tips.	3.77 (0.71)
ParentCoach fits my needs well.	3.08 (1.16)
ParentCoach stimulates me to apply the exercises and explanations at home.	3.50 (1.07)
ParentCoach is a helpful means to practice.	3.69 (1.19)
ParentCoach is accessible.	4.35 (0.69)
ParentCoach is easy to use.	4.31 (0.68)
ParentCoach is fun to use.	3.85 (0.97)

[a]Likert scale (range 1-5).

From the open-ended questions, we could gather recommendations for improvement. The participants perceived the child as somewhat unrealistic in difficult situations. The feedback and explanation by the coach were found to be too wordy and complicated. In addition, users missed the possibility to either pause or replay certain segments. Some participants pointed out that the assignments were too short and should consist of more information about how to react in a certain situation (eg, when your child does not want to go to bed). Parents also reported that they wanted to receive more emotional support (eg, through the coach saying that practicing can be hard and that there are moments when parenting strategies may not work even though they are doing their best). Finally, parents requested more options, further indicating that the coach should emphasize that, besides the given parenting principles, other parenting strategies could also be good.

Low-Literacy Testing

On the basis of the last iteration, further improvements were made. A final evaluation was aimed at also assessing a fit with people with lower health literacy skills given that the convenience sample did particularly comprise people with higher education. This final prototype was evaluated with 4 participants who had (formerly) low literacy skills by means of individual interviews in May 2019. Participants were recruited from a test panel of language ambassadors of ABC Foundation in the Netherlands, a panel consisting of members with (formerly) low literacy skills. All participants (4/4, 100%) had children; 50% (2/4) had young children, and the other 50% (2/4) had adult children. This test focused on evaluating ParentCoach in terms of accessibility for users with low literacy, poor health skills, and low abstract thinking ability. Low-literacy testing consisted of methods requesting the testers to read aloud written text (eg, *Would you please read aloud what is written here?*), summarize and teach back information in their own words (eg, *What did you just hear?What do they mean with* refusal behavior*?* or *What can you do here?*), and give advice on how to rephrase certain expressions to increase comprehensibility (eg, *What was (un)clear?How would you resolve this?*).

The test panel was very positive and enthusiastic about ParentCoach and its features. The testers perceived the content as useful and comprehensible, and the videos were perceived as instructive. For this reason, they graded ParentCoach with an 8.3 on a scale of 1 to 10. The panel also mentioned some points of improvement. For instance, they pointed out that a short introduction video should be added to explain how ParentCoach works and how to use it, with an explanation of the menu. Furthermore, to enhance usability and acceptability, the panel advised the adaptation of some specific design features (eg, increasing font size and adapting symbols and text to enhance readability) and syntax (eg, rewording *undesirable behavior* into *negative behavior* and explaining difficult words). Reported difficulties included the time indication integrated in the menu. Here, users mistook the length of the video sequence (0:20) as the time when the action should take place (ie, 20 minutes after midnight). To resolve this issue, the indication was clearly labeled *duration*. In addition, examples of options for action were asked to be illustrated through animation. All feedback and advice from the test panel was processed in the final version of ParentCoach.

Finalization of Prototype

On the basis of the input from the last evaluation, a final version of ParentCoach was created [14]. As a result of user-centered design and iterative testing, an introductory movie was included explaining how ParentCoach can be used. The menu included enables the user to either run chronologically through the program or choose from 3 practice scenarios or advice regarding positive and negative behavior (Figure 4). In each of the 3 scenarios, the audiovisual material is delivered within 18 to 20 seconds. Scenarios to practice positive parenting principles include *it's bedtime*, *putting on one's pajama*, and *going to bed*. The scenarios start with a short sequence in which the problematic behavior of the child is depicted (eg, the mother makes it clear that it is time to go to bed, and the child whiningly responds saying that she does not want to). Following the short sequence, parents are offered two reactions; for instance, *I want you to put on your pajama. It is quarter to seven* or *Okay, 5 more minutes then*. Upon choosing one of the possible reactions, the user receives immediate feedback from the animated coach,

providing the user with advice and information regarding the given response. To enable users to practice with different situations, there are several ways in which the child may react so that the user is offered a broad range of situations to foster their learned skills.

Figure 4. Introductory home screen of ParentCoach (on the left hand side, the menu of the interactive video is shown).

In addition to practicing skills through scenarios, ParentCoach provides several tips and advice (eg, having positive contact or rewarding the child). Parents can either choose between positive or negative behavior as a response to the dialogue with the coach or directly select the desired element through the menu. Each piece of advice includes certain examples of how to stimulate positive behavior (eg, *give your child a compliment* by praising how well the child tidied up their room by themselves). This advice is accompanied by animations that support the audio text. Advice regarding negative behavior includes the topics *refusing*, *whining*, and *fierce behavior*, which can be accessed via the dialogue with the coach or in the menu. These behaviors are addressed in the enlisted steps that the user can take to engage with a child displaying the respective behavior. Each step is followed by a consecutive step in case the earlier measure failed to succeed.

Discussion

Principal Findings

In this paper, we elaborated on the application of a user-centered approach toward the development of the innovative web-based video tool ParentCoach. The tool empowers parents to recognize challenging situations and teaches them generic behavioral responses to stimulate the positive behavior of their child or children by means of interactive video e-learning using behavioral techniques such as situational learning, tailoring, and problem solving.

As a result of iterative usability testing, adaptations were made to ParentCoach to address wishes and needs and overcome perceived obstacles. These included the addition, adaptation, or extraction of some features such as text blocks, certain ambiguous symbols, optical change of the coach character, and look of the virtual environment. In addition, the spoken text was changed in terms of (1) ease of wording and (2) breaking up texts into smaller chunks. Furthermore, the response options were adapted content-wise as well as regarding syntax for easier understanding. To make ParentCoach more educational, response options were altered to ensure that the most appropriate response was not too obvious, thereby contributing to a better learning environment for parents. Low-literacy testing enabled the program to be inclusive.

ParentCoach may provide relevant evidence-based tips and practice situations that empower parents to tackle everyday parenting challenges without the need for further human support, thereby relieving pressure on the health care system and increasing the efficiency of support provision. Moreover, the basic parenting principles processed in ParentCoach comply with the national sleep guidelines for preventive child health care professionals [45]. Overall, ParentCoach was well received by parents and professionals. Parents reported (1) recognizable situations; (2) useful examples; (3) accessible use; (4) a pleasant coach; and (5) understandable and clear text, audiotext, and videos. Approximately 46% (12/26) of participants indicated wanting to use ParentCoach, whereas 81% (21/26) reported that they would recommend the tool.

In summary, ParentCoach offers a unique, low-demand, and accessible tailor-made preventive parenting support program in which we hope to have overcome some of the limitations of previous technology-enabled programs [10] that did not provide a practice setting with tailored feedback and advice. ParentCoach could be used as a stand-alone program or be integrated into other parenting programs or YHCSs such as the web-based platform Growth Guide, a platform by YHCSs. Its features allow users flexibility regarding time and duration to pass through the scenarios and tips as suggested by the literature advocating addressing such limiting factors and barriers that comprise childcare and transportation issues [46,47]. By means of ParentCoach, parents are enabled to train their parenting skills in their own time in the comfort of their own home. As such, it seems an important contribution to the existing

information-only or secondary preventive interventions, as was recognized by the YHCPs in the study and a recent review by the steering committee of Growth Guide (representing 18 YHCSs); it also addresses commonly experienced problems of a considerable number of parents in the general population. Furthermore, ParentCoach is unique in its approach as it is built to be inclusive for all parents and, therefore, seems particularly useful for parents with lower health literacy skills as it combines tailoring, interactive learning, and the use of both audio and visual information—strategies that have been shown to be effective in improving the attention and comprehension of this particular group [38,39]. Inclusive design in eHealth applications ensures that products are accessible and usable by the majority and, hence, helps overcome health inequalities, especially for lower-SES groups as it further minimizes the risk of growing health inequalities [48]. Therefore, cocreation with lower-SES groups is a means to ensure that ParentCoach is accessible and functional for everyone.

As pointed out by Davis and Venkatesh [22], early acceptability testing among the target group offers various benefits in the development process. First, initial acceptability testing allows for the prevention of potential pitfalls early on as it provides relevant insights into barriers and postimplementation user acceptance. Thus, it is crucial to promote user acceptability testing early in the design process as it may mitigate later financial deficits because of failing to meet the users' needs and wishes for functionalities before making significant investments [22]. As the expected user population may fall short, predicting user acceptance may not only save significant losses but also guide important decisions in the design process. On the basis of usability testing, certain initial decisions may be abandoned or progressed in an alternate way to focus on certain functionalities to match the end users' needs, as was done during the development of this program. Early testing goes along with a low cost compared with the implications of a huge investment that is not accepted and used by the end user [22].

Conclusions

As a conclusion, early testing of relevance and understanding of factors that contribute to esthetics, utility, understanding, and usability enabled the progressive development of ParentCoach according to the needs and wishes of the potential end users. Cyclical testing among this group positively affected the overall interface and interaction by revealing and correcting certain barriers. Moreover, the user-centered development of ParentCoach in cocreation with participants with lower health literacy skills contributes to the literature in that it offers an example of inclusive development.

Although in this paper we have shown that the working principle of ParentCoach can work, future research may address the extent to which the program actually enables parents to learn and apply positive parenting principles. Furthermore, future directions may include the incorporation of different contexts and other common problems that parents face, such as eating behavior, screen time, or physical activity.

Authors' Contributions

KP was involved with writing the original draft and review and editing. HvK was involved with the funding acquisition, methodology, investigation, and writing as well as review and editing. RA was involved with writing the original draft. SW conducted the investigation. PvE was involved with writing the original draft, reviewing, and editing; supervision; project administration; funding acquisition; and methodology.

Conflicts of Interest

None declared.

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Abbreviations

SES: socioeconomic status
YHCP: youth health care professional
YHCS: youth health care service

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Original Paper

Inpatient Telehealth Experience of Patients With Limited English Proficiency: Cross-sectional Survey and Semistructured Interview Study

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Abstract

Background: Patients with limited English proficiency (LEP) are at a higher risk of poor health outcomes and are less likely to use telehealth than English-speaking patients. To date, there is no formal evaluation of inpatient (IP) telehealth user experience of patients and their families by language preference during visits with their clinicians.

Objective: This study aims to compare the experiences of English- and Spanish-speaking patients and their families using IP telehealth, as well as to evaluate the experience of Spanish interpreters providing services through IP telehealth.

Methods: We prospectively administered a survey to English- and Spanish-speaking patients and their families who used IP telehealth from October 1, 2020, to March 31, 2021. We performed semistructured phone interviews of hospital-based Spanish interpreters who provided services through IP telehealth.

Results: A total of 661 surveys were administered, with completion rates of 18% (112/621) in English and 62% (25/40) in Spanish. On a 10-point scale, the overall satisfaction of Spanish speakers (median 10, IQR 10-10) was higher than that of English speakers (median 9, IQR 8-10; *P*=.001). Both English- and Spanish-speaking patients used IP telehealth for visits with their primary IP care team, subspecialty consultants, and other clinicians. Hospital tablets were used more often than personal devices, and only English-speaking patients used personal laptops. Patients and their families encountered challenges with log-in, team coordination with multiple users, and equipment availability. Interpreters encountered challenges with audio and video quality, communication, safety, and Wi-Fi access.

Conclusions: Both English- and Spanish-speaking patients reported high satisfaction using IP telehealth across multiple disciplines despite the workflow challenges identified by interpreters. Significant investment is needed to provide robust infrastructure to support use by all patients, especially the integration of multiple users to provide interpreter services for patients with LEP.

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KEYWORDS

telemedicine; telehealth; inpatient; social determinants of health; limited English proficiency; health-related social needs; Spanish; English as a second language; English proficiency

Introduction

Health care delivery required redesign during the COVID-19 pandemic. Given the limited availability of personal protective equipment, several aspects of health care were transformed to safely deliver high-quality care from a distance [1,2]. Critical to this redesign was the expansion of telehealth. Although telehealth use in inpatient (IP) settings is not new [3-7], it previously had poor market penetration due to strict regulation and low rates of reimbursement that varied by state [8,9]. IP telehealth expansion during the pandemic was used to support infection control practices, including minimizing personal protective equipment use and the surge of patient demand on hospital systems [10-12].

Beyond infection control, there were simultaneous, ongoing public health crises illuminated during the COVID-19 pandemic, which included health inequity [13]. Equity is a core component of health care access and quality and should be explicitly considered during system design and quality improvement [14]. The legal expectation to provide language access across all federal programs, including health care, originated from the Civil Rights Act and has been expanded under Section 1557 of the Affordable Care Act [15,16]. Successful telehealth implementation is critical to addressing health inequity, which includes linguistic barriers. Patients with limited English proficiency (LEP) have increased risks of poor health outcomes, adverse hospital events, and 30-day emergency department revisits compared to English-proficient patients [17]. Although non–English language preference is associated with higher interest in ambulatory video visits, having LEP is associated with a lower likelihood of ambulatory or urgent care video visits [18-20].

We previously described the rapid implementation of an IP telehealth program to facilitate IP care during the COVID-19 pandemic [21]. Prior evaluation of patient satisfaction with IP telehealth has shown high satisfaction with COVID-19 medical units, rehabilitation, and psychiatric partial hospitalization [22-24]. However, there has not yet been a formal evaluation of IP telehealth user experience by language preference. The experience of users with LEP is dependent on the seamless integration of interpreters; thus, to support this population, we also need to support the interpreter workflow. Our objective is to compare the experiences of English- and Spanish-speaking patients and their families using IP telehealth, as well as to evaluate the experience of Spanish interpreters providing services through IP telehealth.

Methods

Study Setting and Data Collection

This prospective survey study was conducted at Boston Children's Hospital, an academic quaternary care pediatric facility in Boston, Massachusetts. We conducted a mixed methods study of quantitative patient survey data and qualitative interpreter interview data.

Evaluation of the Experience of Patients and Their Families Using IP Telehealth

An 8-question survey (Multimedia Appendix 1) was developed via REDCap (REDCap Consortium) and modified based on the institution's outpatient virtual visit survey. The survey was reviewed and edited by the health literacy team to ensure accessible language use. The survey was translated into Spanish by Boston Children's Hospital Interpreter Services.

Patients and their families who used IP telehealth from October 1, 2020, to March 31, 2021, were identified by crossreferencing reports from the videoconferencing software with IP encounters in the enterprise data warehouse. We further filtered the report by selecting all patients with English or Spanish as their primary language. *Language* in this study is defined as the preferred language listed in the patient's electronic health record. Emails and phone numbers were used for survey distribution. Use of IP telehealth in dialysis, operating rooms, and radiological imaging were excluded as these visit types could not be linked to specific patient encounters. Patients with email listings were sent the survey in their listed language. Patients without email listings were called via phone, and the survey was administered in their listed language by author LP or a trained Spanish interpreter. Due to an initially low Spanish survey response rate and fewer email listings, starting from December 1, 2020, all surveys were administered by phone to patients with Spanish listed as their preferred language. Survey results of de-identified patients were downloaded from REDCap.

Evaluation of the Experience of Interpreters Providing Services Through IP Telehealth

The hospital has a dedicated interpreter services department with 23 staff members available either in person or by phone or videoconferencing, in addition to external interpreters via contracted agencies. During the COVID-19 pandemic, interpreters initially transitioned to remote work exclusively, but during the study period, they were available in person and remotely. Clinicians typically contacted interpreters by paging to arrange a meeting time. With the launch of an IP telehealth initiative, clinicians were instructed to provide a telehealth meeting link to the interpreter when requesting services. There is also a virtual interpreter system provided by a third-party vendor via tablets on wheels in each hospital unit; however, this system was not integrated with IP telehealth at the time of this study. We conducted semistructured phone interviews of 5 hospital-based Spanish interpreters who provided services through IP telehealth to assess their experience with the program and how it may be improved. The semistructured interview guide consisted of the following questions: (1) What issues did you experience during the IP telehealth session? (2) What do you like about IP telehealth? and (3) What are the opportunities for IP telehealth improvement? Responses were reported to include a representative sample and were categorized inductively.

Ethical Considerations

This project was part of a larger quality improvement effort at Boston Children's Hospital and was thus deemed exempt from

Institutional Review Board review by the Department of Pediatrics Performance Excellence Group.

Statistical Analysis

Medians and IQRs were calculated for continuous variables. A *P* value of .05 was considered statistically significant. Wilcoxon rank sum test with continuity correction was performed.

Results

Evaluation of the Experience of Patients and Their Families Using IP Telehealth

Of the 8422 unique patients admitted to the hospital during the study period, 505 (6%) had Spanish listed as their preferred language. Of these 505 unique Spanish-speaking patients, 40 (7.9%) used IP telehealth during the study period. A total of 661 eligible patients were identified and administered the survey, with completion rates of 18% (112/621) in English and 62% (25/40) in Spanish. On a 10-point scale, the overall satisfaction of Spanish speakers (median 10, IQR 10-10) was higher than that of English speakers (median 9, IQR 8-10; *P*=.001). On a 10-point scale, the median scores for how well they felt their questions were answered during their visit were equal: 10 (IQR 10-10) for Spanish speakers and 10 (IQR 9-10) for English speakers (*P*=.03). Both English- and Spanish-speaking patients reported IP telehealth visits with their primary IP care team, subspecialty consultants, and other clinicians (Table 1).

Hospital tablets were used more often than personal devices, and notably, only English-speaking patients used personal laptops (Table 2).

Of patient and family respondents with Spanish listed as their preferred language, 80% (20/25) reported using an interpreter during their visit. Feedback on how to make the system easier to use was most frequently regarding log-in, team coordination with multiple users including interpreters, and equipment availability (Table 3). We coded the responses into categories.

Table 1. Comparison of inpatient telehealth visit type by language.

Telehealth visit type	English-speaking respondents[a] (n=112), n (%)	Spanish-speaking respondents[a] (n=25), n (%)
Primary inpatient care team	54 (48)	12 (48)
Specialist consult	50 (45)	12 (48)
Other	48[b] (43)	9[c] (36)

[a]The sum of each column is greater than the number of respondents because the survey question permitted multiselect answers. The denominator for each cell is the number of respondents.

[b]Other telehealth visit types for English-speaking respondents included behavioral health therapy, child life, dietician, music therapy, nasogastric pump instructions, parent calling patient, patient calling provider from outside facility, patient unsure of type, pet therapy, and social work.

[c]Other telehealth visit types for Spanish-speaking respondents included dietician, music therapy, patient unsure of type, pet therapy, and social work.

Table 2. Comparison of inpatient telehealth device type by language.

Device type	English-speaking respondents (n=112), n (%)	Spanish-speaking respondents (n=25), n (%)	All respondents (N=137), n (%)
Hospital tablet	50 (45)	14 (56)	64 (47)
Personal phone or tablet	36 (32)	11 (44)	47 (34)
Personal laptop	26 (23)	0 (0)	26 (19)

Table 3. Categorized comment responses (N=52) to the survey question “How can we make the system easier to use?”

Categories for improvement	Responses, n (%)
Log-in	8 (15)
Multiple users/team coordination	5 (10)
Equipment availability	3 (6)
Privacy	3 (6)
Poor internet connection	2 (4)
Patient engagement	2 (4)
“Unreliable” interpreter	1 (2)
Audio quality	1 (2)
Advertising	1 (2)
Positive comments	26 (50)

Evaluation of the Experience of Interpreters Providing Services Through IP Telehealth

Feedback categories derived from phone interviews with Spanish interpreters include audio and video quality, communication, safety, and Wi-Fi access (Table 4).

Table 4. Interpreter phone interview feedback.

Category	Sentiment	Illustrative quote
General	Positive	• Thank you for caring about our Latino population!
Safety	Positive	• This helped me and my family stay safe from the virus. • I have children at home and was worried about working in person and spreading COVID to them.
Audio quality	Constructive	• It is challenging to hear the team when they are in full PPE [personal protective equipment]. • Make sure the iPad is close to the patient, volume is high, and it is clear who is taking turn to speak. Otherwise it is overwhelming.
Communication	Constructive	• Our Latino population is more responsive with texts than emails. Can we send the invite link through a text instead of an email? • Physical therapy was difficult because we could not touch the patient to instruct them to turn around.
Video quality	Constructive	• It is tough to visualize the patient and family at the same time. • We need more family education on pointing the camera at the correct angle.
Wi-Fi access	Constructive	• Most patients [who I interpret for] do not have Wi-Fi at home so they use data on their cell phones. We should help them use hospital Wi-Fi to download the application on their phones while inpatient. This will help them with their follow-up outpatient televisits.

Discussion

Principal Findings

We found that the patients in this sample had high satisfaction with IP telehealth, but Spanish-speaking patients' median satisfaction scores were higher than those of English speakers despite the workflow challenges identified by interpreters. Broad use cases of IP telehealth were present for both language groups, including visits with the primary IP care team, specialty consultants, social workers, and dieticians. Overall, hospital tablets were used more than personal devices, especially by Spanish-speaking patients. This finding suggests the need for further investment in dedicated hospital devices. Survey respondents provided useful feedback that was shared in departmental educational sessions and can inform future improvements (eg, regarding session log-in and audio and video quality with multiple team members).

Notably, interpreters expressed appreciation for the opportunity to deliver care from a distance during the COVID-19 pandemic. This finding highlights the value of IP telehealth as a tool to ensure staff safety from infectious diseases.

Comparison With Prior Work

Previous literature on IP telehealth implementation has described a broad range of use cases and patient satisfaction that is comparable to in-person care [22-26]. Our study adds to this literature by specifically addressing the experience of patients and their families who have LEP. The positive experience reported by Spanish speakers in our survey aligns with prior work in ambulatory settings that shows high interest in telehealth among non–English speakers [20].

Spanish-speaking patients primarily using hospital tablets and not personal laptops emphasizes the importance of investing in IP telehealth infrastructure for patients with LEP [27]. In one paper, narratives of patients with LEP who experience social isolation while hospitalized highlight the importance of careful tablet technology implementation to address communication barriers [28]. Other hospital systems describe the use of Amazon Echo Show devices, laptops on wheels, and tablets on wheels as part of telehealth [25,26]. Carts with the ability to pan and tilt, hands-free voice-activated command devices, and supplementary speakers may also help address the audio and video quality challenges noted by survey respondents.

Similar to previous findings, we found that work-arounds for integrating multiple users to include interpreters compromised audio and video quality [25]. Literature has shown better communication outcomes for interpreters connected by video than by phone, further supporting the need for robust infrastructure, including integrated interpreter services, to support IP telehealth initiatives [29].

Limitations

This study has limitations, particularly the switch to phone-administered surveys for Spanish-speaking patients due to a low response rate and fewer email listings than English-speaking patients. The use of phone surveys may introduce acquiescence or conformity bias, which may explain the higher median satisfaction score among Spanish-speaking respondents than English-speaking respondents. Satisfaction may also be inflated due to a perceived lack of anonymity or a fear of disapproval from health care professionals [30,31]. In addition, language preference as documented in the electronic health record may not accurately identify patients with LEP.

This could lead to miscategorization, affecting both our survey response rate and survey results. Our mixed methods approach meant that the interpreters—a small cohort—were interviewed, whereas the larger cohort of patients received the structured survey. Survey data have limitations that include inflexibility and lack of depth, which we attempted to address by including textboxes for open-ended questions. Finally, our findings may not apply to patients who speak languages other than English and Spanish, although this institution supports 15 languages through in-house interpreters and more than 100 languages through externally contracted interpreter services.

Conclusions

Both English- and Spanish-speaking patients reported high satisfaction using IP telehealth across multiple disciplines despite the workflow challenges identified by interpreters. Significant investment is needed to provide robust infrastructure to support use by all patients, especially the integration of multiple users to provide interpreter services for patients with LEP.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient survey in English and Spanish.
[DOCX File , 13 KB - formative_v6i4e34354_app1.docx]

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Abbreviations

IP: inpatient
LEP: limited English proficiency

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Original Paper

Developing a Technology Acceptability and Usage Survey (TAUS) for mHealth Intervention Planning and Evaluation in Nigeria: Pilot Study

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Abstract

Background: Technology acceptability and usage surveys (TAUS) are brief questionnaires that measure technology comfort, typical daily use, and access in a population. However, current measures are not adapted to low- and middle-income country (LMIC) contexts.

Objective: The objective of this pilot study was to develop a TAUS that could be used to inform the implementation of a mobile health (mHealth) intervention in Nigeria.

Methods: A literature review of validated technology comfort and usage scales was conducted to identify candidate items. The draft measure was reviewed for face validity by an expert panel comprised of clinicians and researchers with cultural, methodological, and clinical expertise. The measure was piloted by radiologists at an oncology symposium in Nigeria.

Results: After expert review, the final measure included 18 items organized into 3 domains: (1) comfort with using mobile applications, (2) reliability of internet or electricity, and (3) attitudes toward using computers or mobile applications in clinical practice. The pilot sample (n=16) reported high levels of comfort and acceptability toward using mHealth applications in the clinical setting but faced numerous infrastructure challenges.

Conclusions: Pilot results indicate that the TAUS may be a feasible and appropriate measure for assessing technology usage and acceptability in LMIC clinical contexts. Dedicating a domain to technology infrastructure and access yielded valuable insights for program implementation.

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KEYWORDS

measure development; survey methods; technology acceptability and use; global health; mHealth; Nigeria

Introduction

Background

Over the past decade, mobile Health (mHealth)–based interventions have become affordable, accessible options for health education and care, particularly in low- and middle-income country (LMIC) contexts [1,2]. Developing an mHealth-based intervention typically involves iterative cycles of design, testing, and rapid adaptation, as well as retesting in the targeted population. Technology acceptability and usage surveys (TAUS) may streamline these cycles by providing insight into the social context of device implementation and use. TAUS are brief questionnaires that measure technology comfort, typical daily use, and access in a population. Although TAUS have been used to inform digital interventions such as telehealth [3], they are seldom adapted to LMIC contexts or developed in the local language, despite their potential to support pre-implementation planning.

For global health intervention planning, there is a need for validated TAUS that are appropriate for use in LMIC settings, particularly in locations with limited electricity or digital infrastructure. Previously developed TAUS are either out of date, referencing technology platforms that no longer exist (eg, Alta Vista), or were developed in settings with large technology infrastructures such as the United States [4]. Additionally, previous literature also indicates that the use of mobile devices is culturally patterned [5,6]. For instance, in sub-Saharan Africa, the use of mobile applications has "leapfrogged" over computer-based platforms as a primary tool for work information-seeking in digital spaces [7]. Thus, it is necessary to develop TAUS tools that are not only adapted to local infrastructure but also tailored to the local cultural context.

Goal of This Study

The objective of this pilot study was to develop and pilot a TAUS that could be used to inform the implementation of an mHealth intervention in Nigeria. In this paper, we describe our methods for developing the TAUS and preliminary insights from piloting the measure among a group of Nigerian health professionals.

Setting

Nigeria is the most populous country in Africa and has the highest breast cancer mortality rate [8]; breast cancer is the leading cause of death among Nigerian women [9]. Although breast cancer is typically diagnosed via ultrasound-guided breast biopsy in most high-income countries, this approach is less frequently available in LMICs due to the prohibitive costs of imaging devices, materials, and maintenance [10]. In the absence of imaging, breast cancer is commonly diagnosed in LMICs either through blind biopsy, which is less accurate, or surgical excision, which increases morbidity [10].

However, battery-operated, mHealth tablet-based devices have the potential to expand ultrasound access in LMICs. An mHealth tablet-based ultrasound device is both less expensive and less costly than hospital-grade ultrasound machines. This device consists of a portable, high-frequency, ultrasound probe that attaches by USB to either a tablet or smartphone, which displays and send images to a secure mobile application. The device proposed for use in this intervention was developed in the United States (Philips Ultrasound Inc, Bothell, WA) but has been successfully used by midwives at Aga Khan hospital in Nairobi, Kenya [11]. However, this device has not been piloted in oncology settings nor within the context of the Nigerian hospital system. Therefore, this project presented an ideal opportunity to develop and administer a novel TAUS to help us understand radiologists' current technology use, access, and comfort in clinical settings, which would inform the implementation strategy of this tablet-based ultrasound intervention.

Methods

Measure Development

To select candidate items for the measure, we conducted a literature search of questionnaires related to physician technology usage as well as validated technology comfort and usage scales developed for clinical settings [2,3,12-14]. Drawing on themes identified in the literature, we created a first draft of the TAUS, organized into 4 domains: (1) comfort with using mobile applications; (2) reliability of internet, Wi-Fi, and electricity; (3) utilization of computers or mobile applications in clinical practice; and (4) attitudes toward using computers or mobile applications in clinical practice. Each domain contained 7 to 10 closed-ended or 5-point Likert scale items. The draft measure was then reviewed for face validity by an expert panel comprised of clinicians and researchers with cultural, methodological, and clinical expertise. This review enabled us to tailor the measure to the local Nigerian context and reduce the number of items needed to assess each construct to reduce respondent fatigue. Experts gave feedback independently and then convened to reach consensus on item consolidation and removal during a 60-minute feedback session. After revising the measure, experts re-reviewed and approved the final version prior to piloting.

Ethical Review

To pilot the measure, we obtained approval from the Institutional Review Board at Memorial Sloan Kettering Cancer Center (number IRB 18-114) for our study. All pilot study procedures were performed in accordance with the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Piloting the Measure

Data collection occurred in April 2019 at the sixth annual symposium of the African Research Group for Oncology (ARGO), a National Cancer Institute–recognized cancer consortium that aims to improve outcomes for cancer patients in Nigeria. The symposium was hosted by Obafemi Awolowo University Teaching Hospital in Ile-Ife, Nigeria. This setting was chosen because it presented an opportunity to simultaneously survey Nigerian radiologists working in diverse community and geographic contexts. During the conference, radiologist attendees attended a didactic and training session focused on mHealth tablet-based ultrasound device–guided breast biopsy. Following a hands-on demonstration of the

mHealth device, radiologists completed a paper copy of the TAUS. Responses were analyzed descriptively.

Results

After expert review of the responses, we consolidated "Comfort" and "Utilization" into a single domain given the overlap in constructs, expanded the "Reliability" domain to 10 items to reflect local infrastructure challenges, and reduced the "Attitudes" domain to 4 key items to reduce potential respondent fatigue. The final measure included 18 items organized into 3 domains: (1) comfort with using mobile applications (n=4), (2) reliability of internet and electricity (n=10), and (3) attitudes toward using computers or mobile applications in clinical practice (n= 4). The full measure can be found in Multimedia Appendix 1.

The survey was completed by 16 radiologists (Table 1). The survey took respondents approximately 5 minutes to complete. Respondents reported high levels of comfort and acceptability toward using mHealth applications in clinical settings. However, they reported a low level of technology infrastructure: 12 (12/16, 75%) reported that their hospital does not use an electronic medical record, and 9 (9/16, 56%) indicated that they are responsible for funding their own internet/Wi-Fi at their clinical practice. Approximately two-thirds (10/16, 63%) indicated that their hospital loses electricity more than once per day; 13 (13/16, 81%) noted that when electricity goes out, internet access is also disabled. In addition, 9 (9/16, 56%) indicated that it can take over 1 month for a malfunctioning device to be repaired at their hospital.

Table 1. Results of the technology comfort and use survey (n=16) in Ile-Ife, Nigeria in 2019.

Questions and Responses	Results, n (%)
Comfort with using mobile applications: "How comfortable are you with using computers or mobile applications for clinical purposes?"	
Very comfortable	8 (50)
Extremely comfortable	8 (50)
Comfort with using mobile applications: "How comfortable are you with using computers or mobile applications for professional educational purposes?"	
Somewhat comfortable	1 (6)
Very comfortable	7 (44)
Extremely comfortable	8 (50)
Utilization of computers or mobile applications in clinical practice: "I have taken an online/e-learning course in the past."	
No	3 (19)
Yes	13 (81)
Utilization of computers or mobile applications in clinical practice: "What is the primary way you communicate clinical information with your colleagues?"	
In-person	1 (6)
Phone call	6 (38)
Multiple forums (including text message, mobile application)	9 (56)
Technology access: Reliability of internet, Wi-Fi, and electricity: "I have reliable access to the internet/Wi-Fi at my hospital."	
Disagree	2 (13)
Neutral	1 (6)
Agree	9 (56)
Strongly agree	3 (19)
Technology access: Reliability of internet, Wi-Fi, and electricity: "Who provides funding for your access to the internet/Wi-Fi for your clinical practice?"	
Self	9 (56)
Hospital	1 (6)
Combination of self and hospital	6 (38)
Technology access: Reliability of internet, Wi-Fi, and electricity: "What proportion of your average day do you have access to internet/Wi-Fi for your clinical practice?"	
Entire day	5 (31)
Most of the day	7 (44)
Half of the day	2 (13)
Less than half of the day	2 (13)
Technology access: Reliability of internet, Wi-Fi, and electricity: "What is the connection type for intranet/internet/Wi-Fi that you use for your clinical practice?"	
Dial-up	1 (6)
Wireless broadband	15 (94)
Technology access: Reliability of internet, Wi-Fi, and electricity: The hospital loses electricity.	
1 per day	2 (13)
>1 per day	10 (63)
1-3 times per week	4 (25)
Technology access: Reliability of internet, Wi-Fi, and electricity: "Does your hospital have a generator?"	
No	0 (0)
Yes	15 (94)
Missing	1 (6)

Questions and Responses	Results, n (%)
Technology access: Reliability of internet, Wi-Fi, and electricity: "When the electricity goes out, how long does it take to come back on?"	
<1 hour	6 (38)
1-2 hours	4 (25)
2-3 hours	3 (19)
4-6 hours	1 (6)
>12 hours	1 (6)
Missing	1 (6)
Technology access: Reliability of internet, Wi-Fi, and electricity: "When the electricity goes out at your hospital does this also disable the internet/ Wi-Fi access?"	
No	2 (13)
Yes	13 (81)
My hospital does not have internet/Wi-Fi	1 (6)
Technology access: Reliability of internet, Wi-Fi, and electricity: "When a device malfunctions at your hospital how long does it take to get a repair?"	
<7 days	2 (13)
7-14 days	2 (13)
15-30 days	3 (19)
≥31 days	9 (56)
Technology access: Reliability of internet, Wi-Fi, and electricity: "Does your hospital have an electronic medical record?"	
No	12 (75)
Yes	3 (19)
Unsure	1 (6)
Attitudes toward using computers or mobile applications in clinical practice: "I find online/e-learning courses to be helpful."	
Strongly disagree	1 (6)
Neutral	1 (6)
Agree	3 (19)
Strongly agree	9 (56)
Attitudes toward using computers or mobile applications in clinical practice: "Using a computer or mobile application makes it easier to maintain or improve the health condition of my patients."	
Agree	4 (25)
Strongly agree	12 (75)
Attitudes toward using computers or mobile applications in clinical practice: "I think that using a computer or mobile health application to assist with maintaining or improving the health condition of my patients fits well within my clinical practice."	
Agree	4 (25)
Strongly agree	12 (75)
Attitudes toward using computers or mobile applications in clinical practice: "It is easy for me to use a computer or mobile application to assist with maintaining or improving the health condition of my patients."	
Agree	4 (25)
Strongly agree	12 (75)

Discussion

This pilot study demonstrates promise for TAUS' applicability and use in LMIC contexts. By including a domain with detailed questions related to technology infrastructure and access, this survey uncovered key concerns for mHealth use, despite high reported levels of technology comfort and acceptance. Although mHealth-based interventions are widely used, it is necessary to evaluate their feasibility and acceptability with TAUS that are tailored to the cultural context of the targeted population. Pilot results indicate that the TAUS is a feasible and appropriate measure for assessing technology usage and acceptability in

LMIC clinical contexts. Dedicating a specific domain to technology infrastructure and access yielded valuable insights for program implementation. For example, administering the TAUS in the context of the current project identified the need for precharged or battery-operated devices, given electricity instability. A limitation of this study is the fact that, while participants completed the measure, they did not provide direct feedback on the measure itself. Future directions include cognitive interviews to assess content validity among the target population.

The findings of this study justify the need to create a flexible TAUS that can be tailored to specific settings. The pilot reveals that the TAUS is a promising measure to support mHealth intervention planning in LMIC contexts. Future directions include larger-scale trials to support validation of the TAUS measure.

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Authors' Contributions

All authors contributed to the study conception and design. KAL, TMA, ADO, and ES contributed to the development of the methodology. KAL, ADO, and ES contributed to the acquisition of the data. All authors contributed to the analysis and interpretation of data. All authors contributed to the writing, review, and revision of the manuscript. ADO contributed to the administrative, technical, or material support. ES, TPK, and OIA contributed to the study supervision. All authors read and approved the final manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

EAM reports funding from Grail Inc for breast cancer research not related to the present work. The remaining authors have no conflicts of interest to disclose.

Multimedia Appendix 1
The Technology Acceptability and Usage Survey (TAUS) Scale.
[DOCX File , 18 KB - formative_v6i4e34035_app1.docx]

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Abbreviations

ARGO: African Research Group for Oncology
LMIC: low- and middle-income country
mHealth: mobile health
TAUS: technology acceptability and usage surveys

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Original Paper

Formative Provider Testing of a New Encounter Decision Aid for Smoking Cessation: Questionnaire Study

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Abstract

Background: Smoking cessation is an essential part of preventing and reducing the risk of smoking-associated morbidity and mortality. However, there is often little time to discuss smoking cessation in primary care. Decision aids (DAs) designed for clinic visits (encounter DAs) need to be clear, short, and concise to optimize therapeutic education, increase interaction, and improve the therapeutic alliance. Such a DA for smoking cessation could potentially improve counseling and increase the use of pharmacological treatments.

Objective: We aimed to collect feedback on an electronic encounter DA that facilitates physician-patient interaction and shared decision-making for smoking cessation in primary care.

Methods: We developed an electronic, encounter DA (howtoquit.ch) from a paper version created by our team in 2017 following user-centered design principles. The DA is a 1-page interactive website presenting and comparing medications for tobacco cessation and electronic cigarettes. Each smoking cessation medication has a drop down menu that presents additional information, a video demonstration, and prescribing information for physicians. To test the DA, we submitted a questionnaire to approximately 20 general practitioner residents of an academic general medicine department, 5 general practitioners, and 6 experts in the field of smoking cessation. The questionnaire consisted of 4 multiple-choice and 2 free-text questions assessing the usability or acceptability of the DA, the acquisition of new knowledge for practitioners, the perceived utility in supporting shared decision-making, perceived strengths and weaknesses, and whether the participants would recommend the tool to other clinicians.

Results: In all, 6 residents, 3 general practitioners in private practice, and 2 tobacco cessation experts completed the questionnaire (N=11), with 4 additional experts providing open-text feedback. On the 11 questionnaires, the DA was rated as practical and intuitive (mean 4.6/5), and providers felt it supported shared decision-making (mean 4.4/5), as comparisons were readily possible. Inclusion of explanatory videos was seen as a bonus. Several changes were suggested, like grouping together similar medications and adding a landing page to briefly explain the site. Changes were implemented according to end-user comments.

Conclusions: The overall assessment of the encounter DA by a group of physicians and experts was positive. The ultimate objective is to have the tool deployed and easily accessible for all to use.

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KEYWORDS

decision aid; smoking cessation; electronic tool; shared decision-making

Introduction

Smoking is the leading cause of avoidable, premature death worldwide, with over 8 million deaths per year [1], including 9500 in Switzerland [2]. This excess mortality is explained by increases in cardiovascular and pulmonary diseases and of different types of cancer, including lung cancer (of which 90% is attributable to smoking) [3]. Currently, 30% of men and 21% of women regularly or occasionally smoke in Switzerland, and 18% of the population smokes daily [3]. After many years of decreases, these figures have stagnated over the last decade. Smoking cessation progressively and sustainably reduces the risk of death and the development of smoking-related diseases [4]. Patients wish to discuss smoking during consultations, and more than half of them want counseling about smoking cessation [5].

Primary care physicians play an essential role in promoting tobacco control and smoking cessation. Current international recommendations propose that physicians use every opportunity to discuss smoking during consultations to assess patients' level of addiction, knowledge, and motivation to stop smoking; to support an eventual quit attempt; and to provide an efficient follow-up [6].

Different pharmacological treatments for smoking cessation are available, including nicotine replacement therapy in the form of bupropion (a dopamine, noradrenaline reuptake inhibitor) and varenicline (a nicotinic cholinergic receptor partial agonist). These treatments, when accompanied by medical follow-up, are associated with quit rates as high as 30% [7] as opposed to rates of 3% to 6% when no aid is provided. Electronic cigarettes (e-cigarettes) are emerging as alternative nicotine delivery devices, are very popular, and seem to be effective aids for smoking cessation [8]. However, long-term data about their safety and efficacy remain limited. Treatments should be prescribed in parallel with intensive follow-up during quit attempts, as repeated consultations have been shown to increase the success of quit attempts [9]. Indeed, the combination of behavioral therapy and pharmacotherapy has demonstrated better results than has either separately [10]. Other nonpharmacological interventions such as hypnotherapy, acupuncture, or mindfulness meditation have less strong evidence of efficacy [11-13].

These different therapeutic alternatives differ by their dosing, mechanisms of action, adverse effects, contraindications, costs, and insurance reimbursement. Giving clear, concise, and appropriate information can be challenging within the time constraints of a consultation. However, guiding patients toward smoking cessation and in the choice of and adherence to a treatment is crucial.

An increasing amount of evidence shows that the relationship between the physician and the patient, often referred to as the therapeutic alliance, plays an important role in treatment adherence and outcomes. Sharing information during shared decision-making can strengthen the physician-patient relationship, involve the patient in the decision-making process, and thus empower the patient to engage in the treatment schedule and adherence. Shared decision-making is described as a 3-step process [14], in which the health care provider formulates the existence of multiple alternatives, describes these options, and finally supports the patient in the assessment of the risks and benefits while exploring their values and preferences. Establishing and strengthening the therapeutic alliance is thereby essential to increasing the number of quit attempts and smoking cessation rates.

Decision aids (DAs) facilitate shared decision-making; they can improve patient knowledge and risk perception while helping to create consistency between the patient's choices and values [15]. These tools come in different forms: pamphlets, brochures, audiovisual material, web-based apps, or websites. DAs can be employed during consultations (encounter DAs) or can be designed to be used before, after, or independently of clinical encounters [16]. They optimize therapeutic education by increasing interaction [15] and by allowing the patient to be more active in the decisional process [16]. Several DAs have been developed to aid with tobacco cessation, most often as paper or website-based documentation. Their efficacy is supported by a recent systematic review by Moyo et al [17] that analyzed 7 studies evaluating smoking cessation DAs. The systematic review showed a tendency toward an increase in the smoking cessation knowledge, decisional quality, and the number of quit attempts.

A DA was developed in 2017 by our study group [18] through use of an illustrated chart condensing the different methods of delivery, dosing, daily price, efficacy, and principal adverse effects of smoking cessation treatments.

Given the growing evidence about the efficacy of DAs [17] and their impact on the success rate of smoking cessation, this aforementioned tool was reproduced and adapted in an electronic form. In this paper, we aimed to document the characteristics of this new DA and provide results of formative user testing during consultations by general practitioners and experts in the field. The information collected during the testing could lead to changes and improvements to this DA.

Methods

Design and Setting of the Study

Herein, we describe the formative testing of a novel DA, exploring the acceptability of the electronic, encounter DA to assess its design, usage, content, and perceived changes in consultation. A formative test is conceived to assess if a product meets users' needs and to identify potential usability issues [19]. Our assessment was conducted in an urban, academic, primary care practice with approximately 40 residents in Lausanne, Switzerland.

Ethical Considerations

Ethics approval was not required as no information was collected from patients and the study is considered quality improvement by local definitions [20].

Description of the DA

The DA used in this study is based on the one developed in 2017 using a user-centered design [21], which is a methodology centered on the user that gathers information about the utilization and progressively adapts the tool in order to optimize usage. Six general practitioners used iterative versions of the model in consultation over several months and helped define which items and criteria seemed to matter most to patients. Price and insurance reimbursement were considered more important than was the possible effect of medications on weight gain. The tool was inspired by Elwyn's model of shared decision-making [22].

The original paper-based DA was a 1-page table containing essential information to compare available treatments for smoking cessation (Multimedia Appendix 1). Patients and providers identified several inherent limitations of this DA that could not be addressed in its paper format: notably, the small size of the pictures showing each medication, a difficulty in understanding the differences between nicotine replacement therapies, a lack of information about e-cigarettes (vapes), and a lack of prescribing information for physicians.

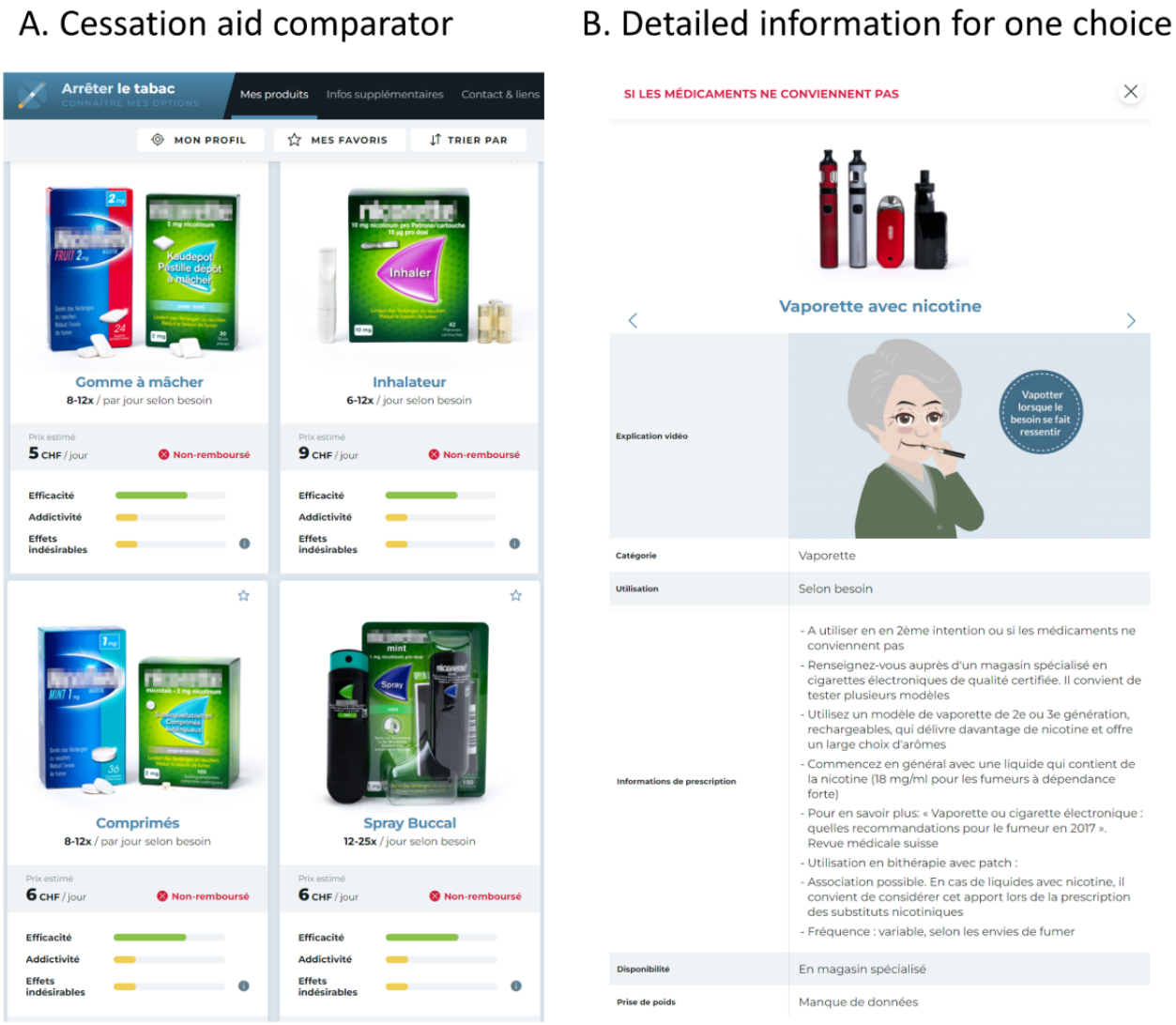
The new electronic form described in this study contained the same information, including the form of delivery, price per day, main adverse effects, contraindications, and visual analog rating scales that compared the efficacy, addiction potential, and adverse effects of each agent. Comparisons between the treatments were based on data from systematic reviews for efficacy [7] and weight gain [23], on expert opinion for addictiveness, and on published drug information for adverse effects. Finally, short, animated video clips were incorporated, offering animated explanations on the delivery method and tips for use. The new DA also integrated information about e-cigarettes, noting that they are only recommended when medications are not effective and underlining their addictive potential. An image presented examples of vape pens, a box mod (tank system), and a pod mod. Comparisons between e-cigarettes and medications were based on expert opinion.

This DA was designed for use during consultations, making it an encounter DA or a conversation aid. Encounter DAs encourage and directly support patient-clinician conversations when making decisions together [24]. In our opinion, smoking cessation consultations focused on a quit attempt should include an assessment of the patient's level of addiction that presents the therapeutic alternatives to stop smoking and value clarification. By facilitating the comparison between medications and e-cigarettes, the DA offers implicit value clarification, which can be further explored with the clinician during the consultation. Nonpharmacological treatment alternatives were not included in this DA although the DA should be used in parallel to behavioral counseling during multiple consultations. The combination of behavioral and pharmacological treatments is most effective. We felt that given the limited evidence to support hypnotherapy, acupuncture, and exercise, these should not be included as first-line therapies.

A tool calculating the level of addiction was integrated into the DA, based on the 2 questions from the Heaviness of Smoking Index. Furthermore, a means for patients to specify if they are pregnant or lactating was included. This information is used to create an automatic contraindication alert located above the treatments, written in red, and specifying if the treatment is a contraindication or if it is to be used with precaution. The user has to choose to click on this tool on the left side of the web page to open it.

An illustrative image of the decision aid can be seen in Figure 1.

Figure 1. Illustrative screenshots of the decision aid taken on howtoquit.ch. (A) Three of nine available smoking cessation aids in the comparator. (B) Detailed information about one option (electronic cigarettes).



Population

The population enrolled consisted of potential general practitioner and tobacco cessation specialist end users. A convenience sample of approximately 20 residents from the General Practice of Unisanté (academic service for general medicine) both familiar and unfamiliar with smoking cessation practices were asked to provide feedback after using the DA in consultation at least once with their patients. Participating physicians were free to choose the patients with whom they would use the DA. Physicians used the DA during specialized tobacco consultations or during primary care consultations. Subsequently, 5 selected general practitioners in a private practice were sent an email that explained the study, invited them to familiarize themselves with the DA and, in case of interest, gave them the opportunity to try the tool and give feedback. Finally, the questionnaire was submitted to 6 smoking cessation specialists affiliated with our institution. The expert group included general practitioners, psychologists, and psychiatrists specialized in tobacco cessation or shared decision-making. Two experts in clinical practice were asked to test the DA with their patients and complete the questionnaire.

Questionnaire

The participants were invited to fill out an online questionnaire. The questionnaire was developed locally and included 4 quantitative and 5 qualitative questions. The quantitative questions assessed the usability or acceptability of the electronic encounter DA, the acquisition of new knowledge for practitioners, the perceived utility in supporting shared decision-making, and whether the participant would recommend the tool to other clinicians. The answers were based on a 5-point Likert-scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree). We also inquired about the participants' level of medical training, age, and gender. Two open-text questions asked about the strengths and weaknesses of the DA, and requested recommendations for improvements.

Analysis

The answers to the quantitative questions based on the 5-point Likert-scale measured the responders level of agreement to the different questions. These results were assembled, and the mean values and SDs were calculated. The open-text questions allowed us to collect information about the enrolled physicians. The questions exploring the weaknesses and strengths of the

DA and subsequent recommendations for improvement were considered one by one. They were sorted by categories to allow for better visibility and to help identify recurrences. This brought us to consider the possible changes to the DA.

Results

We collected the questionnaires described above from 6 residents and 3 general practitioners in private practice who tested the DA. A further 6 smoking cessation experts gave qualitative feedback, 2 of whom also responded to the questionnaire after testing the DA with patients during a consultation. Of the 11 people who completed the questionnaire, 55% (n=6) were women, and all had obtained their medical diploma between 1983 and 2018.

The various groups who provided feedback on the DA and their characteristics are listed in Table 1.

The responders found the electronic interface practical and intuitive, with a mean rating of 4.6 on the 5-point Likert-scale (Table 2). They felt the DA helped improve their knowledge (mean rating 4.4/5). They perceived the tool as facilitating their patients' decision-making process (mean rating 4.4/5). Finally, globally the physicians strongly agreed that they would recommend the tool to a colleague (mean rating 4.8/5).

The open-text feedback was generally related to content and interface. Content was described as sufficient and relevant. Smoking cessation experts gave advice suggesting to provide more detailed information for e-cigarettes, particularly regarding the fact that e-cigarettes are not considered to be a medication, and that the first-line treatment recommendation include the other presented alternatives only.

Users found the interface to be clear, intuitive, and easy to use. Advice for improvements consisted of making information more noticeable and easier to find. For example, some physicians recommended separating the different types of treatments in groups to facilitate their introduction during the consultation. In the experts' opinion, the automatic contraindication alert based on the users' characteristics should be completed with inclusion of other comorbidities and users should be required to answer the questions regarding their level of addiction with a pop-up to draw attention to it. Some physicians recommended separating the different types of treatments in groups to facilitate their introduction. A landing page was suggested as a means of engaging users at their moment of arrival on the website and to provide preliminary information about the tool.

Based on qualitative feedback, the research team ultimately changed the DA in order to improve its content and usability (Table 3).

Table 1. Description of user groups providing feedback and their responses.

Group	Participants, n	Type of feedback	Description
General internal medicine residents	6	Quantitative and qualitative	Residents provided feedback after using the DA[a] in consultation
General practitioners	3	Quantitative and qualitative	GPs[b] provided feedback after using the DA in consultation
Smoking cessation experts	6 (2 completed questionnaire, 4 open-text responses)	Qualitative	Local experts provided feedback after exploring the DA

[a]DA: decision aid.

[b]GP: general practitioner.

Table 2. Overview of quantitative feedback (N=11).

Questions	1=strongly disagree, n	2=disagree, n	3=neutral, n	4=agree, n	5=strongly agree, n	Mean (SD)
1. Interface is practical and intuitive	0	0	0	4	7	4.6 (0.52)
2. DA[a] helped me improve my knowledge	0	0	1	5	5	4.4 (0.68)
3. DA enhanced patient's decision-making process	0	0	0	6	5	4.4 (0.52)
4. I would recommend this DA to my colleagues	0	0	0	2	9	4.8 (0.42)

[a]DA: decision aid.

Table 3. Changes made to the DA in response to feedback.

Categories of changes to the DA[a]	Users' comments from open text	Description of changes
Landing page as an entry pop-up	"It was difficult to understand quickly the objective of the website."	A landing page was added explaining the tool's objective and advising use with a medical practitioner.
Level of addiction calculator	"Addiction level score isn't noticeable enough. A popup would be better to draw attention on it."	A pop-up exploring the level of addiction and patients' specifications (current pregnancy or lactation) was added.
Item layout	"1.It would be simpler to cluster treatments according to their type. 2. It would be better to separate NRT[b]/varenicline/bupropion/e-cigarette[c]."	Order of the different therapies was adjusted according to a logical setting: short-acting nicotine replacement/long-acting nicotine replacement/combined short and long-acting nicotine replacement/oral medication (bupropion, vernicline)/e-cigarette.
Additions to the content	"E-cigarette: specify that it isn't a medical treatment and is not recommended as first line treatment."	Content was upgraded with more detailed information.
Documentation for practitioners	"Would be helpful to better integrate other electronic resources."	A link was added containing documentation on management of smoking cessation.
Documentation for patients	Should interact with other official websites for smoking cessation in Switzerland	Useful links to official websites giving information, resources, and support for smoking cessation, as well as a local smoking cessation hotline number, were added.
"About us" tab	"It is unclear who made the site and whether they can be trusted"	A tab was added describing the Unisanté tobacco cessation unit, smoking cessation consultation with contact details, and information on project funding and the ongoing randomized trial [25].

[a]DA: decision aid.

[b]NRT: nicotine replacement therapy.

[c]e-cigarette: electronic cigarette.

Discussion

This paper describes the preliminary user testing and subsequent improvements made to a newly created electronic DA to facilitate decision-making between different types of smoking cessation treatments. Overall, the physician end users found the content to be clear, concise, and useful, and the interface to be practical and intuitive. Based on the self-reported answers to the questionnaire and thus, according to the physicians' perspective, the tool helped improve users' knowledge about smoking cessation treatments and assisted patients' decision-making process.

The development of this new DA was based on user-centered design, an approach originally used to develop products and services [26,27] and used in the health field to create DAs [28]. Hence, a first DA prototype was created based on the content of our first paper-based DA developed in 2017. The user tests allowed us to gather information and comments on this DA. This led to a greater knowledge of users' needs, as well as the strengths and limitations of the DA. Ultimately, the user feedback identified inherent limitations of the paper format, leading to the elaboration of an electronic format.

The current DA, for use during medical encounters, is not a classic, stand-alone DA with content about disease processes and values clarification. Traditional DA development should follow guidelines from the International Patient Decision Aid Standards (IPDAS) Collaboration, whose extensive criteria allow a standardized assessment of quality in terms of content development and effectiveness [25,29]. Instead, encounter DAs like ours need to be short and intuitive while fitting patient-provider interactions in order to encourage its adoption, as this is dependent on its perceived usability and usefulness by physicians. In this respect, this study chose to specifically focus on the physicians as the DA's end users and testers.

A few existing DAs for smoking cessation have been developed and are mentioned in the literature. Their formats are diverse, but there is a trend toward implementing computerized DAs. Like ours, some of them collect information on patients' smoking behaviors to provide personalized information and contain written and multimedia-based information [30,31]. One recent study evaluated an app-based DA (iPad app) including, like our DA, information about e-cigarettes, explaining its risks and benefits. This DA was used prior to the clinical encounter. The study showed a higher rate of clinical discussions about smoking cessation, overall patient satisfaction, and acceptability about giving information about e-cigarettes among smokers [32].

Willemsen et al [33] developed a multicomponent DA containing several materials, such as an informative booklet with information on smoking cessation treatments, videos, and samples of some pharmacological treatments. Informative websites exist as well, providing information on smoking cessation treatments and resources functioning as DAs [34]. Most of these DAs are designed to prepare patients for a future clinical encounter. To our knowledge, there are no existing DAs for use during consultations (encounter DAs) that can provide structure, guide information transmission, and promote interactivity and shared decision-making between the practitioner and the patient.

One of the upgrades made to the DA was the inclusion of online material to inform physicians and patients about other existing smoking cessation resources in Switzerland. This includes a reference document with the local epidemiology and recommendations on smoking cessation counseling and treatments (6), web links to the specialized tobacco cessation consultation in Unisanté [35], and 2 official Swiss websites [36] offering information and support to help patients willing to stop smoking. These resources, integrated into the DA, can inform physicians of local resources. It can be easily adapted to other countries and their tobacco-control programs.

After completion of testing and upgrading, the DA has become a new tool for use during a consultation (encounter DA), allowing for better information sharing and ultimately guiding patients into a high-quality decision-making process. Some providers told us of patients' reactions, but patients were not asked to assess the DA directly.

The strengths of this study include the following: the electronic DA builds on previous experience with a similarly organized paper DA that was tested with patients, responses were collected from target users (clinicians), and feedback was collected at a stage when substantial changes could still be made to the DA.

There are also several limitations. First, the small sample size might not have provided perspectives from all types of physician users and might have reduced the number of suggestions of other upgrades. However, in the field of usability testing, it is common to have only a few testers as end users, based on the 5-user assumption [37] where a small number of testers can identify the most usability issues although this concept is debated [38]. In our case, the DA content was mostly developed by one of the final end users (medical doctors), tested by physicians during consultations, and reviewed by experts; thus, most of the critical content and usability issues should have been identified. A selection bias is probably present, given that a significant part of the enrolled physicians (general internal medicine residents) worked in our institution. Thus, a more solid assessment would probably have been obtained with a more diversified physician enrollment. Second, we collected the perspectives of general practitioners as end users but not those of patients. Although general practitioners were likely influenced by patient reactions, we are unable to report patient satisfaction with the DA, usability issues from the patients' perspective, or whether patients felt the DA aided with shared decision-making. However, our DA was designed to be used during a consultation as an encounter DA to help physicians present and describe various treatment alternatives for smoking cessation. In this way, we considered the general practitioners as the end users and the ones most likely to influence uptake of the DA. This study was not designed to evaluate the DA's effectiveness in terms of number of quit attempts, smoking cessations, or its impact on consultation duration. A clinical trial integrating use of the DA is underway [39]. Finally, we are currently implementing the DA in a study setting where we train general practitioners to use the DA in parallel with intensive counseling; in the future we should clarify for all users that pharmacological treatments and behavioral counseling should be used in parallel.

A new, electronic, encounter DA was generally well received and appreciated by physicians. With their feedback, we were able to implement useful upgrades. This tool will hopefully improve patients' knowledge and enhance their decision-making regarding smoking cessation. Future objectives include a clinical trial incorporating the DA and making it accessible to all health care providers.

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Conflicts of Interest

MAD has developed Option Grid patient decision aids, which are licensed to EBSCO Health, and has received consulting income from EBSCO Health and royalties. KS receives salary support from the Leenaards Foundation. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Paper version of encounter decision aid.
[PDF File (Adobe PDF File), 318 KB - formative_v6i4e32960_app1.pdf]

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Abbreviations

DA: decision aid
e-cigarette: electronic cigarette
IPDAS: International Patient Decision Aid Standards

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Original Paper

Promoting Physical Activity in a Spanish-Speaking Latina Population of Low Socioeconomic Status With Chronic Neurological Disorders: Proof-of-Concept Study

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Abstract

Background: Physical activity (PA) is known to improve quality of life (QoL) as well as reduce mortality and disease progression in individuals with chronic neurological disorders. However, Latina women are less likely to participate in recommended levels of PA due to common socioeconomic barriers, including limited resources and access to exercise programs. Therefore, we developed a community-based intervention with activity monitoring and behavioral coaching to target these barriers and facilitate sustained participation in an exercise program promoting PA.

Objective: The aim of this study was to determine the feasibility and efficacy of a community-based intervention to promote PA through self-monitoring via a Fitbit and behavioral coaching among Latina participants with chronic neurological disorders.

Methods: We conducted a proof-of-concept study among 21 Spanish-speaking Latina participants recruited from the Los Angeles County and University of Southern California (LAC+USC) neurology clinic; participants enrolled in the 16-week intervention at The Wellness Center at The Historic General Hospital in Los Angeles. Demographic data were assessed at baseline. Feasibility was defined by participant attrition and Fitbit adherence. PA promotion was determined by examining change in time spent performing moderate-to-vigorous PA (MVPA) over the 16-week period. The effect of behavioral coaching was assessed by quantifying the difference in MVPA on days when coaching occurred versus on days without coaching. Change in psychometric measures (baseline vs postintervention) and medical center visits (16 weeks preintervention vs during the intervention) were also examined.

Results: Participants were of low socioeconomic status and acculturation. A total of 19 out of 21 (90%) participants completed the study (attrition 10%), with high Fitbit wear adherence (mean 90.31%, SD 10.12%). Time performing MVPA gradually increased by a mean of 0.16 (SD 0.23) minutes per day (P<.001), which was equivalent to an increase of approximately 18 minutes in MVPA over the course of the 16-week study period. Behavioral coaching enhanced intervention effectiveness as evidenced by a higher time spent on MVPA on days when coaching occurred via phone (37 min/day, P=.02) and in person (45.5 min/day, P=.01) relative to days without coaching (24 min/day). Participants improved their illness perception (effect size g=0.30) and self-rated QoL (effect size g=0.32). Additionally, a reduction in the number of medical center visits was observed (effect size r=0.44), and this reduction was associated with a positive change in step count during the study period (P.=04).

Conclusions: Self-monitoring with behavioral coaching is a feasible community-based intervention for PA promotion among Latina women of low socioeconomic status with chronic neurological conditions. PA is known to be important for brain health in neurological conditions but remains relatively unexplored in minority populations.

Trial Registration: ClinicalTrials.gov NCT04820153; https://clinicaltrials.gov/ct2/show/NCT04820153

(JMIR Form Res 2022;6(4):e34312) doi:10.2196/34312

KEYWORDS

exercise; quality of life; motivation; promotion; community study; clinical trial

Introduction

In the last decade, studies have established the vital role of physical activity (PA), particularly sustained moderate-to-vigorous PA (MVPA), in chronic neurological disorders due to its ability to improve neurological outcomes, quality of life (QoL), and reduce disease progression [1-5]. Currently, the generalizability of these findings to US minority populations and different socioeconomic status groups in the United States is unclear given the fact that the vast majority of clinical research has been predominantly conducted on White males with affordable access to medical care.

Studies examining individuals who are regularly engaged in exercise in the United States have indicated that lack of PA is prevalent in Latinx groups compared to other ethnic groups [6]. In terms of sex, a high percentage (74%) of Latina women do not participate in exercise activities, and this number increases with age [7,8]. While there are numerous reasons for this occurrence, a substantial contributor includes the lack of resources and accessibility to programs that promote PA and exercise [9]. Therefore, it is paramount that clinical studies focus on development of accessible interventions that are capable of increasing PA in underrepresented communities and ethnic groups. One potential approach includes the implementation of a community-based intervention consisting of activity monitoring by personal activity monitors, such as wrist-worn Fitbit devices, with behavioral coaching. Numerous studies have demonstrated that this approach is impactful and successfully promotes PA among healthy individuals as well as those with medical conditions, including obesity, diabetes, and neurological disorders [10-12]. It is yet to be established whether specific motivational strategies can demonstrate efficacy in a Latina population among individuals with chronic neurological conditions.

The purpose of this proof-of-concept study was to examine the feasibility and efficacy of a community-based wellness center intervention to promote PA in a Latina population with chronic neurological disorders.

Methods

Ethical Considerations

The University of Southern California Institutional Review Board (IRB) approved all study procedures (IRB No. HS-18-00993). The funder did not require registration; however, the trial was retrospectively registered at ClinicalTrials.gov (NCT04820153) for publication. The authors confirm that any related clinical trials have been registered. All study participants provided written informed consent.

Study Participants

The target sample size for this proof-of-concept study was 20 participants, as this is similar to sample sizes used in previous preliminary Fitbit wear studies [11,13]. Inclusion criteria included the following: (1) diagnosed with a neurological disorder, (2) able to use the Fitbit activity monitor as determined by participant self-report after receiving instructions from a study coordinator, (3) own a smartphone device, (4) ambulatory without assistance, (5) able to provide informed consent, (6) live within commuting distance to The Wellness Center (TWC) at The Historic General Hospital in Los Angeles, (7) Spanish speaking, and (8) have internet access. Exclusion criteria included any physical condition that precluded engagement in exercise or PA.

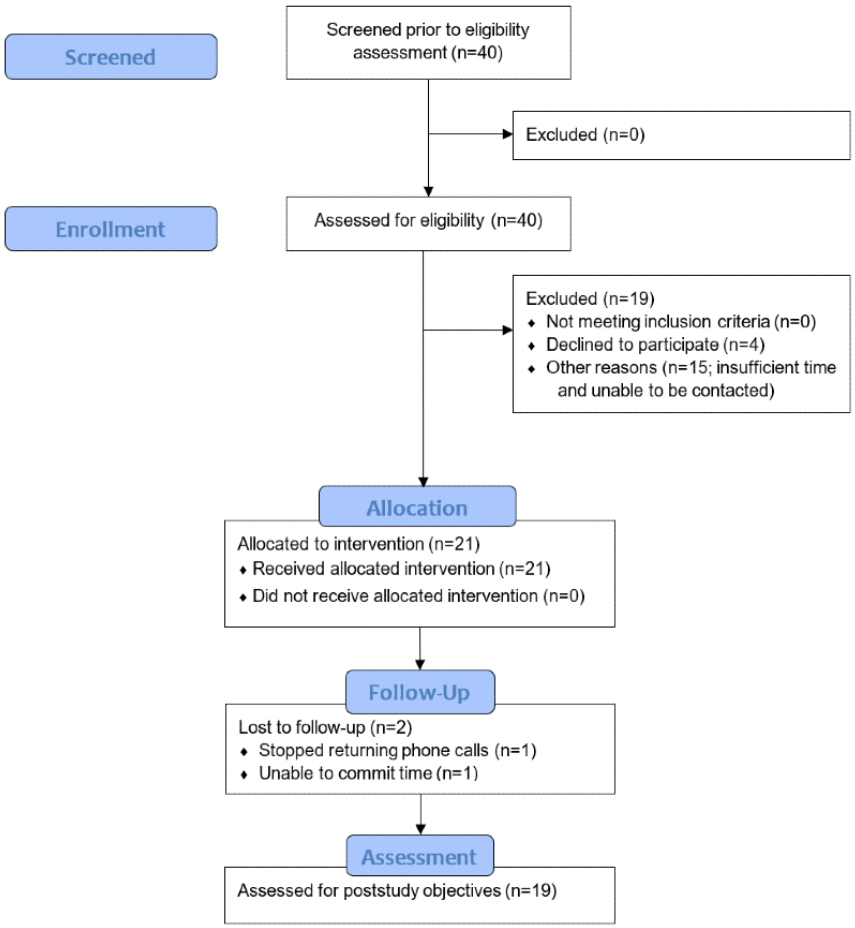
Study Design

Recruitment and Community Site

Candidate Latina participants living in Central and East Los Angeles were identified by bilingual attending neurologists in the Department of Neurology; candidates were identified in the clinic at the Los Angeles County and University of Southern California (LAC+USC) Medical Center. The LAC+USC neurology clinic primarily serves a Latinx population of low socioeconomic status who have a wide spectrum of neurological conditions, including epilepsy, chronic headache, migraine, stroke, Parkinson disease, and multiple sclerosis. A total of 21 individuals consented to participate in the study (Figure 1); these participants enrolled in the study at TWC, a community center located within the Boyle Heights community of East Los

Angeles that offers free health and wellness classes and programs. TWC was founded in 2014 and provides a wide range of services to patients, caregivers, and their families.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Community-Based PA Intervention

The study consisted of a 16-week community-based intervention aimed at promoting PA through behavioral coaching and self-monitoring via a Fitbit Alta HR activity device (Fitbit, Inc). Intervention length was based on the success of similar PA promotion studies using Fitbit devices among healthy individuals and those with various medical disorders [11,12]. Upon enrollment, individuals received Fitbit personal activity monitors and were instructed on their usage and maintenance. Participants were notified at the commencement of the study that they would be allowed to keep their Fitbit activity monitor upon study completion.

Fitbit Personal Activity Monitors

Individuals were provided with the Fitbit device and charger and were asked to wear the Fitbit device every day during the 16-week study except when bathing or swimming. Individuals had the Fitbit app program set up on their smartphones, thus allowing for continuous self-monitoring of PA by the Fitbit device and longitudinal monitoring to collect data by the Fitbit app throughout the 16-week study period. Participants' Fitbit wear compliance was encouraged by a once-a-week behavioral coaching phone call. Monitored PA data from the Fitbit were downloaded weekly.

Behavioral Coaching

Navigators at TWC are Latina women who come from Central and East Los Angeles communities. Their role at the TWC is to perform outreach, perform health coaching, and guide members to health resources. Within the study, navigators provided assistance by motivating participants and providing support for any technological issues. Behavioral coaching consisted of the following: (1) 1 hour of Lifestyle Redesign at baseline and at week 4 with an occupational therapist of Latino background located at TWC and (2) weekly contacts of 5 to 10 minutes in length from TWC navigators by telephone. Lifestyle Redesign is a well-established program for promoting behavioral modification including PA by addressing physical, psychosocial, and environmental barriers to health. It incorporates self-care strategies and goal setting and has been validated in Latinx populations [14]. For this intervention, goal setting centered on supporting increased PA for each participant. This was accomplished by asking participants at baseline what activities they wanted to do to increase PA in their lives and by subsequently collaborating on plans to incorporate these activities into their daily lives. The weekly contacts from navigators occurred either in person or via phone and focused on promotion of PA, Fitbit wear, and goal review.

Study Participant Characteristics

Sociodemographics

Sociodemographic information included age, sex, primary language, highest education level achieved, health perception, neurological diagnoses, primary care provider status, insurance status, housing status, and food insecurity. Zip code data were collected and subsequently assessed to infer income category [15]. Specifically, median incomes for participant zip codes were compared to the Los Angeles County (LAC) median income and were categorized as very low income (<50% of LAC median income), low income (50%-80% of LAC median income), or not low income (>80% of LAC median income) per the US Department of Housing and Urban Development recommendations.

Acculturation

Acculturation is defined as the cultural modification of an individual or group by adapting to or borrowing traits from one culture and displacing characteristics, habits, attitudes, and mode of life of another culture. Acculturation was assessed through the Short Acculturation Scale for Hispanics (SASH), a 12-item questionnaire where questions are answered using a 5-point Likert scale. The SASH is used to assess the level to which participants acculturate or adopt the attitudes, values, customs, beliefs, and behaviors of another culture. The scale provides an overall score as well as three subscale scores in language use, media preference, and ethnic and social relations. A higher score indicates higher acculturation with the culture of the United States [16].

Outcomes Measures

Fitbit Data Measures

Objective PA and wear-time data gathered from the Fitbit device were stored, visualized, and aggregated through a commercially available service (Fitabase Inc, Small Steps Labs) using Health Insurance Portability and Accountability Act–compliant deidentified unique participant emails. PA measures included step count and time spent on (1) sedentary activity; (2) light, moderate, and vigorous PA (LMVPA); or (3) MVPA. Activity intensity was quantified via a Fitbit proprietary algorithm based on metabolic equivalents of task. To evaluate compliance to Fitbit device wearing, day wear was calculated as the "total wear minutes" (derived from minutes where Fitbit captured heart rate value) minus the "in-bed minutes" (derived from the Fitbit proprietary sleep detection algorithm). Data for each day were first inspected for technical adherence, defined as having accurate sleep data (ie, in-bed minutes greater than 180 minutes if day wear minutes were greater than 1080 minutes out of the maximum of 1440 minutes per day) and activity data (ie, LMVPA minutes greater than 0 minutes if day wear minutes were greater than 600 minutes [10 hours]). Personal adherence, defined as greater than 10 hours of Fitbit wear per day, was subsequently assessed for days that were technically adherent. Fitbit-recorded PA measures were only analyzed for days with valid technical adherence and personal adherence.

Quality of Life Scale

The Quality of Life Scale (QoLS) was used to assess an individual's view of their health, how well they feel, and how well they were able to complete their usual activities [17]. The QoLS is a 16-item assessment, with items rated on a 7-point Likert scale, measuring five life domains: (1) material and physical well-being; (2) relationships with others; (3) social, community, and civic activities; (4) personal development and fulfillment; and (5) recreation. A higher score is indicative of a higher perceived QoL.

Illness Perception Scale

The Brief Illness Perception Questionnaire (BIPQ) was administered to assess individuals' perceptions of their health and well-being [18]. The BIPQ is a 9-item questionnaire, with questions rated on a 10-point Likert scale. Each question assesses one dimension of illness perception, including cognitive and emotional representation, level of personal and treatment control, and sense of identity and concern. A higher score indicates a more threatening view of a participant's illness.

System Usability Scale

The System Usability Scale was used to ascertain an individual's opinion on the usability of the Fitbit phone app, Fitbit activity monitor, and the combination of the Fitbit device and app [19].

LAC+USC Medical Center Visits

The total number of outpatient and inpatient visits to the LAC+USC Medical Center was determined during the 16-week period prior to study initiation and during the period of the study intervention using electronic medical records. LAC+USC Medical Center visits were monitored to gather insight into participants' overall health behaviors as well as to specifically understand the impact of PA promotion on health care use.

Data Analysis

Analyses were completed using the statistical analysis package R (version 3.6.0; The R Foundation) [20]. The mean and SD of the data were calculated to describe the sociodemographic characteristics, scale outcomes, and Fitbit-recorded PA. Individuals' rates of change in Fitbit-recorded PA measures were quantified by an activity (eg, MVPA) by day regression slope. Promotion of PA was determined by examining whether time spent performing MVPA increased throughout the 16-week intervention period or stayed stationary. To accomplish this, a Kwiatkowski-Phillips-Schmidt-Shin (KPSS) test was performed on the time-series MVPA data. If the KPSS test was significant, indicating that MVPA data were nonstationary, an MVPA by time (day) Pearson correlation was calculated to determine whether time spent performing MVPA significantly increased or decreased throughout the intervention period. A Kruskal-Wallis test was employed to evaluate differences in PA measures on days with varying behavioral coaching contact types (ie, phone, in person, or no contact). When appropriate, the Dunn test was performed to determine the locus of significance [21]. Changes in scale outcomes from baseline to postintervention and medical center visits from baseline to the study period were assessed by paired *t* tests (2-tailed) or Wilcoxon signed-rank tests depending on normality. Hedges *g*

was used to calculate effect size when changes were quantified by paired *t* tests. The *r* statistic—obtained from the formula *r* = *Z* statistic / sqrt(n)—was used with the Wilcoxon signed-rank test. A Pearson correlation assessed the relationships between participant-level rates of change in PA measures and changes in medical center visits. An α level of less than .05 was considered statistically significant.

Results

Participant Characteristics

Key demographics of study individuals are presented in Table 1. A total of 21 Latina participants were enrolled, and 19 (90%) of them completed the study, giving an attrition rate of 10%. The mean age of the sample was 47 years (SD 9.0, range 29-64). Neurological diagnoses included chronic headaches and migraines (n=13, 68%), Parkinson disease (n=2, 11%), multiple sclerosis (n=2, 11%), and trigeminal neuralgia (n=2, 11%). The majority of individuals were considered to be of low socioeconomic status. A total of 76% (13/17) of participants were living in low- or very low–income areas; 63% (12/19) completed less than a high school–level education; 41% (7/17) reported housing insecurities, defined as not having housing or being worried about losing housing; and 53% (9/17) reported food insecurities, defined as being worried about running out of food before having money to buy more. Overall, study participants had low acculturation to United States culture, as evidenced by a mean acculturation score of 1.81 (SD 0.65).

Table 1. Sociodemographic characteristics of the study participants.

Characteristics	Values (N=19)
Age (years), mean (SD, range)	47 (9.0, 29-64)
Sex (female), n (%)	19 (100)
Neurological diagnosis, n (%)	
Chronic headaches and migraines	13 (68)
Parkinson disease	2 (11)
Multiple sclerosis	2 (11)
Trigeminal neuralgia	2 (11)
Primary language, n (%)	
Spanish	18 (95)
English	1 (5)
Self-reported overall health (n=17), n (%)	
Excellent or good	5 (29)
Fair or poor	12 (71)
Socioeconomic status (n=17), n (%)	
Zip code family income category	
Not low income	4 (24)
Low income	10 (59)
Very low income	3 (18)
Highest education level achieved	
≤11th grade	12 (63)
≥12th grade	7 (37)
Housing status (n=17), n (%)	
Have housing	10 (59)
Worried about losing housing or do not have housing	7 (41)
Insurance status	
Public insurance	11 (58)
Other, none, or do not know	8 (42)
Primary care provider	
Yes	13 (68)
No	6 (32)
Food insecurity (n=17), n (%)	
Yes	9 (53)
No	8 (47)
Acculturation, as measured by the SASH[a], mean (SD)	
Average score	1.81 (0.56)
Language use score	1.52 (0.73)
Media preference score	2.09 (1.10)
Ethnic and social relations score	1.96 (0.53)

[a]SASH: Short Acculturation Scale for Hispanics. Total average and subscale scores range from 1 to 5. Higher scores indicate higher acculturation.

Intervention Adherence and Safety

A total of 19 out of 21 (90%) participants completed the intervention study, while 2 (10%) participants were lost to follow-up. No adverse events were reported by participants. A mean of 93.6% (SD 9.5%) of days during the intervention period had valid technical adherence. There was also high personal adherence, as the average participant wore their Fitbit for 10 hours or greater on a mean of 90.31% (SD 10.12%) of days throughout the 16-week trial (mean 5.95, SD 1.02 days/week). Further, while the recommended day wear time was 10 hours, the average participant wore their Fitbit for a mean of 15.44 (SD 1.06) day waking hours. Participants rated the usability of the Fitbit device and app as good (score 71.4) to excellent (score 85.5) [22], potentially reflecting the high adherence (Table 2).

Table 2. Fitbit wear adherence, physical activity, and system usability feedback.

Measure	Mean (SD)
Adherence	
Technical adherence (% days)	93.6 (9.50)
Personal adherence (% days)	90.31 (10.12)
Valid personal adherence days per week	5.95 (1.02)
Wear minutes per day waking hour	926.61 (63.27)
Physical activity per day	
Number of steps	9859.99 (2616.22)
Sedentary minutes	583.51 (80.15)
LMVPA[a] minutes	336.84 (80.09)
MVPA[b] minutes	36.63 (18.26)
Individual rate of change per day	
Number of steps	–0.91 (27.69)
Sedentary minutes	–0.07 (0.62)
LMVPA minutes	0 (0.71)
MVPA minutes	0.16 (0.23)
System Usability Scale[c] feedback (%)	
Fitbit device	76.3 (7.4)
Fitbit app	78.4 (8.0)
Fitbit device and app combined	82.9 (10.5)

[a]LMVPA: light, moderate, and vigorous physical activity.

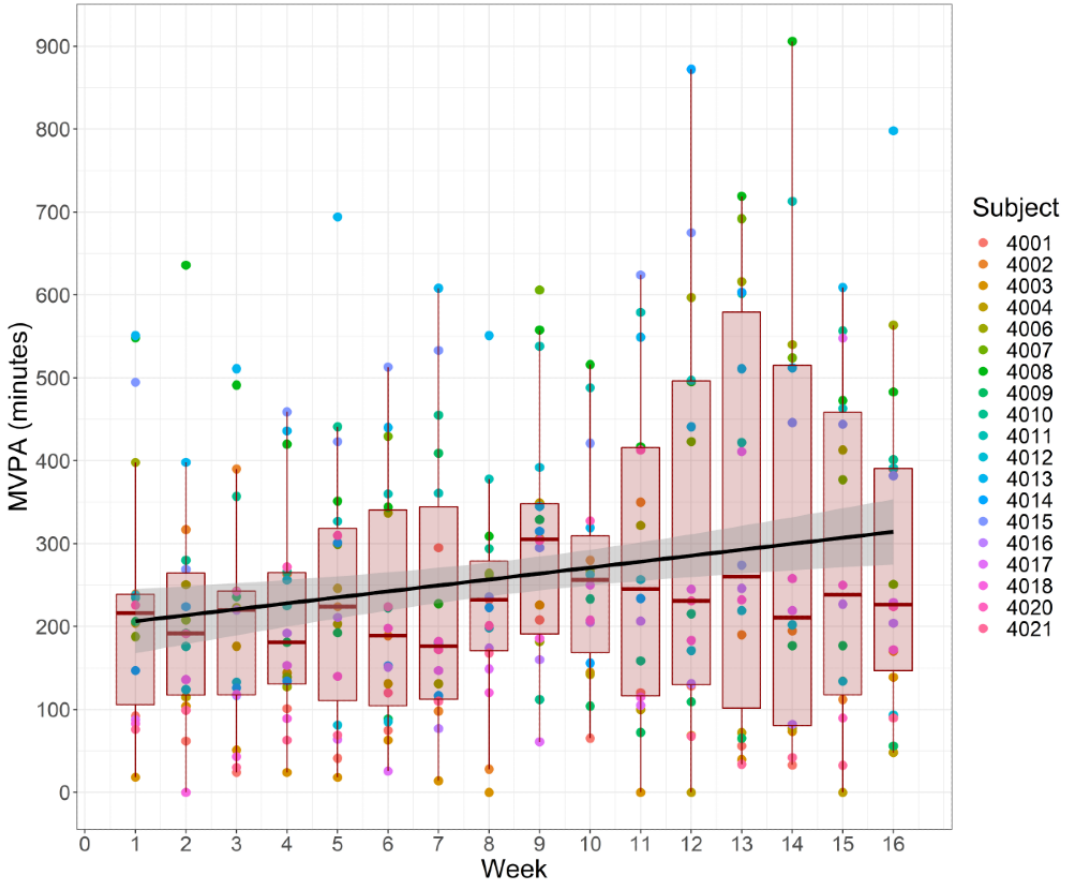
[b]MVPA: moderate-to-vigorous physical activity.

[c]Higher percentages of feedback for the System Usability Scale indicate higher usability.

Promotion of Physical Activity

The average participant increased their time spent performing MVPA by a mean of 0.16 (SD 0.23) minutes per day over the 16-week study period, which was equivalent to a cumulative increase of approximately 18 minutes. PA was promoted as indicated by a significant KPSS test (P=.01 and subsequent significant positive Pearson correlation [r=0.457, 95% CI 0.297-0.592]; P<.001) detailing that time spent performing MVPA increased throughout the 16-week study period (Figure 2). No changes were observed during the intervention period for other PA measures (Table 2).

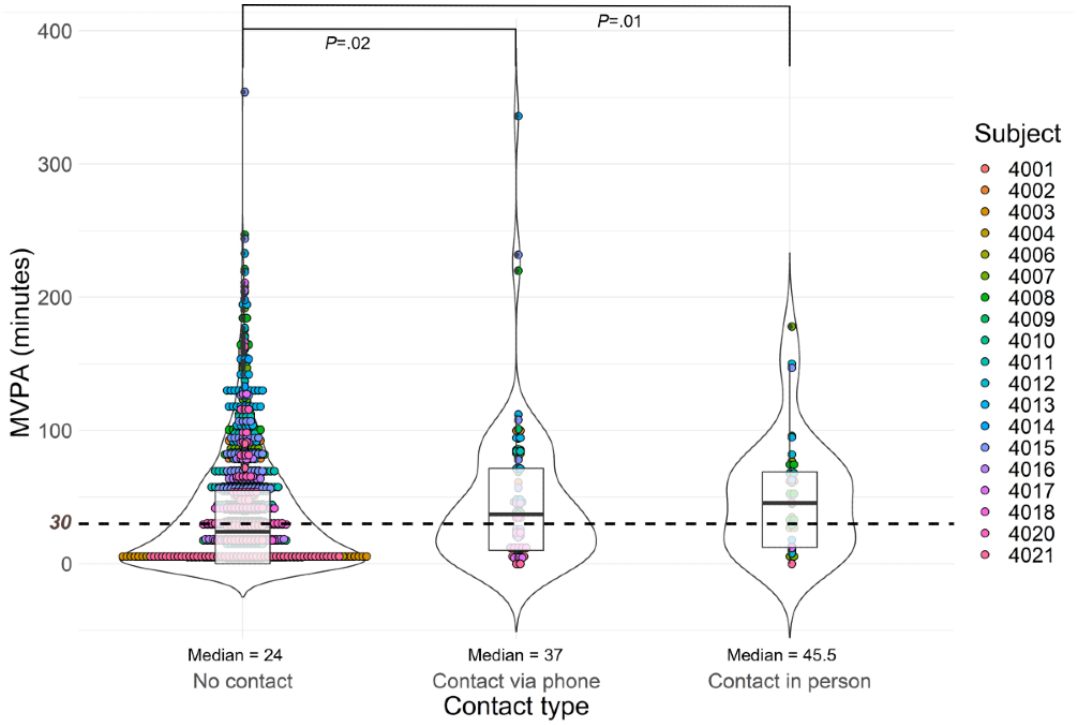
Figure 2. Moderate-to-vigorous physical activity (MVPA) throughout the 16-week intervention. Each dot represents a single week, with the color of the dot specifying the participant. Numbers beside the colored dots represent participant numbers. The box plots detail weekly medians (horizontal red lines) and quartile minutes performing MVPA for the group, while the black line illustrates the slope of MVPA over time for the group.



Impact of Behavioral Coaching

Participants were contacted for behavioral coaching an average of 5.26 (SD 1.88) times by phone and 2.11 (SD 1.63) times in person over the 16-week study period. A Kruskal-Wallis test revealed that median steps and MVPA were greater on days when individuals were contacted via phone (10,495 steps/day, IQR 8547.5-12,979.5, *P*=.03; MVPA: 37 min/day, IQR 10-71.5, *P*=.02) and in person (11,369.5 steps/day, IQR 9886.23-14,214.8, *P*=.01; MVPA: 45.5 min/day, IQR 12.3-69, *P*=.01) compared to days when individuals were not contacted (10,161 steps/day, IQR 6639-12,371; MVPA: 24 min/day, IQR 0-55; Figure 3). Median sedentary minutes were reduced on days when participants were contacted by phone (561 min/day, IQR 470-639.5, *P*=.04) but not in person (580 min/day, IQR 516.3-637.8, *P*=.43) relative to days with no contact (580.5 min/day, IQR 493-669). No differences were seen in LMVPA regardless of contact (contact by phone: 351 min/day, IQR 282-416, *P*=.10; contact in person: 364.5 min/day, IQR 278.5-422.8, *P*=.16; no contact: 334 min/day, IQR 255-408).

Figure 3. The effect of contact type on daily moderate-to-vigorous physical activity (MVPA) minutes. Each dot represents a single day, with the color of the dot specifying the participant. Numbers beside the colored dots represent participant numbers. The violin outline details the overall distribution of each contact type condition, while the box plots depict the medians and quartiles. The horizontal dashed line at 30 MVPA minutes illustrates the recommended number of MVPA minutes per day.



Scales

Small effect sizes were observed for improvement in BIPQ scores (g=0.30, P=.19) and increases in QoLS scores (g=0.32, P=.16). A medium effect size was observed for reductions in visits to the LAC+USC Medical Center (effect size r=0.44, P=.06; Table 3). A positive rate of change in steps correlated with reduced LAC+USC Medical Center visits (correlation coefficient r=–0.47, P=.04; Figure 4). There was no correlation between change in medical center visits and change in other PA measures.

Table 3. Measurements before, during, and after the intervention study period.

Measure	First measurement[a], mean (SD)	Second measurement[b], mean (SD)	*P* value	Effect size
Brief Illness Perception Questionnaire score[c]	43.05 (13.11)	39.21 (14.32)	.19	0.30[d]
Quality of Life Scale score[e]	82.37 (19.05)	87.53 (11.72)	.16	0.32[d]
Number of medical center visits (4 months)	4.32 (2.43)	3.47 (2.84)	.06	0.44[f]

[a]The first measurements for the scales took place at baseline, whereas those for medical center visits took place during a period 16 weeks prior to the start of the study.

[b]The second measurements for the scales took place after the intervention study period, whereas those for medical center visits took place during the 16-week study.

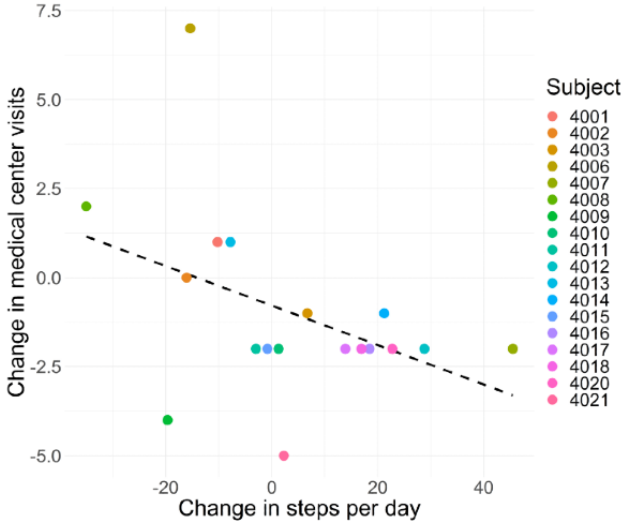
[c]Total scores range from 0 to 80; a higher score indicates a more threatening view of a participant's illness.

[d]This effect size was Hedges *g*.

[e]Total scores range from 16 to 112; a higher score indicates a higher perceived quality of life.

[f]This effect size was the *r* statistic.

Figure 4. The association between change in medical center visits with rate of change in steps. A negative change in medical center visits indicates that a participant went to the medical center fewer times during the study period than during the period 16 weeks prior to study initiation. Numbers beside the colored dots represent participant numbers.



Discussion

Principal Findings

The aim of this proof-of-concept study was to assess the feasibility and efficacy of a community-based intervention to promote PA through (1) a wearable Fitbit and (2) behavioral coaching in a sample of Latina women of low socioeconomic status with chronic neurological disorders recruited from the LAC+USC county outpatient neurology clinic. Studies have demonstrated the importance of PA and exercise in reducing morbidity and improving QoL for individuals with chronic neurological disorders, including Parkinson disease, multiple sclerosis, and chronic pain [1,2,4,23]. However, these studies typically do not include individuals from minority populations of low socioeconomic status. In general, underserved populations, particularly Latina women, are also less physically active due to numerous barriers to exercise, placing them at high risk for disease burdens associated with chronic illness [6-8]. These barriers include environmental factors, such as great distances with limited public transportation; low socioeconomic status; long working hours; lack of health literacy; limited social support, including extensive family and caregiver demands; and lack of facilities, including gym spaces, outdoor parks, or recreational sites [9]. Health care–related resources delivered at the community level may remove these barriers by maximizing accessibility and redesigning lifestyles [24]. For example, behavioral coaching and encouragement delivered within the community can help individuals identify goals and develop strategies to incorporate PA into their daily lives that otherwise would have not been considered [14]. Additionally, recent personal activity monitoring technology, such as Fitbit devices, enable individuals to monitor their goals through continuous and goal-directed real-time feedback emphasizing self-selected PA rather than structured exercise.

This proof-of-concept study provided preliminary evidence that programs designed to promote PA through self-monitoring with a personal activity monitor, such as a Fitbit wearable device, in conjunction with behavioral coaching are feasible and impactful among Latina women of low socioeconomic status and acculturation. Specifically, we observed high adherence to Fitbit wear, consistent with similar intervention studies using the same personal adherence definition (10 waking hours/day) in samples largely consisting of non-Latina, White females [11]. Potential motivating factors underlying high adherence include (1) initial goal setting, (2) frequent contact with wellness center navigators [25] to motivate the participants and help with any technological issues, and (3) the incentive for individuals to keep the Fitbit after study completion. Further, it is likely that the community-based nature of the intervention facilitated adherence by reducing barriers to exercise commonly experienced by this population of low socioeconomic status.

Importantly, this study demonstrated the efficacy of the intervention to promote PA over a 16-week period. In general, participants experienced an increase of approximately 18 minutes in daily MVPA over the course of the 16-week period, which nears the World Health Organization recommendations for approximately 20 minutes of PA per day (150 minutes of PA/week) to improve general and brain health [26]. This increase in MVPA was steady (0.16 minutes/day), which suggests that these gains in PA are gradual in nature. Taken together, these findings suggest that reaching recommended MVPA levels may be an achievable and realistic goal. While an increase in MVPA has been observed in similar self-monitoring intervention studies [12,27], it is notable that Latina women and individuals with chronic neurological conditions typically do not achieve recommended levels of PA [7,28] and report many barriers to exercise [9,29].

Interestingly, this study demonstrates that the observed PA promotion was significantly influenced by behavioral coaching within the setting of a community wellness center. Specifically, both behavioral coaching by phone from a wellness center navigator and by in-person visits with an occupational therapist increased individuals' activity as reflected by time spent performing MVPA and daily step count. This finding is consistent with previous reports demonstrating that community-based interventions can promote PA among Latina

women, particularly when led by those within their own community [30,31]. While the use of Fitbit wearable devices as an intervention is rising in popularity and studies have demonstrated its benefit in promoting PA in the general population of women [11-13], our results support the importance of a community-based intervention model that combines Fitbit wear and behavioral coaching to promote PA for Latina women with low socioeconomic status and acculturation characteristics.

Group-level changes in the number of daily steps, illness perception, QoL, and clinical visits were not significantly altered in this study. However, further analyses revealed that an increase in daily step count during the study period was correlated with a reduction in clinical visits. Two potential drivers of this relationship may include either the following: (1) increasing step count to improve the health of individuals, thus reducing medical center visits, or (2) the degree of health-related problems that required medical center visits resulted in reduced step counts. While the former demonstrates the importance of interventions that increase step count, both potential drivers show how monitoring change in daily number of steps may inform health status and the need for clinical visits. In fact, previous work has found that increased step count during inpatient recovery from cancer surgery is predictive of reduced likelihood for hospital readmission [32]. Results from this preliminary study suggest that the predictive strength of daily step count extends to community-based activities. A larger-scale study aimed at examining the relationship between steps and medical center visits is required to better understand the precise underlying mechanisms of this association.

There are limitations to this study due to its nature as a proof-of-concept study assessing feasibility and efficacy of an intervention in a targeted population. The sample size was relatively small, drawn from a specific geographical area, and consisted of a narrow range of neurological disorders, thus limiting our ability to generalize our findings to a larger population of Latina women with chronic neurological disorders. However, this study can be used as a guide for a future large randomized clinical trial examining PA promotion in this population with specific neurological disorders, including individuals suffering from chronic pain, Parkinson disease, or multiple sclerosis. While not a limitation, variability, including a potential ceiling effect in some individuals, was observed in activity levels between participants throughout the 16-week study. This variability is unsurprising given the proof-of-concept nature of this study focusing on an understudied and underresourced population commonly at risk for adverse health conditions in which little is known about PA engagement. As such, the authors did not use exclusion criteria or stratify based on preintervention activity levels. An additional limitation includes a lack of prestudy PA measurements. Due to this limitation, it is not possible to determine whether the high initial activity levels and step counts observed in the study were due to an initial increase that was secondary to Fitbit wear or whether individuals were already physically active at a high level. Similarly, PA levels or other outcomes following cessation of the formal intervention period were not measured, so we cannot determine whether the long-term benefits of the intervention persisted. Lastly, participants did not keep sleep or activity logs, which resulted in an overreliance on Fitbit data to accurately record these metrics.

Conclusions

This proof-of-concept study supports the feasibility and efficacy of a community-based intervention consisting of self-monitoring by a personal activity monitor, such as a Fitbit, combined with behavioral coaching by phone or in person promoting PA in a sample of Latina women with chronic neurological conditions. Behavioral coaching appears to enhance PA promotion when delivered by a culturally competent intervention team consisting of wellness center navigators from the community as well as an occupational therapist of Latino background. These initial results support the development of future large-scale intervention studies with the goal of providing evidence for the feasibility and effectiveness of PA promotion in this underrepresented population.

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Data Availability

Access to data can be obtained by reasonable request to the contributing or senior authors (AG and GP).

Conflicts of Interest

None declared.

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Abbreviations

BIPQ: Brief Illness Perception Questionnaire
IRB: Institutional Review Board
KPSS: Kwiatkowski-Phillips-Schmidt-Shin
LAC: Los Angeles County
LAC+USC: Los Angeles County and University of Southern California
LMVPA: light, moderate, and vigorous physical activity
MVPA: moderate-to-vigorous physical activity
PA: physical activity
QoL: quality of life
QoLS: Quality of Life Scale
SASH: Short Acculturation Scale for Hispanics
TWC: The Wellness Center

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Original Paper

Integration of Augmented Reality and Brain-Computer Interface Technologies for Health Care Applications: Exploratory and Prototyping Study

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Abstract

Background: Augmented reality (AR) and brain-computer interface (BCI) are promising technologies that have a tremendous potential to revolutionize health care. While there has been a growing interest in these technologies for medical applications in the recent years, the combined use of AR and BCI remains a fairly unexplored area that offers significant opportunities for improving health care professional education and clinical practice. This paper describes a recent study to explore the integration of AR and BCI technologies for health care applications.

Objective: The described effort aims to advance an understanding of how AR and BCI technologies can effectively work together to transform modern health care practice by providing new mechanisms to improve patient and provider learning, communication, and shared decision-making.

Methods: The study methods included an environmental scan of AR and BCI technologies currently used in health care, a use case analysis for a combined AR-BCI capability, and development of an integrated AR-BCI prototype solution for health care applications.

Results: The study resulted in a novel interface technology solution that enables interoperability between consumer-grade wearable AR and BCI devices and provides the users with an ability to control digital objects in augmented reality using neural commands. The article discusses this novel solution within the context of practical digital health use cases developed during the course of the study where the combined AR and BCI technologies are anticipated to produce the most impact.

Conclusions: As one of the pioneering efforts in the area of AR and BCI integration, the study presents a practical implementation pathway for AR-BCI integration and provides directions for future research and innovation in this area.

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KEYWORDS

digital health; augmented reality; brain-computer interface; health professional education; clinical performance support; interprofessional teamwork; patient education; mHealth; mobile health; technology integration

Introduction

Augmented reality (AR) and brain-computer interface (BCI) technologies are among the most promising technologies to date offering to revolutionize human-computer interaction in health care and health professional education. AR provides a mixed user experience where virtual and real elements seamlessly coexist to allow the user to see the real world supplemented by virtual objects and data. Most modern AR implementations represent a fusion of computer-generated imagery and real environment using a head-mounted display (HMD) or goggles typically used in gaming, maintenance training, rehabilitation, and surgical performance support. An HMD allows the users to maintain a clear line-of-sight alignment with real elements

in the actual environment, which can be beneficial in any data-intensive setting [1]. This is particularly important in clinical environments where a physician's situational awareness depends on multiple sources of information and simultaneously maintaining effective communications and eye contact with members of the clinical team as well as the patients [1,2].

The BCI represents a communication pathway between the brain and a computer device using a variety of biosensors that gather and interpret the signals from body and mind to enable neural controls over computer functions. The BCI has been used in a wide variety of applications, including rehabilitation, robotics, entertainment, and virtual reality [3-6]. No longer seen as a purely assistive technology, BCI has been gaining interest as a noninvasive physiological observation mechanism applicable to health care and education settings [7]. AR provides an opportunity to integrate feedback into a real-world environment and enhance a user experience by advancing human-computer interaction capabilities, while the BCI enables a new hands-free interaction modality and provides information about the user's mental state, which supports adaptive training and performance improvement [8,9].

While there has been a growing interest in the AR and BCI technologies in the recent years, the combined use of these technologies remains a relatively uncharted territory both in research and practice. The last decade has brought significant advancements in the area of AR and BCI technologies; however, both of them still exist in a relative isolation from each other. While the idea of bringing these two technologies together has prevailed among futurists, technology enthusiasts, and government research silos for quite some time, it still remains a fairly unexplored area, which had been associated with the realm of science fiction requiring paradigm shifts in digital innovation dynamics [10].

As the researchers and consumers are starting to recognize the benefits for combining BCI and AR fields, this interest continues to fuel the innovation around improved technology interaction and visualization capabilities. There is a growing body of literature suggesting the potential to revolutionize health care through the use of emerging AR and BCI technologies, with a few intriguing examples starting to demonstrate the applicability of these emerging technologies in a variety of health care contexts; for example, surgery, ophthalmology, elderly care, sensory system rehabilitation, and others [8,11-13]. Despite the growing interest in the AR and BCI technologies, the research in this area is currently somewhat fragmented, and the awareness of the true potential of AR and BCI is still rather limited [1,14].

A combination of AR and BCI technologies can offer an enhanced user experience both for patients and health care professionals, particularly from procedure-intensive specialties, by allowing them to interact with a mix of real and virtual objects, contextual elements, and each other, while using the BCI as an additional communication vehicle, besides the spoken word and hand gesture traditionally used in AR. For instance, through interactive 3D visualizations, an AR component can be used to help a health professional explain a disease or a medical procedure to a patient during a clinical encounter or provide visual cues to a physician during a complex procedure, while a BCI component can simultaneously use biosensors, such as an electroencephalogram (EEG), to enhance the range of options for performing clinical tasks through a combination of verbal, tactile, and neural triggers as well as provide new information about the user's mental state.

This paper presents the results of a recent effort aimed to advance an understanding of how AR and BCI technologies can work together to transform modern health professional education and clinical practice by providing practical mechanisms to support the established principles of patient-centered care [15] as they relate to patient safety, effective patient-provider communication, shared decision-making, and patient education. The aim of this study was to explore the integration of commercially available wearable AR and BCI technologies that can be applied in medical education, clinical practice, and other areas to address a variety of real-world challenges in health care. The study produced a novel integrated AR-BCI technology solution, which was demonstrated within the context of practical use cases focused on health professional education and clinical performance support.

Methods

Methods Overview

The study methodology included an environmental scan and analysis of modern AR and BCI technologies, a use case analysis of practical applications for combined use of AR-BCI technologies in health care, and the development of a proof-of-concept AR-BCI technology integration prototype situated within the modeled use case scenarios, as summarized in the following paragraphs.

Environmental Scan and Analysis of Modern AR and BCI Technologies in Health Care

The environmental scan [16] and analysis component constituted a broad-scale review of existing applications of AR and BCI technologies in health care through literature review, research and industry reports, technology demonstrations in health care settings, and other sources. The literature review included publications identified from health care and technology research databases (eg, PubMed, IEEE, EBSCO, and others) using the following Medical Subject Headings (MeSH) terms: "augmented reality," "brain-computer interfacing," "healthcare," "clinical performance support," and "health professional education." The survey of industry reports and technology demonstrations was performed at a number of major technology innovation venues (eg, Consumer Electronics Show, Interservice/Industry, Simulation, Training, and Education Conference, Healthcare Information and Management Society, International Meeting for Simulation in Healthcare, and others). The environmental scan revealed the strong potential for bringing the AR and BCI technologies for health care applications, particularly within the context of complex medical interventions and treatment planning (eg, surgery, invasive testing procedures, intensive therapies, and others). Leveraging the combination of AR and BCI in such cases would help improve communication and shared decision-making between providers and patients as well

as members of an interprofessional team. At the same time, the environmental scan has confirmed that while the use of AR and BCI technologies in health care is growing, their combined use remains an unexplored area where the majority of innovations currently reside in research laboratories and apply to a limited range of clinical applications and disease conditions.

Use Case Analysis of Practical Applications for Combined AR-BCI Technologies in Health Care

To explore the potential for the combined use of AR and BCI technologies in health care, a use case analysis technique [17] was used, which helped identify the requirements for the AR-BCI within the context of practical health care applications. Through multidisciplinary collaboration with experts from health professional education, clinical sciences, and computer and cognitive sciences, a series of use cases were developed, which focused on the following key areas where the combined use of AR-BCI technologies can produce the most impact:

- Medical or health professional education
- Patient education
- Patient-provider communication
- Shared decision-making
- Clinical performance support
- Interprofessional teamwork

These use cases provided the basis for modeling the simulation scenarios used to demonstrate and validate the AR-BCI proof-of-concept technology, which is described in the *Results* section.

AR-BCI Technology Integration Prototype Development

The prototype development effort involved a proof-of-concept integration of AR-BCI technologies with the intent of demonstrating the potential of the combined technologies within the context of the practical use cases and serve as a test bed for future use case scenarios and implementation. The prototype development effort focused on the integration of commercially available consumer AR and BCI devices to minimize the common barriers associated with the use of specialized technologies, which frequently stand in the way of technology implementation and adoption.

The proof-of-concept AR-BCI integration was performed using Microsoft HoloLens as the AR technology component and NeuroSky Mind Wave 2 as the BCI component. While neither of the two devices were designed to work together "out of the box" in a plug-and-play fashion, they do come equipped with a software development kit and application programming interface components, which make integration with other technology platforms and devices possible in principle. It is important to note, however, that coupling these devices involved a technology development and programming effort to create a software interface to enable the communication between them. A WebSocket relay server was implemented as an intermediary component between HoloLens and NeuroSky Mobile Wave 2 because both devices support the internet connection over an HTTPS internet protocol. The WebSocket protocol was selected on the basis of its effective real-time performance as a relay messenger, which, in this case, listened for the messages from the BCI device (NeuroSky) and relayed them to the connected AR device (HoloLens). As part of the prototype validation efforts, this technology integration method was also successfully coupled with other consumer-grade BCI or neurosensing devices, such as MUSE, and is currently being extended to other AR devices, such as Magic Leap and MERGE.

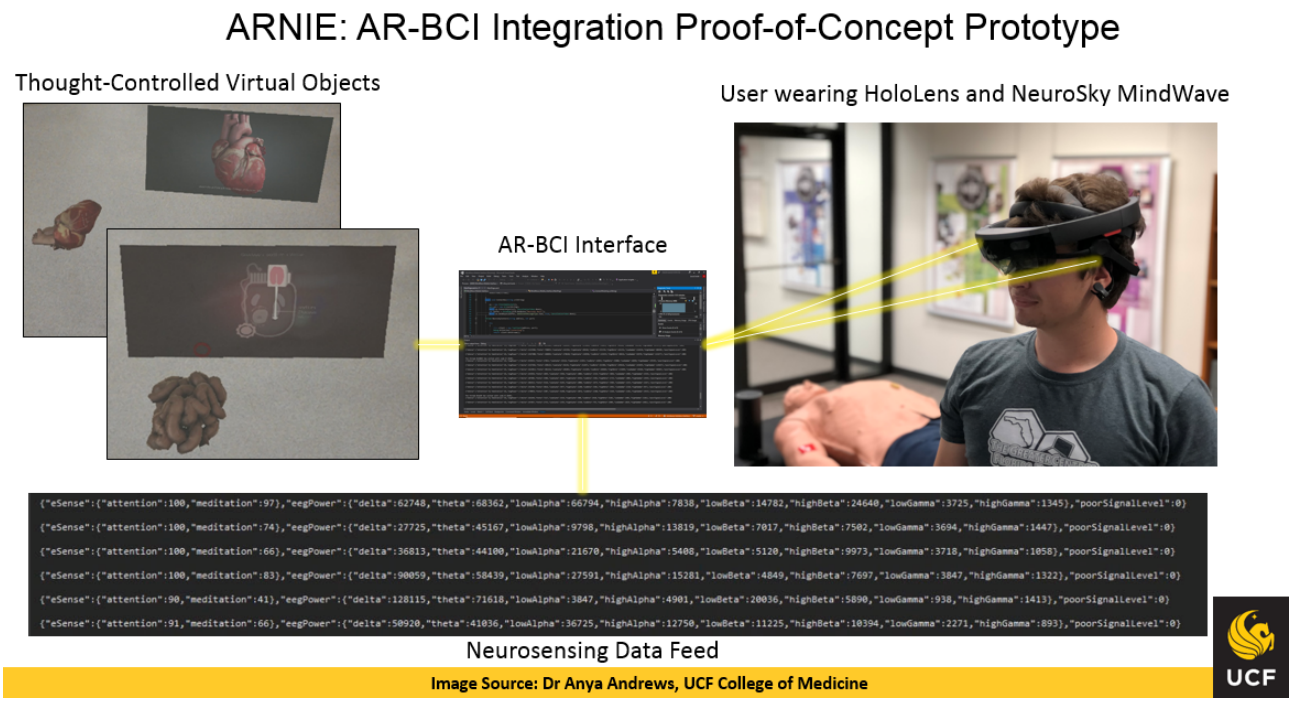
Results

The principal outcome of this exploratory assessment and prototype development is that the new technology interface that resulted from it enables the coupling and communication between these devices—a capability that previously did not exist. Specifically, the study resulted in a proof-of-concept integration of mainstream consumer AR and BCI technologies and development of a novel integrated technology platform to demonstrate their potential within the context of medical education and clinical performance support use cases and serve as a test bed, based on which future developments can be performed and evaluated.

Named "*Augmented Reality and Neurosensing Interaction Environment (ARNIE)*," the resultant solution represents a flexible AR-BCI interface platform and a technology test bed that is specifically intended for consumer-grade devices and is technology brand–agnostic. This solution is designed to enable an enhanced learning experience for health professionals in training and enhanced clinical experience for patients and physicians. The ARNIE platform currently enables thought-controlled manipulation of multiple virtual and data objects in AR similar to a simple computer "mouse click." Figure 1 illustrates a working model of the ARNIE system within the context of a medical education use case represented via two learning modules—one focused on the cardiovascular disease and the other one on Crohn disease.

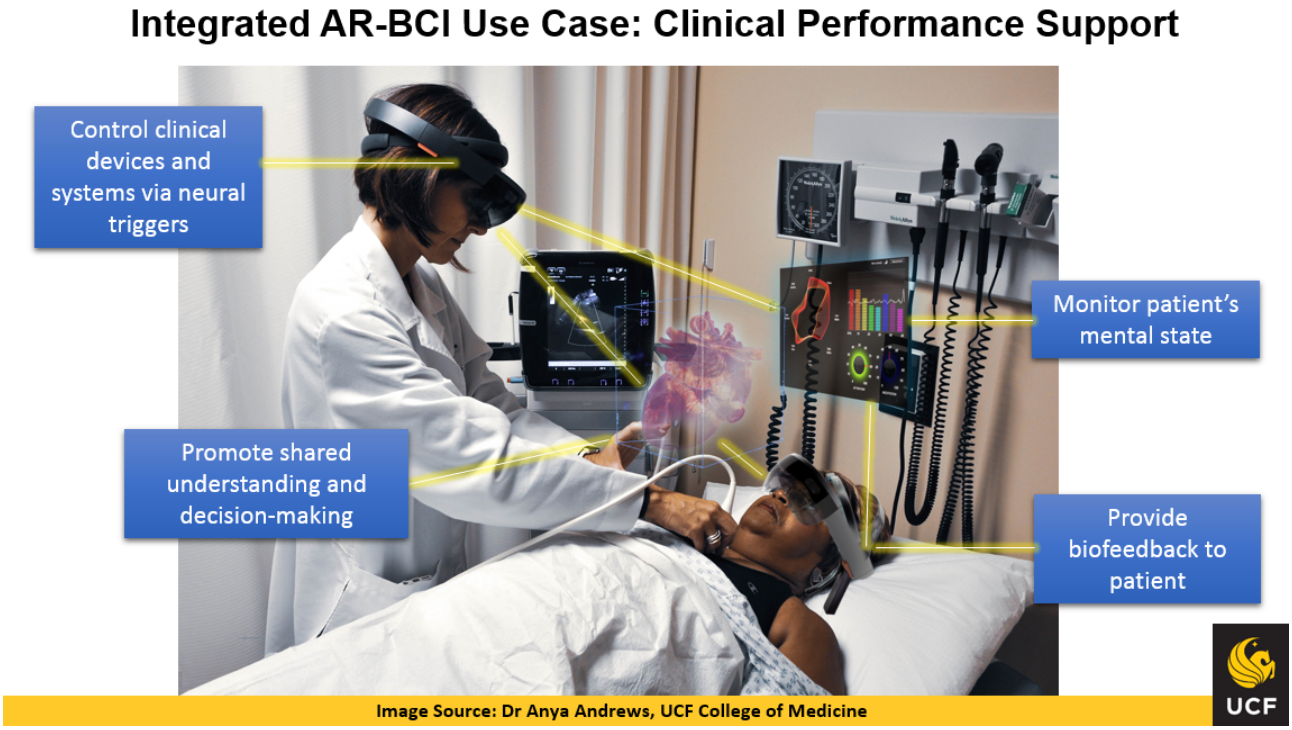
The ARNIE system enables the 3D models visualizing a human heart and a gastrointestinal tract to be controlled by a neurosensing BCI component using a unique communication protocol developed to enable coupling of AR-BCI components. As pictured in Figure 1, the student demonstrates wearing an AR headset integrated with a BCI headband and controls the virtual objects—that is, the human heart and gastrointestinal tract—in the AR environment entirely with his thoughts. Specifically, by concentrating on a particular virtual object—for example, "the heart" presented in the AR environment—the student's EEG waves are captured by the BCI headband, and upon reaching a predetermined attention measure threshold, send a signal using the communication protocol to launch a training video illustrating the functions of the cardiovascular system.

Figure 1. Augmented reality and brain-computer interface (AR-BCI) proof-of-concept integration prototype: medical education use case. ARNIE: Augmented Reality and Neurosensing Interaction Environment, UCF: University of Central Florida.



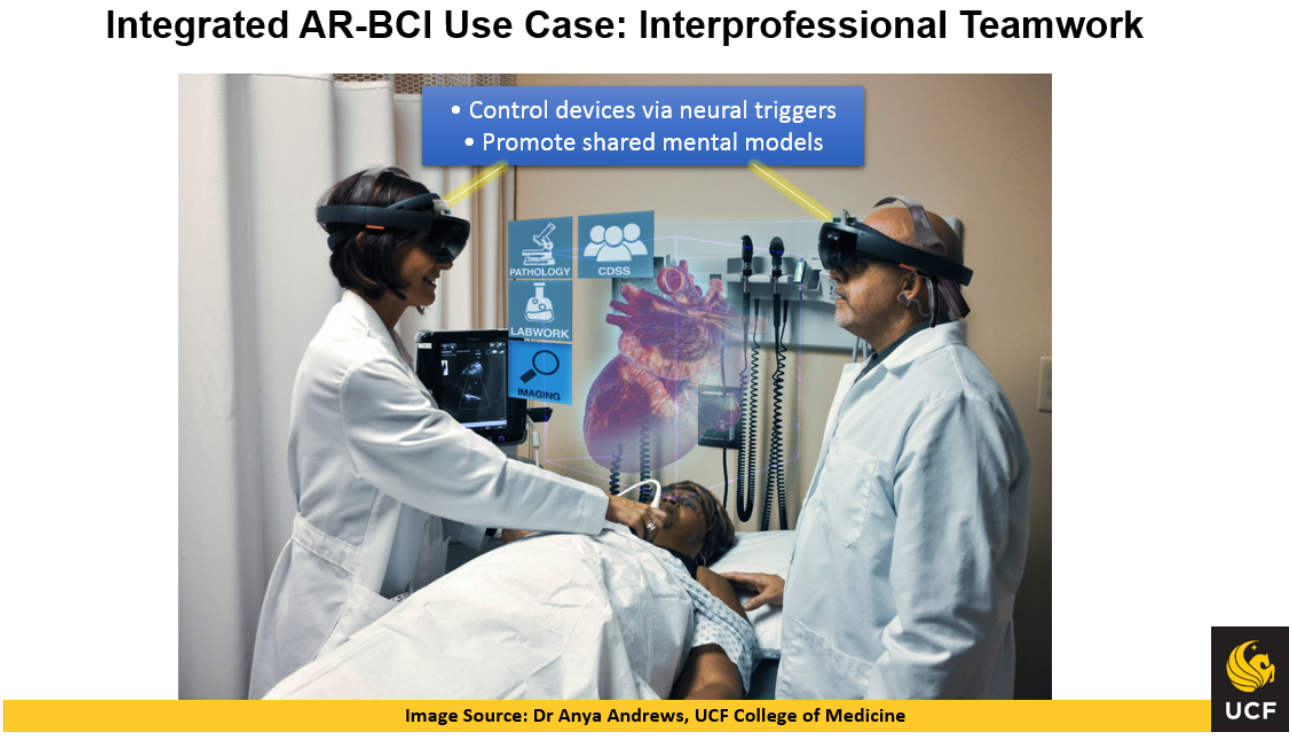
Besides the education and training use cases, the potential of the integrated AR-BCI solution was explored within the context of clinical performance support modeled in a health care environment. Thus, Figure 2 below illustrates a clinical scenario where the integrated AR-BCI capability would allow the physician performing a clinical procedure (eg, an ultrasound of the heart) to control certain clinical devices and systems using neural triggers (ie, attention and concentration), use shared visualizations with the patient (also wearing the AR-BCI devices) to promote effective communication and shared decision-making, while also maintaining enhanced clinical awareness of the patient's mental state enabled by the patient's BCI component, which can also be used to provide biofeedback to patient, as needed.

Figure 2. Integrated augmented reality and brain-computer interface (AR-BCI) use case: clinical performance support. UCF: University of Central Florida.



The clinical applications of the integrated solution can also augment interprofessional teamwork by allowing members of the health care team to control devices and data in the clinical environment via neural triggers, which would help maintain situational awareness and promote shared mental models and shared decision-making as illustrated in Figure 3.

Figure 3. Integrated augmented reality and brain-computer interface (AR-BCI) use case: interprofessional teamwork. UCF: University of Central Florida.



Shared mental models are shared cognitive structures that enable members of an interprofessional team to function collaboratively through implicit coordination while performing clinical tasks that require coordination, cooperation, and mutual support. Shared mental models represent a key prerequisite for shared decision-making in interprofessional teamwork.

The medical education, clinical performance support, and interprofessional teamwork use case scenarios described above were modeled within the academic technology research and clinical skills simulation environment and provided the context for demonstrating the potential of the integrated AR-BCI prototype solution. The medical education use case scenario illustrated in Figure 1 has served as the primary mechanism for demonstrating and validating the functionality of the prototype. The initial testing and validation of the technology prototype was performed within a small group of approximately 10 health care simulation and multimedia technology experts familiar with a variety of both AR and BCI platforms whose formative inputs helped calibrate the prototype for broader testing and implementation.

After the initial testing by the technology experts, the prototype has been demonstrated to a diverse mix of 2500 potential user representatives, including students, educators, and health care and technology professionals, approximately 600 of whom volunteered to further examine and perform hands-on testing of the integrated AR-BCI solution within the simulation laboratory. The testing volunteers were instructed to don both the HoloLens and NeuroSky Mind Wave 2 devices simultaneously and concentrate their attention on specific 3D objects within the AR environment; for example, “the heart” in order to activate the learning content associated with these objects via neural triggers. All of the volunteers have been able to go through the use case scenarios using the two devices without any problems, which indicates that the technical targets of the integrated AR-BCI system and its individual components have been met under basic operating conditions within the testing environment. The volunteers’ reactions and feedback regarding the overall AR-BCI integration concept and the experience using the prototype have been overwhelmingly positive, ranging from comparisons with science fiction coming to real life to sincere expressions of awe from being introduced to a novel capability that holds tremendous potential for health care applications.

Discussion

Principal Findings

This study has successfully proved the concept of integrating commercially available consumer AR and BCI technologies. The results of the described effort present new advancements in the areas of cognitive and computer sciences by providing new capabilities for (1) human-machine interfacing, (2) advanced technology interoperability and Internet of Things networking, (3) multimodal data analytics, and (4) smart and mobile learning technologies in health care. These new capabilities have been realized within the ARNIE technology interface solution that enables interoperability between

consumer-grade AR and BCI devices demonstrated within the context of the practical use cases for health professional education and clinical performance support. The proof-of-concept demonstration scenarios involved participation of a broad community of potential end users, including physicians, allied health professionals, medical students, technologists, scientists and researchers, health care administrators who helped validate the integrated AR-BCI technology capability and provided early feedback regarding the prototype, which has been consistently optimistic and supportive in terms of its perceived usability and utility, and also encouraging in terms of its broader testing and implementation in real-life settings.

The resultant new technology solution offers a research test bed and enabler for advancing knowledge and understanding about human-computer interaction in health care by creating an opportunity to connect people (health professionals, patients, and trainees), systems, and data in health care environments through a combination of AR and BCI. This test bed represents a foundation for moving toward plug-and-play integrated AR-BCI technology interoperability, which currently represents a significant barrier to adoption of these new technologies for health care applications.

Limitations

The study represents an exploratory and developmental technology integration and use case modeling effort, which, thus far, has been successfully demonstrated and implemented in a simulation-based education and research setting, but not in an actual health care delivery environment. The focus of the effort was on technology development and proof-of-concept demonstration of the integrated AR-BCI capability within the realistic use case scenarios. The volunteer participant interaction with the platform was not systematic, and their feedback is considered informal.

Comparison With Prior Work

The following three major differentiators of the described study from the current state of the science in this area can be distinguished:

Expanded Range of Controls for AR Technology Interaction

The world of human-machine interfaces is rapidly transitioning from legacy physical instrumentation to a world driven by gesture, spoken word, and now neural command, which is likely to become far more precise than gesture or spoken word in the future. The results of this study demonstrate an expanded range of AR controls, which includes a neurosensing capability that allows the users to control digital objects in an AR environment using the power of their mind.

Consumer-Grade AR-BCI Technologies and Broader Application Focus

A growing body of research suggests the great potential to revolutionize human-computer interaction through the use of emerging AR and BCI technologies, with several early examples starting to demonstrate the applicability of these emerging technologies in a variety of health care contexts, including prosthetic interfaces [18], sensory system rehabilitation [19], behavioral health [20], and others. However, many existing combined AR-BCI implementations use highly specialized technologies and devices that are custom-built for a narrow focus, experimental in nature, and may not be easily adaptable or extensible for wider use, which makes it challenging for them to cross a so-called technology adoption chasm [21] in order to enter mainstream use any time soon. The ARNIE solution brings together the AR-BCI capabilities using the consumer-grade technology and devices available today with the intent to accelerate the transition of this new integrated capability to the consumers in health care in the near future.

Technology-Agnostic Solution

The described effort represents a new step toward bringing the AR-BCI technologies together in a device-agnostic way via a novel interface solution that enables communication between consumer-grade wearable AR and BCI devices and provides the user an ability to control digital objects in AR using neural commands. Envisioned to promote effective communication and shared decision-making between health care providers and patients, this new interface represents an extensible and device-agnostic test bed for evaluating future development efforts in this area. Intended to support a wide range of AR and BCI devices, the technology-agnostic integration approach will help promote the adoption of integrated AR-BCI technologies in health care.

Future Directions

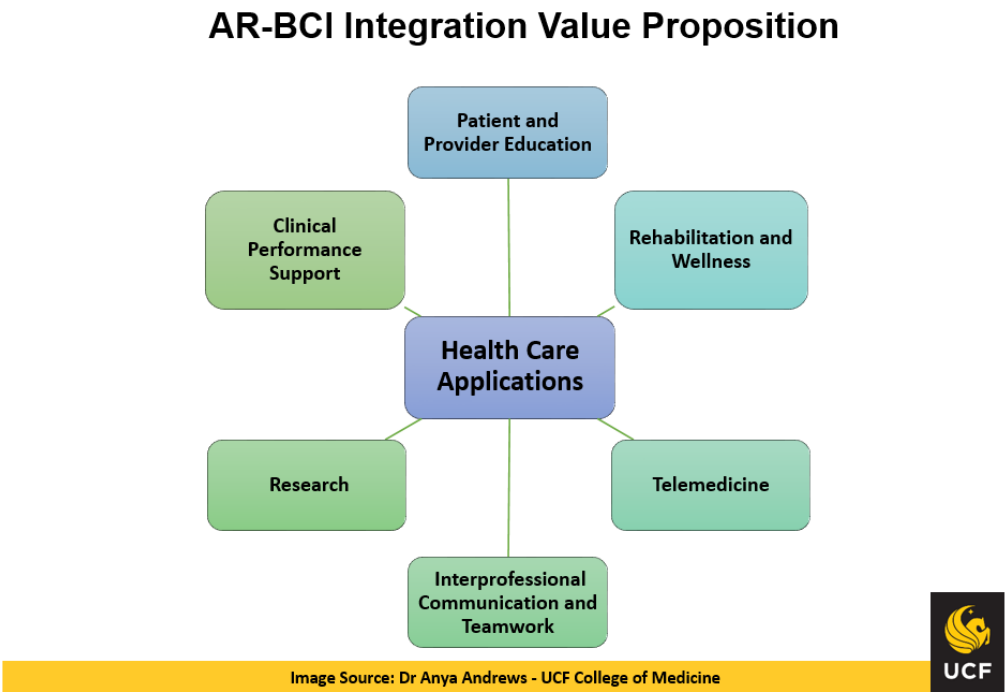
Next steps in this direction would include the development of an expanded set of integrated AR-BCI capabilities and include further testing and implementation of this platform within the health professional education curriculum of the University of Central Florida (UCF) Academic Health Sciences Center. Further research efforts need to advance an understanding about how AR and BCI technologies can be used to (1) facilitate or enhance shared understanding between human agents in health care, (2) support teaching and learning of complex biomedical and medical information, (3) enable strategies to capture mental states and promote metacognition and comprehension in medical trainees and patient populations, and (4) support the identification of neural signatures of complex cognitive, metacognitive, and affective processes during clinical training and performance.

Broader Impacts

There are many opportunities for broader impacts from the application of integrated AR-BCI solutions in health care, including patient and provider education, physician clinical performance support, interprofessional teamwork, rehabilitation, wellness, telemedicine, and research, as summarized in Figure 4. The results of this study can play an important role in transforming health professions education by enabling the integration of people, systems, and data during the learning process. They can also serve as a powerful enabler for enhanced clinical experiences for patients and providers by improving communication, shared decision-making, and patient health literacy, all of which are associated with patient-centered care [22,23]. The clinical applications of the integrated solution can

also augment interprofessional teamwork and help clinical teams maintain situational awareness and shared mental models, which also have a direct impact on patient health outcomes [24]. Additionally, the integration of AR and BCI technologies offers unique opportunities for supporting telemedicine and remote rehabilitation and wellness approaches, which have become particularly important during the COVID-19 pandemic. Finally, the AR-BCI value proposition includes opportunities to advance research in the areas of health care quality improvement and the other health care application areas highlighted in Figure 4.

Figure 4. Augmented reality and brain-computer interface (AR-BCI) integration for health care applications: value proposition.



This described study offers a foundation for future efforts to accelerate the integration of AR and BCI technologies to connect people, data, and systems to enable transformation in health and medicine. As our society continues to become more diverse and global, every effort should be made toward the development of shared understanding in health care [25]. The results of this study and future efforts in this area should help promote shared understanding between health professionals and patients from all walks of life, including underrepresented minorities, patients with limited education background, immigrants, patients in rural communities, and others. A famous quote by a historical figure in medicine, Martin H Fischer, stating that "*In the sick room, ten cents' worth of human understanding equals ten dollars' worth of medical science*," still holds true today, particularly as patient-centered care remains one of the fundamental aims of the US health care system. Whether it is about communication between providers and patients or between members of an interprofessional team, the development of shared understanding and mental models is an important prerequisite and enabler for shared decision-making.

Conclusions

Technology-based innovations can serve as a game-changer for supporting patient and provider education, communication, and shared decision-making, which would improve care and engagement of patients and ultimately population health [22]. Through the purposeful integration of multiple disciplines, including cognitive and computer sciences, engineering, and medicine, this study explored the integration of wearable AR and BCI technologies and resulted in a novel integrated AR and BCI technology solution and test bed that brings together two of the most promising technologies to date, both of which have tremendous potential to revolutionize health care. Broad applications for this technology are anticipated in health professions education, clinical performance support, surgery, telemedicine, and patient education. Future research directions in this area should aim to expand the range of current AR-BCI capabilities while addressing existing technical challenges and also generate new evidence on human-computer interaction in health care and health professional education.

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Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
ARNIE: Augmented Reality and Neurosensing Interaction Environment
BCI: brain-computer interface
EEG: electroencephalogram
HMD: head-mounted display
UCF: University of Central Florida

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Original Paper

Technology Acceptance and Usability of a Virtual Reality Intervention for Military Members and Veterans With Posttraumatic Stress Disorder: Mixed Methods Unified Theory of Acceptance and Use of Technology Study

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Abstract

Background: Military members and veterans exhibit higher rates of injuries and illnesses such as posttraumatic stress disorder (PTSD) because of their increased exposure to combat and other traumatic scenarios. Novel treatments for PTSD are beginning to emerge and increasingly leverage advances in gaming and other technologies, such as virtual reality. Without assessing the degree of technology acceptance and perception of usability to the end users, including the military members, veterans, and their attending therapists and staff, it is difficult to determine whether a technology-based treatment will be used successfully in wider clinical practice. The Unified Theory of Acceptance and Use of Technology model is commonly used to address the technology acceptance and usability of applications in 5 domains.

Objective: Using the Unified Theory of Acceptance and Use of Technology model, the purpose of this study was to determine the technology acceptance and usability of multimodal motion-assisted memory desensitization and reconsolidation (3MDR) on a virtual reality system in the primary user group (military members and veterans with treatment-resistant PTSD, 3MDR therapists, and virtual reality environment operators).

Methods: This mixed methods embedded pilot study included military members (n=3) and veterans (n=8) with a diagnosis of combat-related PTSD, as well as their therapists (n=13) and operators (n=5) who completed pre-post questionnaires before and on completion of 6 weekly sessions of 3MDR. A partial least squares structural equation model was used to analyze the questionnaire results. Qualitative data from the interviews were assessed using thematic analysis.

Results: Effort expectancy, which was the most notable predictor of behavioral intention, increased after a course of 3MDR with the virtual reality system, whereas all other constructs demonstrated no significant change. Participants' expectations of the technology were met, as demonstrated by the nonsignificant differences in the pre-post scores. The key qualitative themes included feasibility and function, technical support, and tailored immersion.

Conclusions: 3MDR via a virtual reality environment appears to be a feasible, usable, and accepted technology for delivering 3MDR to military members and veterans who experience PTSD and 3MDR therapists and operators who facilitate their treatment.

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KEYWORDS

PTSD; UTAUT; technology acceptance model; trauma; mental health; therapy; rehabilitation; digital health; psychotherapy; military; veteran; psychotherapy; 3MDR; technology acceptability; technology acceptance; Canadian Armed Forces; virtual reality

Introduction

Background

Military services commonly involve engagement in high-risk activities, whether during physical training, daily trade-related tasks, overseas deployment or in response to natural disasters. Such activities place military members, individually and collectively, at a heightened risk of physical and psychosocial injury. Canadian Armed Forces (CAF) military members and veterans exhibit higher rates of injuries and illnesses, such as posttraumatic stress disorder (PTSD), major depressive disorder, generalized anxiety disorder, substance abuse, sleep disorders, and mild traumatic brain injury compared to their civilian counterparts [1,2]. These conditions can have far-reaching implications such as occupational, social or familial, and psychological impairment and can affect activities of daily living. Numerous studies conducted in Canada, the United States, and the United Kingdom have demonstrated a high prevalence of PTSD specific to deployments during conflicts in the Middle East from 2001 to 2013 [1-5]. The rate of probable PTSD among UK military personnel has been reported to be 6.2% [3] and, among veterans who were deployed in combat roles, 17.1% [4]. The rate of PTSD among Canadian veterans is estimated to be 16% [5]. Owing to the prevalence of these mental health conditions among military personnel and veterans, evidence-based interventions and treatments are needed to assist in recovery and rehabilitation. As our understanding of trauma evolves, novel interventions for PTSD in this population are needed. In particular, the use of technology as a facilitator of treatment may introduce avenues of recovery that were not previously possible.

Multimodal Motion-Assisted Memory Desensitization and Reconsolidation

Multimodal motion-assisted memory desensitization and reconsolidation (3MDR) is an innovative, technology-assisted, exposure-based trauma therapy that holds promise for treating combat-related PTSD (crPTSD). 3MDR is a structured, personalized, exposure-based, virtual reality (VR)–supported intervention developed in the Netherlands and used with military members and veterans with PTSD in the Netherlands, the United Kingdom, the United States, Israel, and Canada [6]. 3MDR is an emerging VR-assisted therapy delivered in an immersive VR environment (VRE) such as the Motek Gait Realtime Analysis Interactive Lab or Motek Computer Assisted Rehabilitation Environment (CAREN). The most commonly used VRE for 3MDR has been CAREN, which is a room-sized, 3D VRE with a central treadmill surrounded by 240° floor-to-ceiling motion-capture screens.

The 3MDR intervention comprises 10 sessions, including selecting images and music, trauma processing, and reconsolidation, and six 90-minute therapy sessions in the VRE, including a 30-minute debrief [7]. The 3MDR sessions include a *preplatform session* (session 1), during which the participant selects and orders images and music. Symbolic representations in the form of images (ie, photographs and sketches) related to their traumatic experiences are selected and ordered from least to most distressing. Music that reminds the participant of the traumatic event or events and facilitates the emotional memory network is also identified, which supports a return to the present. Sessions 2 to 7 are *platform sessions* that involve 3 phases. In the *preplatform phase* of the session, the therapist and participant confirm the order of the images and music for the session. During the *platform phase*, the participant dons a safety harness and is accompanied by a 3MDR therapist while walking continuously on a treadmill at a self-selected pace. The participant first warms up by walking on the treadmill while listening to self-selected music connecting them to traumatic experiences and then, during each of seven 3- to 5-minute cycles, walks down a 3D hallway on the screen toward a self-selected trauma-related image. The participant describes the image, physical sensations, and feelings, followed by communicating descriptive words and phrases with the help of a therapist. These words and phrases are projected in front of the image and then read aloud by the participant. For a duration of 30 seconds, the participant then reads aloud numbers as they appear on a ball oscillating horizontally in the foreground of the image and words. The participant cools down after the seventh cycle by walking while listening to self-selected music, which facilitates reconnection to the present. Each session is concluded with a *postplatform phase*, which includes discussion, reconsolidation, and a mental wellness check or self-care plan. *Postplatform session*s 8 to 10 focus on reconsolidation and contribute to the meaning making of the acquired gains [7]. In-depth descriptions of 3MDR have been published elsewhere [6,7,8].

Initial randomized controlled trials with 3MDR participants have shown a reduction in PTSD symptoms, which was maintained over time [9,10]. Although these results indicate that 3MDR may be a promising new therapeutic treatment for PTSD, key areas of exploration are required before 3MDR can be implemented as a frontline trauma modality. One such area of needed exploration is the technology acceptance and usability of 3MDR from the perspective of the end users, including CAF military members and veterans with crPTSD and the therapists and operators delivering 3MDR. Questions on feasibility must be addressed before in-context clinical investigations regarding specificity, reliability, validity, and sensitivity can take place. Without addressing acceptance and usability, technological innovations may not be adopted or implementations sustained. For 3MDR specifically, the combination of a military context and the intervention potentially affects multiple user levels; careful exploration to determine whether the technological

components of 3MDR are acceptable and beneficial is warranted.

Technology Acceptance and Usability in Contexts

Technology offers health care professionals a variety of benefits, including improving the efficacy, efficiency, safety, and cost-effectiveness of assessments, interventions, data collection, data analysis, reporting, record keeping, and communication. The acceptance of such technologies by health care professionals is an important topic for health care professionals and researchers [11,12]. Without technology acceptance and usability for the user, technological assessments, interventions, and other aspects that would assist with evolving health care needs may not be adopted into clinical practice despite their potential effectiveness. Therefore, evaluation of the acceptance and usability of emerging technology is integral to advancing best practices in health care [12].

The use of digital and mobile health innovations is becoming widespread in military and veteran populations [13, 14-17]. This has been amplified by the recent COVID-19 pandemic, when web-based health solutions have become increasingly common in all health care practices, including military environments [14-17]. It is essential to, directly and indirectly, assess the technology acceptance of different user groups, including military personnel, within their context using a framework or model to ascertain this factor, which contributes to the feasibility of implementing technological innovations.

Purpose

The purpose of this mixed methods pilot study is to use the Unified Theory of Acceptance and Use of Technology (UTAUT) model to determine the technology acceptance and usability of 3MDR within a VRE in the end user groups of (1) military members and veterans with crPTSD, (2) 3MDR therapists, and (3) VRE operators. On the basis of previous research in this area, it is hypothesized that performance expectancy (PE) and facilitating conditions (FC) will be the most influential variables on behavioral intentions (BI) and use, respectively. In addition, it is hypothesized that social influence (SI) will have the least influence on BI.

Methods

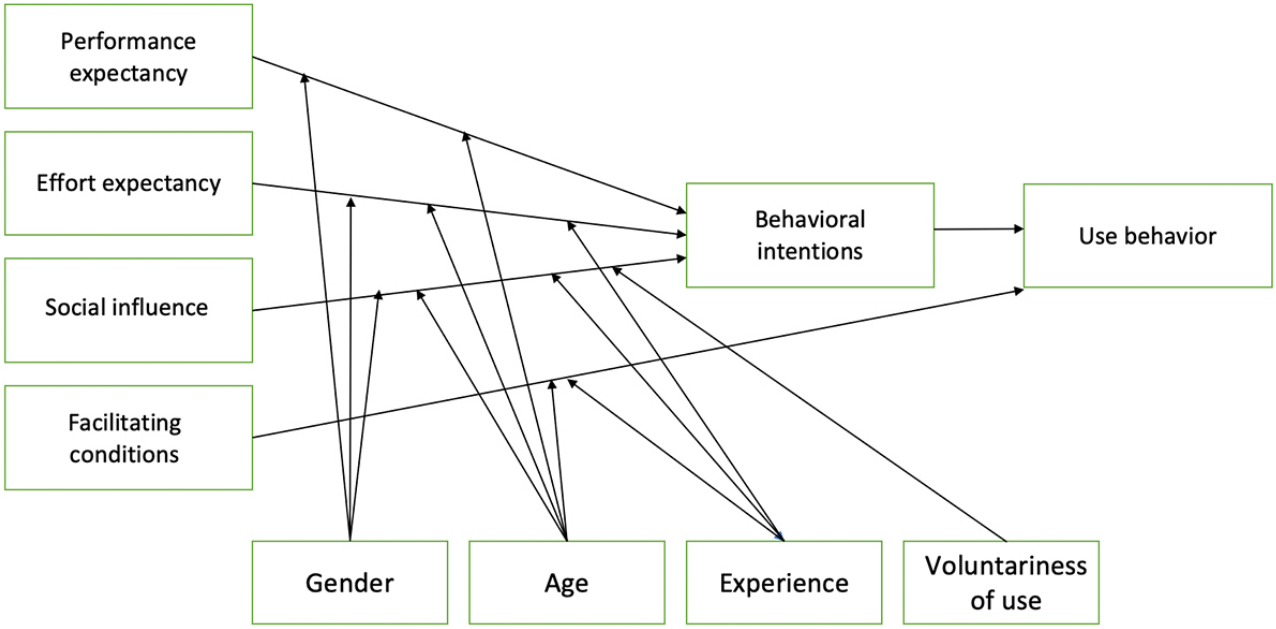
Study Design

This study used a mixed methods, embedded study design with a pre-post quasi-experimental approach. A quantitative approach using partial least squares structural equation modeling (PLS-SEM) and other nonparametric statistics was the primary method of data collection; a qualitative thematic analysis was secondary to this. This study was embedded in a larger study that used a mixed methods staggered entry clinical trial to test the efficacy, effectiveness, and safety of 3MDR [8].

The UTAUT Model

The UTAUT model was developed based on previous theories and models for the acceptance and adoption of technologies and consumer products that address the perceived technology acceptance of a user group with the goal of predicting use behavior (Figure 1) [18]. UTAUT has been demonstrated to explain as much as 70% of the variance in the intention to use technology compared with its technology acceptance model predecessors [18].

Figure 1. The Unified Theory of Acceptance and Use of Technology Model [18].



The UTAUT model addresses the perceived expectations of technological acceptance of new technology in five constructs: PE, effort expectancy (EE), and SI (direct determinants of BI), as well FC and BI, which have a direct impact on use behavior [18]. This model was developed from the point of view of the implementation of new technologies in practice within specific organizations rather than the technology for mass consumer consumption [18-20]. The UTAUT is a model that is commonly tested using PLS-SEM and is an example of a reflexive partial least square (PLS) path model [18]. The exogenous latent

variables (PE, EE, and SI) have an effect on the endogenous latent variable (BI), which in turn affects the construct of use [18]. In addition, FC can also have a direct effect on use [18]. Moderator variables, which include age, gender, experience, and voluntariness of use, also affect the interaction between indicators and constructs [18,19].

BI is defined as the intention to use technology, and use is defined as the actual use [18]. BI predicts whether the technology in question will be adopted by the user in reality. The three direct determinants of BI to use technology are PE, EE, and SI. PE is defined as the degree to which an individual believes that using the system will help a person attain gains in task performance [18]. The EE construct is defined as the degree of ease associated with the use of the system, and SI is the degree to which an individual perceives the importance of others believing that they should use the new system [18]. FC is defined as the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system [18]. FC, PE, and EE are considered beliefs or the information a person has about an object, and SI is considered the subjective norm [18]. The UTAUT has well-established construct and content validity.

The UTAUT has been used in recent years as a model and framework for addressing technology use and acceptance in health care [11,12,21]. To date, most research on health technology using the UTAUT has involved the exploration of computerized medical records where the primary intended user, or end user, is a health care professional [11,12]. Studies that focus on the patient as the end user are beginning to emerge in the literature for specific demographics, such as older adults and youth, as well as specific populations with specific diagnostic categories such as cardiovascular disease, mental health, and diabetes. These studies evaluated the technology acceptance and usability of a multitude of digital and mobile health technologies, including health apps, wearable measurement technology, augmented reality, and web-based access to medical records. Hypotheses regarding the effect of the latent variables on BI and use have been formed regarding health care professionals as end users [11]. Studies focusing on the patient as the end user have demonstrated variable results, making the formation of a directional hypothesis challenging. In addition, studies examining technology acceptance models among military personnel are scarce [22,23].

Sample Eligibility and Size

The target study sample size was set at a minimum of 40 military members and veterans to account for a 20% dropout rate and allow for power at 32 participants. With 4 latent variables, for 80% significance at a 5% significance level, the sample size required for this study was 24 (R^2=0.50) [24].

Recruitment and Sampling

Recruitment of regular and reserve CAF military members and veterans was conducted by word of mouth among potential participants and their mental health providers as convenience and snowball sampling. Service providers supporting CAF military members and veterans, after being informed of the study via word of mouth and institutional email, informed patients who met the study inclusion and exclusion criteria. Potential participants who showed interest in participation were provided with a *Permission to Share Contact Information with the Research Team* form by their service provider. The completed forms were then forwarded to the research team. The researchers then contacted the potential participants via phone or email with a request for them to meet with the research team to learn more about the study and be evaluated to confirm eligibility to participate. Voluntary verbal and written informed consent were obtained from all CAF military members and veterans participating in the study.

Recruitment of the 3MDR therapists and operators was initiated via email circulated by key stakeholders associated with the 3MDR studies at 7 sites within Canada, the Netherlands, the United Kingdom, and the United States. 3MDR therapists and operators interested in participating in the study were instructed to email the research team to indicate consent to be contacted. Participants who met the inclusion criteria were forwarded a web-based consent form via a secure server (REDCap [Research Electronic Data Capture]) or hard copy, and an interview time was scheduled. Potential participants were informed that engagement in the study was voluntary.

Ethics Approval

This study received approval from University of Alberta Research Ethics Board (Pro00084466) and CAF Surgeon General Research Program (E2019-02-250-003-0003).

Inclusion and Exclusion Criteria

The 3MDR study participants included regular and reserved CAF military members and veterans aged 18 to 60 years under the care of a mental health clinician or service provider working at or associated with a Canadian Forces Base, an Operational Stress Injury Clinic, or Veterans Affairs Canada. All participants met the Diagnostic and Statistical Manual–Fifth Edition [25] criteria for PTSD diagnosis and had a score of ≥30 on the Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders–Fifth Edition Worst Month version. Participants were required to be stable on their current psychotropic medication for at least 4 weeks before entering the study. Individuals with comorbidities were included if they satisfied other inclusion and exclusion criteria. The participants were English speaking and able to provide informed written consent. The detailed 3MDR protocol has been previously published [8].

The 3MDR therapists and operators included in this study were English-speaking current or previous 3MDR therapists and operators who were trained by the developer of 3MDR. Participants must have completed a full course of 3MDR delivery with at least one patient (ie, had completed six 3MDR platform sessions using a VRE).

Measurements and Instruments

A demographic questionnaire was provided via email to participants through the REDCap server or in hard copy form. Variables collected from patient participants included age, sex, marital status, employment status, military status, enrollment era, rank, element, and years of service. For the 3MDR therapists

and operators, the collected variables included the participants' sex, profession, role in delivering 3MDR, years using 3MDR, location, VRE used, and level of education.

Two UTAUT questionnaires specific to the end users were developed specifically for this study. Version 1 (time point 0 [T0]) included questions in the future tense, whereas version 2 (time point 1 [T1]) included the same questions but was modified to reflect the past tense. The 12 questions' outcome measures were based on a Likert scale, with a score of 1 to 7 assigned to each question, with 1 being *strongly disagree* and 7 being *strongly agree*. A Likert scale with 7 points was used as the original UTAUT questionnaire by Venkatesh et al [18] used a 7-point scale. The maximum and minimum scores were 105 and 15, respectively. The 15 included questions addressed the five different constructs of the UTAUT (n=3, 20% PE; n=3, 20% EE; n=3, 20% SI; n=3, 20% FC; and n=3, 20% BI) that influence the use of technological innovations. Gender and age demographic information were also collected via the UTAUT questionnaire as they are modifier variables within the UTAUT model. The UTAUT questionnaire was provided only to those participants in the Canadian arm of a larger study who used the CAREN as the VRE.

Data Collection

The UTAUT questionnaires were completed by patients, therapists, and operators before and after 6 sessions of the 3MDR. The questionnaires were administered by a member of the research team before the qualitative semistructured interviews. Version 1 of the UTAUT questionnaire was presented before its first introduction to the CAREN and 3MDR. This version was future tense oriented and intended to measure expectations of the technology. After completing this questionnaire, the participants engaged in 3MDR for 6 sessions over approximately 6 weeks before completing the version 2 UTAUT questionnaire. This version was written in the past tense, intending to measure the actual intention to use technology once the participants had some experience with it.

A semistructured interview guide was developed to collect qualitative data. The research team conducted individual 40- to 60-minute semistructured interviews either in person or via telephone or a secure Zoom videoconferencing platform with the 3MDR patients, therapists, and operators. All interviews were recorded and subsequently transcribed by the research team.

Data Analysis

The research team conducted both quantitative and qualitative analyses. Quantitative analysis was based on the UTAUT, which uses a reflexive path model and PLS-SEM. The expectations from T0 and actual experience from T1 were statistically analyzed using PLS-SEM with a within-sample path model. Structural equation modeling (SEM) is considered a second-generation technique of multivariate analysis that allows researchers to incorporate unobservable variables measured indirectly by indicator variables [26]. PLS-SEM is variance based, as it accounts for the total variance and uses this to estimate the parameters [27]. In this method of analysis, the algorithm computes partial regression relationships in the measurement and structural models using ordinary least squares regression [26,27]. In an exploratory study such as this, data analysis is concerned with testing a theoretical framework from a prediction perspective, making PLS-SEM an ideal method for analysis [27].

The path model must be analyzed through measurement and structural model assessments [26,27]. Reflexive measurement models were evaluated based on internal consistency (Cronbach α), convergent validity (average variance extracted [AVE]), and discriminant validity (cross-loading analysis, Fornell-Lacker Criterion Analysis, and heterotrait-monotrait ratio) [26]. Evaluation of the structural model included an analysis of collinearity, significance, coefficients of determination (R^2), size and significance of the path coefficients, effect size (f^2), and predictive relevance (q^2). Goodness of fit was not assessed as this was an exploratory PLS path model with both reflexive (measurement model) and formative (structural model) components, rendering current model fit measurements unnecessary and inappropriate [28].

As PLS-SEM does not assume that data are normally distributed—it relies on a nonparametric bootstrap procedure to test the significance of the estimated path coefficients in PLS-SEM. With bootstrapping, subsamples are created with randomly drawn observations from the original set of data (with replacement) and then used to estimate the PLS path model [28].

SmartPLS [29] was used for the PLS analysis. The maximum iterations were set at 300 with +1 as the initial value for all outer loadings, and the path weighting scheme and the stop criterion at 1×10^7. Basic bias-corrected bootstrapping was used with 1000 samples at a significance level of $P<.05$. SPSS (2017) [30] was used for the analysis of descriptive statistics (mean and SD), and frequency counts, the Harman single-factor test, and a Wilcoxon signed-rank test was used to detect before and after changes in scores [31,32]. Webpower [33] was used to verify the nonnormality of the data before the analysis.

Qualitative interview data were subjected to thematic analysis (inductive and deductive) to identify, analyze, and report patterns (themes) in rich detail and allow the researcher to interpret various aspects of the topic [34]. Although inductive analysis allowed for themes to emerge from the data, deductive analysis was guided by the research questions regarding the perceived technology acceptance and usability of 3MDR among end users, including the perceived strengths, weaknesses, and recommendations for future use. Following a review of the data and completion of the secondary level of analysis, the themes were narratively summarized with the aim of organizing, describing, exploring, and interpreting the data. Key quotations were selected to substantiate these findings. To ensure the validity, reliability (dependability), and conformability of the analysis, researcher bias was clarified and bracketed, and an external audit of the analysis was conducted by other members of the research team [35-37]. The main theme with 3 subthemes emerged through thematic analysis of the data, which was relevant to the question of technology acceptability.

A concurrent parallel approach following a data transformation model was used in the data analysis process to convert data to compare quantitative statistical results with qualitative findings [38].

Results

Demographics

A total of 29 end users of 3MDR participated in this study. The demographic information of the military (3/29, 10%) and veteran (8/29, 28%) sample is displayed in Table 1 and of the 3MDR therapists (13/29, 45%) and operators (5/27, 17%) in Table 2. Of the total sample, only some military members and veterans (9/11, 82%), 3MDR therapists (4/13, 31%), and 3MDR operators (2/5, 40%) had the ability to fill out the pre- and post-UTAUT questionnaires. All participants (N=29) participated in the qualitative interviews. The sample was largely composed of men (19/29, 66%), which prevented the use of gender as a moderator variable in the UTAUT research model. In addition, the age of participants (young or middle-aged) did not demonstrate an effect in the research model and was, therefore, removed from the final PLS model.

Table 1. Sample demographic information of the military and veteran sample (N=11).

Characteristics	Participants, n (%)
Sex	
Female	1 (9)
Male	10 (91)
Age (years)	
30-39	2 (18)
40-49	6 (55)
50-59	3 (27)
Marital status	
Common law	2 (18)
Divorced	1 (9)
Married	5 (45)
Separated	1 (9)
Single	2 (18)
Employment status	
Employed	6 (55)
Unemployed	5 (45)
Military employment status	
Active military member	3 (27)
Veteran	8 (73)
Military enrollment era	
1976-1990	2 (18)
1991-2000	8 (73)
2001-2015	1 (9)
Rank	
Junior NCM[a]	6 (55)
Senior NCM	4 (36)
Unknown	1 (9)
Element	
Air	2 (18)
Land	9 (82)
Sea	0 (0)
Duration of military service (years)	
5-10	2 (18)
11-15	1 (9)
≥20	8 (73)

[a]NCM: noncommissioned member.

Table 2. Sample demographics of 3MDR[a] therapists and operators (N=18).

Characteristics	Participants, n (%)
Gender	
Man	9 (50)
Woman	9 (50)
Location	
Canada	7 (41)
The Netherlands	6 (35)
The United Kingdom	3 (17)
United States	2 (11)
Profession	
Occupational therapist	1 (6)
Clinical psychologist	6 (33)
Nursing	1 (6)
Mental health therapist	1 (6)
Mental health chaplain	2 (11)
Researcher	8 (44)
Technician	5 (28)
Military experience	
No	16 (89)
Yes	2 (11)
3MDR role	
Therapist	13 (72)
Operator	5 (28)
Experience with 3MDR (years)	
<1	5 (28)
1-3	9 (50)
3-5	3 (17)
3MDR system	
CAREN[b]	12 (67)
GRAIL[c]	3 (17)
CAREN Light	2 (11)

[a]3MDR: multimodal motion-assisted memory desensitization and reconsolidation.

[b]CAREN: Computer Assisted Rehabilitation Environment.

[c]GRAIL: Gait Realtime Analysis Interactive Lab.

UTAUT Analysis

The psychometric properties of the raw data of the survey items used to measure the latent variables are shown in Table 3. The difference between the means of the pre-post summative scores is a 0.82% increase. When mean pre-post total scores indicate <5% difference in change, it indicates that the expectations of the participants regarding technological innovation were met within the constructs tested [19]. Using a Mann-Whitney *U* test, no significant difference was found between the therapists and operators and participants (*P*=.55).

The results of the measurement model evaluation, including the factor analysis, internal consistency (Cronbach α), convergent validity (AVE), and composite reliability, are shown in Table 4 The factor indicators, known as the outer loadings or reflexive indicator loadings, should be ≥0.5, demonstrating that the indicator variable is a good measurement of the latent variable [26]. Only one outer loading for SI was below this threshold, indicating good indicator reliability (Table 4). All latent variables, with the exception of SI, demonstrated values >0.70 for both Cronbach α and AVE, which would indicate good validity and reliability of the latent variables [26,38]. Composite

reliability is displayed in Table 4 for all values, with the exception of SI ≥0.7, which is acceptable.

To evaluate discriminant validity, cross-loading, Fornell-Larcker Criterion, and heterotrait-monotrait ratio (Table 5) were used. These measures demonstrated good discriminant reliability for all the latent variables. FC demonstrated the highest correlation with BI based on this analysis. Potential common method bias was assessed with the Harman single-factor test, yielding cumulative and variance loadings <50%.

The measure of lateral collinearity of the structural model demonstrated inner variance inflation factor values <5 for 10 (66.67%) latent variables, with the exception of indicator variables number 1 (5.649), 2 (9.215), and 3 (5.410) for PE, 11 (5.584) for FC, and 14 (7.392) for BI. The coefficient of determination (R^2) measures the proportion of variance in a latent endogenous variable that is explained by other exogenous variables, expressed as a percentage. The explained variance (R^2) of the structural model was 0.410, demonstrating moderate predictive accuracy [26,38]. The effect sizes (f^2) for each latent variable are presented in Table 6. On the basis of this analysis of the structural model, EE had the largest path coefficient and effect size, indicating that it was the strongest predictor of BI, although this was not significant (P=.40; Table 5 and Figure 2). The predictive relevance (q^2) was >0 (0.026). None of the latent variables were statistically significant (P=.05).

A multigroup analysis with the PLS path model attempted to compare pre-post scores; however, this was not possible because of sample size restrictions. Instead, a Wilcoxon signed-ranks test was used to determine if there were any statistically significant changes in scores from before the technology was used (before to T0) to after the occurrence of the 3MDR course (after to T1). This showed a significant pre-post increase in the EE score only (Z=65; P=.004), with pre-post scores for all other variables yielding a nonsignificant change (Table 7). This demonstrates that the participants felt that the perceived ease of use of the technology was likely to increase after using 3MDR in the VRE, whereas the scores regarding the other latent variables remained largely unchanged from before to after.

Table 3. Psychometric properties of indicators used to measure latent variables.

Exogenous latent variables (indicators)	Values, mean[a] (SD[b])	Values, median[c]
Performance expectancy (3 indicators)		
• Using the CAREN[d] system improved my medical condition (patient) • Using the CAREN improved the medical condition of my patient (therapist and operator)	5.714 (1.082)	6
• Using the CAREN system had a positive effect on my medical condition (patient) • Using the CAREN system had a positive effect on the medical condition of my patient (therapist and operator)	5.643 (0.961)	6
• The CAREN system improved my quality of life (patient) • The CAREN system had improved the quality of life of my patient (therapist and operator)	5.357 (1.060)	6
Effort expectancy (3 indicators)		
• Interacting with the CAREN system was easy for me (patient, therapist, and operator)	6.429 (0.632)	6
• I believe my interaction with the system was clear and understandable (patient, therapist, and operator)	6.500 (0.516)	7
• I found the system easy to use (patient, therapist, and operator)	6.429 (0.516)	6
Social influence (3 indicators)		
• People who are important to me think that I should be involved in using the CAREN system (patient, therapist, and operator)	5.214 (1.496)	6
• I would use the CAREN system because my colleagues will use it too to improve their medical condition (patient) • I used the CAREN system because my colleagues used it too to improve the medical condition of my patient (therapist and operator)	3.714 (1.944)	6
• In general, my organization has supported my involvement in this initiative (patient, therapist, and operator)	6.286 (1.290)	6
Facilitating conditions (3 indicators)		
• I believe guidance was available to me during my interaction with the CAREN system (patient, therapist, and operator)	6.571 (0.507)	6
• I believe specialized instruction concerning the interaction with the CAREN system was available to me (patient, therapist, and operator)	6.500 (0.640)	6
• A specific person (or group) was available for assistance with CAREN system difficulties (patient, therapist, and operator)	6.500 (0.834)	6
Behavioral intentions (3 indicators)		
• I am willing to use the CAREN system in the next weeks (patient, therapist, and operator)	6.571 (0.632)	6
• I plan I would use the CAREN system if I am willing to do so (patient, therapist, and operator)	6.071 (1.246)	6
• I predict I will use the CAREN system in the future (patient, therapist, and operator)	5.857 (1.438)	6

[a]Raw mean scores of items within the scale, where each item is measured on a 7-point Likert scale; 1=strongly disagree, and 7=strongly agree. The higher the indicator score, the more agreement with the statement.

[b]SD of raw scores.

[c]Median scores of each question.

[d]CAREN: Computer Assisted Rehabilitation Environment.

Table 4. Results of the validity and reliability evaluation of the measurement model.

Latent variables, indicator variables, and outer loadings[a]	Cronbach α[b]	AVE[c,d]	CR[e,f]
PE[g]			
PE indicator			
0.951	.957	0.918	0.971
0.962	.957	0.918	0.971
0.961	.957	0.918	0.971
EE[h]			
EE indicator			
0.913	.797	0.698	0.872
0.662	.797	0.698	0.872
0.906	.797	0.698	0.872
FC[i]			
FC indicator			
0.953	.921	0.853	0.946
0.950	.921	0.853	0.946
0.866	.921	0.853	0.946
SI[j]			
SI indicator			
0.261	.460	0.455	0.978
0.983	.460	0.455	0.978
0.912	.460	0.455	0.978
BI[k]			
BI indicator			
0.915	.918	0.860	0.948
0.972	.918	0.860	0.948
0.893	.918	0.860	0.948

[a]Outer loadings ≥0.5 indicate indicator reliability. With a reflective model, internal consistency is measured by Cronbach α.

[b]Cronbach α ≥.7 indicates good indicator reliability.

[c]AVE: average variance extracted.

[d]AVE ≥0.5 indicates convergent validity.

[e]CR: composite reliability.

[f]CR ≥0.5 indicates good internal consistency.

[g]PE: performance expectancy.

[h]EE: effort expectancy.

[i]FC: facilitating conditions.

[j]SI: social influence.

[k]BI: behavioral intentions.

Table 5. Intercorrelations between study variables measured by the FLC[a] and HTMT[b,c].

Measures and latent variables	BI[d]	EE[e]	FC[f]	PE[g]	SI[h]
FLC					
BI	0.927	—[i]	—	—	—
EE	0.467	0.835	—	—	—
FC	0.378	0.529	0.924	—	—
PE	0.220	−0.262	0.062	0.958	—
SI	0.469	0.305	0.403	0.166	0.675
HTMT					
BI	—	—	—	—	—
EE	0.486	—	—	—	—
FC	0.371	0.695	—	—	—
PE	0.224	0.316	0.122	—	—
SI	0.574	0.595	0.468	0.391	—

[a]FLC: Fornell-Larcker Criterion.

[b]HTMT: heterotrait-monotrait ratio.

[c]Diagonals are the square root of the average variance extracted of the latent variables and indicate the highest in any column or row.

[d]BI: behavioral intentions.

[e]EE: effort expectancy.

[f]FC: facilitating conditions.

[g]PE: performance expectancy.

[h]SI: social influence.

[i]Not applicable.

Table 6. Structural model evaluation and hypothesis testing (prediction of BI[a]).

Relationship	Standard β (SE)	T value	*P* value	Effect size (f^{2b}; 95% CI)
PE[c]>BI	.293 (0.544)	0.869	.39	0.112 (−0.808 to 1.249)
EE[d]>BI	.455 (0.444)	0.812	.40	0.215 (−0.819 to 0.747)
SI[e]>BI	.278 (0.337)	0.734	.47	0.104 (−0.446 to 0.799)
FC[f]>BI	.007 (0.364)	0.014	.99	0.004 (−0.569 to 0.887)

[a]BI: behavioral intentions.

[b]Effect size (f^2) values <0.02 denote small effect size or predictive relevance.

[c]PE: performance expectancy.

[d]EE: effort expectancy.

[e]SI: social influence.

[f]FC: facilitating conditions.

Figure 2. Partial least square path model; path analysis model of Unified Theory of Acceptance and Use of Technology predicting BI. R^2=0.410. BI: behavioral intentions; EE: effort expectancy; FC: facilitating conditions; PE: performance expectancy; SI: social influence.

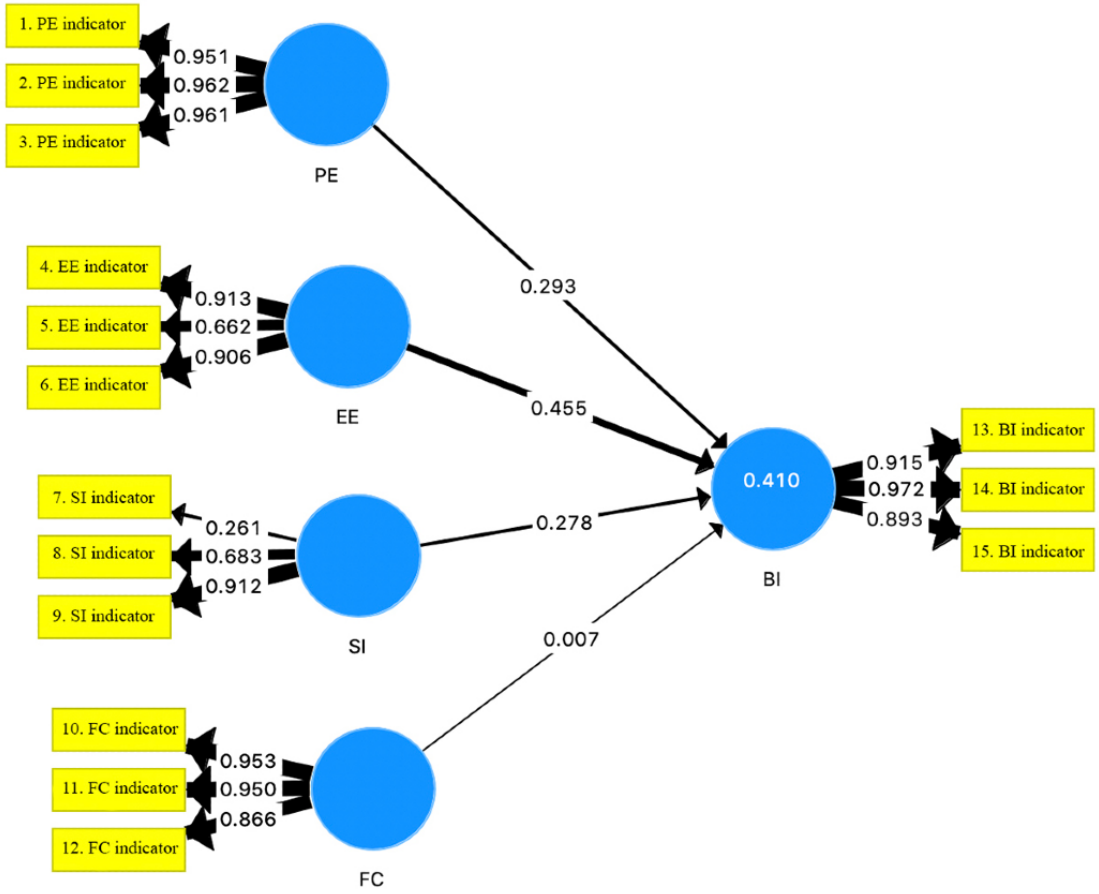


Table 7. Results of the Wilcoxon signed-ranks test for pre-post changes in latent variable ranks[a].

Latent variables	*Z* score (SE)	Significance (*P* value)
BI[b]	33 (9.715)	.57
EE[c]	65 (11.214)	.004[d]
FC[e]	32 (15.843)	.20
PE[f]	39.5 (11.147)	.56
SI[g]	13.5 (8.178)	.27

[a]Total: *Z* score 52.5 (SE 14.283); *P*=.62 (significance).

[b]BI: behavioral intentions.

[c]EE: effort expectancy.

[d]Statistical significance at *P*=.05.

[e]FC: facilitating conditions.

[f]PE: performance expectancy.

[g]SI: social influence.

Thematic Analysis

Overview

Thematic analysis was conducted by analyzing the responses to the open-ended questions from the UTAUT questionnaires and interviews after 3MDR for the participants, therapists, and operators. Three themes emerged: (1) feasibility and function, (2) technical support, and (3) tailored immersion (Table 8).

Table 8. Thematic analysis results of open-ended questions from the Unified Theory of Acceptance and Use of Technology questionnaire and qualitative interviews.

Theme	Illustrative quote
Feasibility and function	• "The look of the program, it just looks a bit outdated and its small, can be more attractive to make it more user-friendly...but it does work, then with the new session [we] have a.PDF file with all the pictures and associations and units of distress, walking speed average...[with] this new system [documentation] looks way better—not just a sheet with all the information...being able to download the data in a clean way." [T13] • "Improve resolution of photos." [T7]
Technical support	• "I suppose that there is a lot of moving pieces, so it is technology dependant, so if something goes down and there is a glitch it throws a monkey wrench in it. You need 'techy' people." [T1] • "I would just give the pictures to the operator, everything worked fine. I feel, like I said, I feel comfortable being in that, or working with that technology." [T5]
Tailored immersion	• "I want to make it more personalized, now the virtual reality has been chosen by a developer who thinks this is the correct virtual environment, but I think this is the wrong way around. I think we should let our patients decide which virtual environment they want to walk in." [T20] • "When people walk fast they are also walking fast to the picture. I would like to have an option to increase the length of the tunnel, so people can walk fast, but so the photo doesn't come up as fast." [T21]

Feasibility and Function

Overall, the CAF military members, veterans, therapists, and operators found that 3MDR was feasible and functional within their given environments for the purpose of the research study. That said, the end users, particularly therapists and operators, noted a number of items that they felt could be improved to enhance the overall functioning and patient experience in hopes that it would lead to better outcomes. Improvements to the technology that would assist with the delivery and functionality of 3MDR for therapists and operators included more streamlined documentation, ease of downloading of data, and overall intuitiveness of the software. This theme fits within the construct of EE, as many of the suggested modifications and improvements targeted to improve the ease of use of the overall 3MDR system elements [19]. In addition, some aspects, such as improving the quality of the images, correlate with PE, for which improved performance or outcomes is a potential goal.

Technical Support

Similarly, CAF military members, veterans, therapists, and operators identified that they felt satisfied with the level of technical support they received. The participants felt that the team was knowledgeable and able to operate the hardware and software with a high level of competence. When there were glitches, they could be troubleshooted and resolved within a reasonable amount of time. Therapists generally felt that the 3MDR operator was their main source of technological support and that the operators were proficient in providing this. The operators generally felt that they were able to receive support from other VRE operators globally, who had also used 3MDR. The experience of the operators with software and hardware support from vendors was variable, with some reporting that the vendor's expertise with technology geared toward physical health interventions rather than mental health was a barrier. The theme of technical support falls under the construct of FC as it regards that organizational and technical infrastructure exists to support the use of the system [19].

Tailored Immersion

The desire to customize the experience of 3MDR for the patient through technology was the strongest theme among the CAF military members, veterans, therapists, and operators. The vast majority of feedback regarding the technological aspects of 3MDR and the associated VRE provided recommendations on how population-specific stakeholders should be used to adapt the hardware and software for future tailoring of the 3MDR intervention. 3MDR therapists desired to have the ability to tailor aspects of the software, such as the length of the tunnel, length of the image exposure, default VRE, and the number of images, in real time based on their clinical observations and needs. Therapists and participants also identified the need to make 3MDR software and hardware accessible to those who may have reduced mobility and who may use a wheelchair. Tailored immersion is correlated with the construct of PE. The desired customization of software and hardware stems from the belief that the system will help the patient or participant attain gains in performance or improved outcomes regarding their PTSD symptoms.

Discussion

Principal Findings

In this preliminary study, the UTAUT model was used as the theoretical foundation for understanding the behavioral intention of CAF military members and veterans with crPTSD, as well as their therapists and operators, in using 3MDR. On the basis of the study results, 3MDR delivered within a VRE appears to be promising as a feasible, usable, and accepted technological intervention for end users, with EE being the most notable predictor of BI and deemed to be the most important to end users. Although the qualitative data support this, it is worth noting that none of the latent variables yielded statistical significance with PLS-SEM. There was also no significant difference detected between the patient end user (CAF military members and veterans) and the health care end user (therapists and operators) scores for PE, EE, SI, FC, or BI. The analysis of the open-ended questions and qualitative interviews revealed

several subthemes that can be attributed to the latent variables, including EE, PE, and FC of the UTAUT, as well as BI as a construct. To triangulate the quantitative and qualitative data, possible explanations for the results were formulated [37].

Overall, end users rated all the latent variables (PE, EE, FC, and SI) and BI favorably for the technological aspect of 3MDR. The data demonstrated that participants generally agreed or strongly agreed with the statements made in the UTAUT questionnaires, especially for the variables of PE, EE, and FC. The results of PLS-SEM analysis demonstrated good internal consistency, convergent validity, composite reliability, and discriminant validity of the indicators, with a moderate predictive accuracy of the model.

EE is the degree of ease associated with the use of a system [19]. EE had the largest path coefficient and effect size, indicating that it was the strongest predictor of BI when compared with the other latent variables. A statistically significant increase in EE was noted in the pre-post analysis, whereas the pre-post changes in the other latent variables were nonsignificant. A change of <5% (0.82%) in the before and after scores indicates that the expectations of the technological aspects of 3MDR were generally met or exceeded. This was further verified by a statistically nonsignificant difference in pre- and post-UTAUT questionnaire results based on the Wilcoxon signed-ranks test.

This is contrary to the hypothesis that FC is the strongest predictor based on previous literature regarding patients and health care professionals in a North American context [12,21]. However, previous literature has hypothesized that military organizations' approach to technology is to measure and maximize operator performance to increase system efficiency, which translates to success in military missions [23]. This may provide some insight into why the CAF military members and veterans felt that ease of use or efficiency was the most important aspect of a favorable user experience. Many of the qualitative quotes within the subthemes fell into the category of EE, demonstrating that 3MDR within the VRE was perceived as easy to use by all study end users, which was of utmost importance. Given that both the qualitative and quantitative data demonstrated that this latent variable was important to the end users in the study, it should be considered further in modifications and adaptations to 3MDR and the used VRE.

As previously mentioned, PE refers to the degree to which an individual believes that using the system will help the person attain gains in performance [19]. In the context of 3MDR within a VRE, performance is measured and communicated via clinical outcome measures, live biofeedback data, feedback from the therapist or patient, and the subjective experience of PTSD symptoms after the intervention session [9]. During the 3MDR platform sessions, the participant is limited to their intrinsic subjective insight to speculate on their performance without any immediate feedback on their performance. Only after the actual 3MDR sessions would the military member or veteran notice any changes in their PTSD symptoms and attribute them to 3MDR and thus their PE. In addition, therapists and operators do not have any direct feedback during the sessions on their own performance unless there is a technological event during the session in which they cannot reconcile, such as a technological malfunction. These notions may be logical explanations as to why PE did not register as an important factor in BI and did not demonstrate a significant pre-post change. It should also not be ignored that the indicator variables for PE demonstrated issues with lateral collinearity, as demonstrated by their variance inflation factors, which may affect the accuracy of this latent variable.

SI is the degree to which an individual perceives that it is important that others believe that they should use the new system [19]. As 3MDR was administered within a research study with limited persons present and confidentiality was maintained, it is unlikely that the patients perceived SI as being relevant specifically to the 3MDR technology. This was demonstrated to be an accurate hypothesis as SI was the least influential latent variable in the prediction of BI. Previous studies have demonstrated that SI is less likely to factor into the perceived acceptance and usability of health care technology than other latent variables for health care professionals [14,21,22]. On the basis of the previous literature, health care providers have demonstrated emphasis on PE, EE, and FC as constructs that influence BI and, therefore, use.

FC is the degree to which an individual believes that organizational and technical infrastructure exists to support the use of the system [19]. This latent variable did not have much impact on BI based on PLS-SEM, as predicted in the hypothesis. In the qualitative themes, technical support came through as a priority for end users in different ways, which would fall under the FC. For the 3MDR therapists, having the belief that the 3MDR operator had the infrastructure and knowledge to effectively run the VRE and facilitate the 3MDR software was important. Subsequently, this confidence in the operator was also transmitted to the participant, who had confidence in both the operator and the therapist that any technological challenges could be quickly and seamlessly fixed. It is logical that the 3MDR participants felt supported by their therapists, operators, study team, organization, and other facilitators in the immediate environment.

Limitations of Study

Although PLS-SEM is ideal for exploratory research and flexible with its nonparametric lack of assumptions regarding data distribution, several limitations need to be considered. First, measurement errors always exist to some degree and are challenging to quantify accurately. PLS-SEM bias refers to the tendency of the path model relationships to be frequently underestimated, whereas the parameters of the measurement model, such as the outer loadings, are overestimated when compared with covariance-based SEM. Measurement errors can also be introduced by variables such as the participants' understanding of the questionnaire items. In addition, the administrative burden of the study, when combined with other outcome measures attributed to the greater clinical trial with which this study was affiliated, may have caused some participants to rush through final questionnaires or experience fatigue and a reduced level of engagement. Second, the lack of global goodness-of-fit measures is an unavoidable drawback of PLS-SEM. Finally, the small sample size because of COVID-19

related shutdowns made it impossible to incorporate the moderator variables of age and gender, as was originally planned in the research model, and the desired sample power was not met (Figure 1). Despite these shortcomings, it is important to discuss preliminary findings and address technology acceptance and usability early in the process of implementing novel interventions to ideally detect and avoid problems with end user buy-ins, which could hinder the uptake and spread of potentially valuable innovations in health care settings. The research team will be continuing data collection to reach the desired sample size in the future.

Future Research

The technology acceptance and usability of 3MDR within a VRE, as well as other interventions using technology, warrant evaluation within military and civilian health care contexts and at multiple user levels, including the patient, health care professional, and organization. This also extends to the use of web-based health care technologies where the patient is in a separate location from the health care professionals—a practice that is becoming increasingly widespread, especially in the wake of a global pandemic [17,18]. Future research that could support the advancement of 3MDR might include studies with larger samples to allow for the ability to incorporate moderator variables such as age, gender, voluntariness of use, and experience, as well as to use other models of technological acceptance and usability. In addition, the exploration of the utility of the UTAUT as a model for health care technology warrants continued investigation in both civilian and military settings, where research is extremely scarce [22,23]. Equally, the improvement of 3MDR hardware and software has evolved at a rapid pace, further complicating accurate research. Since this study, a number of the themes mentioned by end users have already been addressed, and tailored immersions and customizability of the hardware and software for other trauma-affected populations are being trialed. As 3MDR evolves to be more accessible and uses new hardware such as wearable VR, acceptability and usability perceptions of end users will need to be considered. In addition, a cost analysis of 3MDR would also be beneficial to study, as this also affects the implementation of technological innovation in health care. Finally, future research is needed to address its acceptability and effectiveness among other trauma-affected populations, which may improve accessibility to 3MDR.

Conclusions

Numerous military personnel and veterans from around the globe who have returned from deployment continue to struggle with the symptoms of PTSD. Despite the plethora of research, publications, and attention that PTSD has received in recent years, many questions remain regarding the complexities of treating the psychological symptoms attributed to this diagnosis. 3MDR challenges traditional conventions and configurations. It is important to incorporate the study of technology acceptance and usability into the implementation of novel VR-supported health care processes to ensure that technological advances aimed at assisting patients will be embraced by the primary intended users. This is important at the micro, meso, and macro levels, especially within unique organizational contexts such as military and health care systems. 3MDR appears to be a promising intervention for crPTSD, with good acceptability by end users, including CAF military members and veterans, as well as 3MDR therapists and operators. The future for the usability of 3MDR is promising, and new and exciting intervention avenues for crPTSD will emerge because of continued research. As civilian and military health care systems increasingly integrate technological innovations to improve the services and care provided to their patients, research must continue to address questions of technological acceptance of the intervention before its wide-scale adoption.

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Conflicts of Interest

EV created the 3MDR but would not stand to benefit financially were it to be adopted into routine clinical practice.

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Abbreviations

3MDR: multimodal motion-assisted memory desensitization and reconsolidation
AVE: average variance extracted
BI: behavioral intentions
CAF: Canadian Armed Forces
CAREN: Computer Assisted Rehabilitation Environment
crPTSD: combat-related posttraumatic stress disorder
EE: effort expectancy
FC: facilitating conditions
PE: performance expectancy
PLS: partial least square
PLS-SEM: partial least squares structural equation modeling
PTSD: posttraumatic stress disorder
REDCap: Research Electronic Data Capture
SEM: structural equation modeling
SI: social influence
T0: time point 0
T1: time point 1
UTAUT: Unified Theory of Acceptance and Use of Technology
VR: virtual reality
VRE: virtual reality environment

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Original Paper

Message Frame–Tailoring in Digital Health Communication: Intervention Redesign and Usability Testing

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Abstract

Background: Message frame–tailoring based on the need for autonomy is a promising strategy to improve the effectiveness of digital health communication interventions. An example of a digital health communication intervention is Personal Advice in Stopping smoking (PAS), a web-based content-tailored smoking cessation program. PAS was effective in improving cessation success rates, but its effect sizes were small and disappeared after 6 months. Therefore, investigating whether message frame–tailoring based on the individual's need for autonomy might improve effect rates is worthwhile. However, to our knowledge, this has not been studied previously.

Objective: To investigate whether adding message frame–tailoring based on the need for autonomy increases the effectiveness of content-tailored interventions, the PAS program was redesigned to incorporate message frame–tailoring also. This paper described the process of redesigning the PAS program to include message frame–tailoring, providing smokers with autonomy-supportive or controlling message frames—depending on their individual need for autonomy. Therefore, we aimed to extend framing theory, tailoring theory, and self-determination theory.

Methods: Extension of the framing theory, tailoring theory, and self-determination theory by redesigning the PAS program to include message frame–tailoring was conducted in close collaboration with scientific and nonscientific smoking cessation experts (n=10), smokers (n=816), and communication science students (n=19). Various methods were used to redesign the PAS program to include message frame–tailoring with optimal usability: usability testing, think-aloud methodology, heuristic evaluations, and a web-based experiment.

Results: The most autonomy-supportive and controlling message frames were identified, the cutoff point for the need for autonomy to distinguish between people with high and those with low need for autonomy was determined, and the usability was optimized.

Conclusions: This resulted in a redesigned digital health communication intervention that included message frame–tailoring and had optimal usability. A detailed description of the redesigning process of the PAS program is provided.

Trial Registration: Netherlands Trial Register NL6512 (NRT6700); https://www.trialregister.nl/trial/6512

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KEYWORDS

digital health communication; web-based computer tailoring; smoking cessation intervention; message framing; usability testing

Introduction

Background

In 2018, a total of 22.4% of the adult Dutch population indicated to be occasional smokers [1]. In 2017, an attempt to quit smoking at least once was undertaken by 35.7% of Dutch smokers; however, most smokers did not succeed in stopping smoking permanently [2]. Therefore, it is important to provide effective interventions to support smokers to stop smoking and prevent the relapse of smoking. For instance, computer-tailored interventions appear to be a promising and cost-effective solution [3-6].

Computer tailoring refers to an automated communication strategy intended to reach every individual with tailored messages by adapting these messages to the individual's unique characteristics and his or her behavioral and motivational state [3,7,8]. Generally, computer tailoring focuses on tailoring the content of health communication interventions [9-11]. An example of a web-based computer-tailored intervention is Personal Advice in Stopping smoking (PAS) [12]. This is a computer-tailored smoking cessation program, which provides tailored feedback based on respondents' answers to web-based questionnaires based on the Integrated-Change (I-Change) Model [13]. The I-Change Model combines insights from several behavior change theories, such as the Transtheoretical Model [14], Theory of Planned Behavior [15], Social Cognitive Theory [16], and the Health Belief Model [17]. As such, the I-Change Model assumes a person's behavioral intention to be the most proximal predictor of behavior. In turn, this behavioral intention is proposed to be predicted by three motivational constructs: attitude (represented by perceived advantages and disadvantages of the behavior), perceived social influence (composed of perceived social norms, social modeling, and social pressure), and self-efficacy (a person's perceived ability to perform the behavior). Furthermore, the I-Change Model includes several premotivational factors: predisposing (eg, past behavioral experiences), awareness (eg, knowledge), and information (eg, message source) factors. Finally, the I-Change Model suggests that although a positive behavioral intention is needed for behavior change to occur, several postmotivational factors play a role in bridging the gap between intention and behavior [18], with perceived barriers to change widening this gap and ability factors (eg, skills and the formation of action plans) narrowing this gap.

Given its theoretical grounding, the PAS program starts with a baseline assessment consisting of questions on sociodemographic characteristics, smoking behavior, and addiction level, but, then, continues to ask questions about the respondent's intention to quit smoking, attitude, social influence, self-efficacy beliefs, and action and coping planning on how to stop smoking and prevent the relapse of smoking [12]. Then, the PAS participants receive tailored feedback messages based on their answers [12]. Questions and feedback messages alternate, meaning that, participants answer a question—or a set of related questions—and immediately receive the feedback message associated with their answer and, then, receive the next question. At the end of the program, participants receive an overview of their tailored feedback messages, which can be printed and sent to them through email if desired. A detailed description is provided elsewhere [12,19].

An investigation of the effects of PAS among Dutch smokers indicated a significant effect on smoking abstinence, reported 6 weeks after the initiation of participation in the program. However, 6 months after participation initiation, significant intervention effects could no longer be found [19]. In other web-based computer-tailored interventions to promote health behavior, intervention effects also declined after intervention completion [20]. Therefore, and because overall effect sizes remain small [3,20], it is worth exploring additional strategies that might enhance intervention effects. A proposed strategy to improve the effectiveness in addition to tailoring *what* information is presented (ie, content tailoring), is tailoring *how* this information is presented, which is known as message frame–tailoring [10].

Message frame–tailoring refers to an integration of the message frame theory [21] and theory around tailoring of health information [22]. According to the message frame theory, the manner in which information is presented is referred to as framing of information, which contains 2 aspects: selection and salience [21]. Selection refers to choosing several aspects to communicate, and salience is defined as "making a piece of information more noticeable, meaningful, or memorable" [21]. Selecting elements to communicate and making them more (or less) salient to the audience will capture the audience's attention and, as a result, make the information more likely to be read and processed. This is where tailoring theory comes in, as tailoring of information is also done to increase the likelihood that information is read, processed, remembered, and acted upon. Tailoring is "any combination of information or change strategies intended to reach one specific person and increase the personal relevance of the information for this particular person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment" [8]. Relevance of the presented information for an individual is a key concept in this definition, as personally relevant information may lead to more in-depth information processing [22]. Combining message frame theory with theory around tailoring leads us to the definition of the main concept described in this paper, that is, message frame–tailoring, which is "adjusting the perspective when formulating a message based on people's individual needs" [10]. In this study, message frames were tailored to respondents' *need for autonomy*, a theoretical concept derived from self-determination theory (SDT) [23]. Tailoring health messages to respondents' need for autonomy is important because health messages should not only be read and considered as personally relevant but, above all, should encourage behavior change by increasing the recipients' autonomous motivation for change. According to SDT, autonomous motivation plays an important role in enhancing the initiation and maintenance of health-related behavior [24]. To be autonomously motivated, people need to experience a sense of volition and freedom to make their own choices. On the other hand, people are likely to not feel autonomously motivated when they feel controlled and experience pressure to think, feel, or behave in a manner that has been imposed on

them [25]. In SDT, this prerequisite for autonomous motivation is called fulfilling the need for autonomy [23]. However, according to SDT, individual differences in the need for autonomy exist regarding health and health-related decision-making. For example, some people prefer to choose their own path toward lifestyle improvement, whereas others prefer to be guided by clear-cut expert advice [26,27]. To meet these individual differences in the need for autonomy, the manner of information provision in health messages can be tailored based on this need, to accommodate an individual's associated processing and communication style preferences and further increase the personal relevance of the message [10].

In our operationalization, message frame–tailoring based on the need for autonomy consists of 2 components: language (ie, autonomy-supportive or controlling) and choice (ie, provision of choice or no choice) [28,29]. Autonomy-supportive language, or noncontrolling language, is defined as "a vocalization that would allow choice or support self-initiation" [30] and can be used for individuals with high need for autonomy. Autonomy-supportive language encourages individuals to take responsibility for their own behavior and make decisions based on their own values [28,30]. This involves minimizing pressure [28] and using words such as *could*, *might*, and *would*. Controlling language is defined as "a vocalization to pressure a person to behave (or think or feel) a particular *way*" [30] and can be used for individuals with low need for autonomy. Controlling language is characterized by the use of commands, orders, imperatives, and suggestive questions [30]. Examples are words such as *must*, *should*, and *ought*. Choice is operationalized as offering participants the option to receive additional information about a certain topic [31]. Tailoring message frames to a person's need for autonomy may enhance the motivation to change and maintain health-related behavior. As such, message frame–tailoring based on the need for autonomy has been suggested as a promising avenue to explore further [10,26,27,32]. However, to date, to the best of our knowledge, no health-related computer-tailored intervention has been reported that incorporates message frame–tailoring based on the need for autonomy, except the study by Smit et al [10].

Objective

To investigate whether adding message frame–tailoring based on the need for autonomy increases the effectiveness of content-tailored interventions, the PAS program [12] was redesigned to incorporate message frame–tailoring. This paper describes the process of extending framing theory, tailoring theory, and SDT by redesigning the PAS program to include message frame–tailoring. The redesigning process was conducted in close collaboration with communication science students, experts, and the actual end users (ie, smokers).

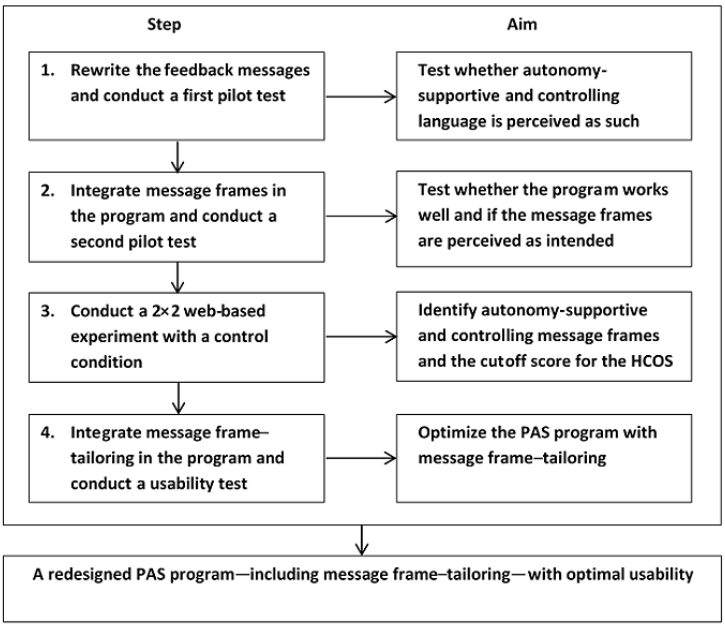
Methods and Results

Overview

The process of redesigning the original PAS program to incorporate message frame–tailoring consisted of four steps: (1) the feedback messages were rewritten in an autonomy-supportive and a controlling manner and a first pilot test was conducted, (2) the message frames were integrated into the program and a second pilot test was conducted, (3) a web-based experiment with a 2×2 between-participants design with a control condition was conducted, and (4) message frame–tailoring was integrated into the program and a usability test was conducted. An overview of the steps is presented in Figure 1, and the 4 steps are described in detail in subsequent sections. OverNite Software Europe provided technical support and usability advice during the redesign process.

The study was registered in the Netherlands Trial Register (NL6512/NRT-6700).

Figure 1. Overview of the redesign process. HCOS: Health Causality Orientations Scale; PAS: Personal Advice in Stopping smoking.



Rewrite the Feedback Messages and Conduct a First Pilot Test

To tailor message frames based on the need for autonomy, the message frames needed to be developed. The feedback messages of the original PAS program were rewritten using autonomy-supportive and controlling language strategies. To test whether the language strategies were perceived as such, a pilot test was conducted among communication science students. After consenting to participate, students were randomly assigned to either evaluate the autonomy-supportive or controlling messages. The students received a questionnaire with 5 messages to be reviewed using a 5-point response scale, ranging from very autonomy-supportive to very controlling [33]. Students were also able to write comments on each message in a textbox. A total of 19 students participated (mean age 23.2, SD 1.44 years; 2/19, 11% were men; 15/19, 79% were nonsmokers). Of the 19 students, 10 (53%) students received the autonomy-supportive messages and 8 (42%) students received the controlling messages. Quantitative results were analyzed using an independent sample *t* test (2-tailed) using SPSS (IBM Corp), and the qualitative comments were inspected to identify relevant comments regarding language use.

As the 5-point scale ranged from very autonomy-supportive (rating=1) to very controlling (rating=5), we expected lower scores for the autonomy-supportive messages than the controlling messages. Results showed significantly lower scores for the autonomy-supportive messages (mean 2.46, SD 0.62; $P<.001$) than the controlling messages (mean 3.68, SD 0.32), which means that participants detected the language manipulation as intended. However, based on participants' comments and inspection of the differences between messages that had high or low scores and those that had average scores, we further emphasized communication style (autonomy-supportive vs controlling). The main change consisted of emphasizing with *signal words* on the type of language style—autonomy-supportive or controlling—used at the beginning of each message (eg, starting the message with "you must..." in a controlling message).

Subsequently, the second message frame element, choice, was added. The following question was included 6 times throughout the program: "Do you want to receive these tips?" which could be answered with "yes" or "no." In addition, participants were asked if they wanted to choose a quit date themselves. Furthermore, participants could choose whether and for which potential difficult situations they wanted to formulate coping plans to refrain from smoking in these situations.

Integrate Message Frames in the Program and Conduct a Second Pilot Test

Adding message frames (autonomy-supportive vs controlling language and provision of choice vs no provision of choice) to the feedback messages of the original PAS program resulted in four versions of the program: (1) autonomy-supportive language and no choice, (2) autonomy-supportive language and choice, (3) controlling language and no choice, and (4) controlling language and choice. Besides the 4 message frames, 1 control condition was added to the program, consisting of generic smoking cessation advice with a neutral message frame (ie, the message frame was not manipulated and was the same as in the original smoking cessation intervention) and no content tailoring (ie, the messages were not tailored based on participants' answers). Following is an example of a control message:

> *When smokers are stressed, tensed, or dreary, they often find it difficult not to smoke. To help you with this, we give you a few tips. If you find yourself feeling emotional and wanting a cigarette, it's good to do something else. You can take a walk: the outside air may do you good. Or you can exercise. This helps you to change your mind and reduces the desire for a cigarette.*

Examples of feedback messages for the 4 message frames are presented in Table 1. For more examples, refer to the study by Altendorf et al [31].

The next step in the redesign process was conducting a second pilot test to investigate the intervention from experts' and smokers' perspectives. Totally, 5 experts (4/5, 80% men) and 11 smokers (8/11, 73% men) participated in the usability test and the subsequent interviews. The experts were working as professionals or researchers in the fields of health communication, public health, eHealth intervention development, and smoking cessation support. First, participants received a link to the website and were instructed to complete the program, while paying attention to the comprehensibility of the program and the feedback messages. Subsequently, a researcher interviewed the participants on the following topics: time taken to conduct the program; comprehensibility of instructions, questions, and answer categories; and awareness of the message frame used. Participants were rewarded with a shopping voucher worth €10 (US $11). During the usability tests and the interviews, the researcher took notes. Results were discussed within the research team to determine whether changes to the program were required to resolve issues mentioned in the feedback.

The participants took between 20-60 minutes (average 35 minutes) to complete the program. As the introduction was perceived as very long, it was shortened. In addition, some questions seemed to be unclear; therefore, a brief instruction was added. Some questions needed to be reformulated (eg, using more familiar words and not using double negatives). In addition, participants wished to receive the summary of feedback messages by email; thus, this option was added. The message frames were generally perceived as intended; therefore, no modifications were made regarding this aspect. After incorporating these changes, the PAS program with message frames was ready for use in the next step.

Table 1. Examples of feedback messages for the different message frames.

Condition and process	Autonomy-supportive language	Controlling language
No choice		
Message	You answered that you will succeed in not smoking if you are stressed, tensed, or dreary. You doubt whether you will succeed in not smoking when you are angry. We would like to offer you some tips. If you notice that you are emotional and would like to have a cigarette, you can try to do something else. For example, you could take a walk: the outside air might do you good. Or you could exercise. This might help you to change your mind and it reduces the desire for a cigarette.	You think that you will succeed in not smoking if you are stressed, tensed, or dreary. You doubt whether you will succeed in not smoking when you are angry. You need to do something else when you are emotional and want a cigarette. Take a walk: the outside air often works well. Or go exercise: this should help to change your mind and reduces the desire for a cigarette.
Choice		
Message 1	You answered that you will succeed in not smoking if you are stressed, tensed, or dreary. You doubt whether you will succeed in not smoking when you are angry. Below, you can choose whether you would like to receive some tips on what you can do when you are emotional and would like to have a cigarette.	You think that you will succeed in not smoking if you are stressed, tensed, or dreary. You doubt whether you will succeed in not smoking when you are angry. Below, you can choose whether you would like to receive some tips on what you can do when you are emotional and would like to have a cigarette.
Choice question[a]	Do you want to receive these tips?	Do you want to receive these tips?
Answer	Yes	Yes
Message 2	If you notice that you are emotional and would like to have a cigarette, you can try to do something else. For example, you could take a walk: the outside air might do you good. Or you could exercise. This might help you to change your mind and it reduces the desire for a cigarette.	You need to do something else when you are emotional and want a cigarette. Take a walk: the outside air often works well. Or go exercise: this should help to change your mind and reduces the desire for a cigarette.

[a]If respondents answered "no" to the choice question, the intervention continued without the provision of the tips.

Conduct a 2×2 Web-Based Experiment With a Control Condition

To tailor message frames based on individuals' need for autonomy, we had to identify (1) the most autonomy-supportive and the most controlling message frame based on participants' perceived autonomy support and (2) the cutoff point to distinguish between people with high need for autonomy and those with low need for autonomy. Therefore, a web-based experiment with a 2×2 (language: autonomy-supportive vs controlling; choice vs no choice) between-participants design with a control condition was conducted. An extensive description of the method and results of this experiment is provided elsewhere [31]. However, we summarize the most important outcomes below.

Participants' need for autonomy was measured using the Health Causality Orientations Scale (HCOS), consisting of 4 vignettes, each of which contained 3 items that could be answered on a 5-point Likert scale (1=low need for autonomy; 5=high need for autonomy) [34]. The primary outcome measure was participants' perceived autonomy support, which was measured with the Virtual Climate Care Questionnaire, consisting of 15 items that can be answered on a 7-point Likert scale (1=low perceived autonomy support; 7=high perceived autonomy support) [35]. Therefore, the HCOS measured participants' general need for autonomy and the Virtual Climate Care Questionnaire measured how the participants perceived the messages in the PAS program; that is, whether they perceived them as autonomy-supporting.

Results showed that participants' perceived autonomy support was generally high (mean 3.46, SD 0.78). On the basis of the results, it was not possible to identify the most autonomy-supportive and the most controlling message frames. Therefore, we decided to follow SDT principles, according to which the provision of choice and the use of autonomy-supportive language enhances an individual's autonomy [23]. Additional inspection of the data supported this decision, as it appeared from the evaluative comments that especially participants with high need for autonomy mentioned that the word *must* was salient in the advice and not appreciated. Furthermore, especially participants with high need for autonomy chose to receive more information when offered choice and wanted to choose a quit date themselves more often than participants with low need for autonomy.

Regarding participants' need for autonomy, the results also showed a high overall score (mean 3.87, SD 0.76). The Johnson-Neyman procedure was followed to identify the need for autonomy score at which the three-way interaction of the need for autonomy, language use, and provision of choice on perceived autonomy support changed from insignificant to significant, resulting in a range of 3.8 to 4.4. The qualitative data showed that participants with need for autonomy ≥3.8 more often made unappreciative comments about not being able to set a quit date themselves and about the word *must* used in their feedback messages. On the basis of these results, 3.8 was chosen as the cutoff point of the HCOS to distinguish between individuals with high need for autonomy and those with low need for autonomy.

On the basis of the evaluative comments from participants, some changes were implemented. First, the participants perceived a period of 2 weeks to set a quit date as very soon. In the original PAS program, the quit date was set 4 weeks after participation initiation, but based on results that showed the importance of immediate action when a quit attempt was considered [36,37], it was decided to shorten the period to 2 weeks. To clarify this to the participants, a brief explanation about the benefits of setting a quit date within a short period was added. Participants in the no choice conditions were still given a quit date within 2 weeks, whereas participants in the choice conditions were offered an additional question of whether they wanted to choose a quit date within 2 weeks. On the basis of their answer ("yes," "no," or "I am not sure yet"), the participants would see a different calendar to set a quit date (ie, a calendar with dates within a time span of 2 weeks, a calendar with dates with a time span of >2 weeks, or a commenting section to enter a date). Second, participants wished to comment on their former quit attempts. Therefore, a question was added about the number of previous quit attempts, followed by a feedback message in which the participants were asked to note why former quit attempts did not succeed and what they have learned from this. Third, participants wanted to receive more information about smoking cessation support tools (eg, medication or nicotine patches), the costs of smoking, and the use of replacing smoking with other oral stimuli (eg, chewing sunflower seeds). New feedback messages regarding these topics were added. Fourth, it was noted that the program was not suitable for a tablet or mobile phone; therefore, the program was made compatible with different devices. This included automatic adjustments to the screen size, alignment of the buttons (eg, forward and print) and pictures, and centering error messages. Finally, as the participants seemed to have difficulties in answering questions that were presented in matrices, all questions were presented as separate questions.

Integrate Message Frame–Tailoring in the Program and Conduct a Usability Test

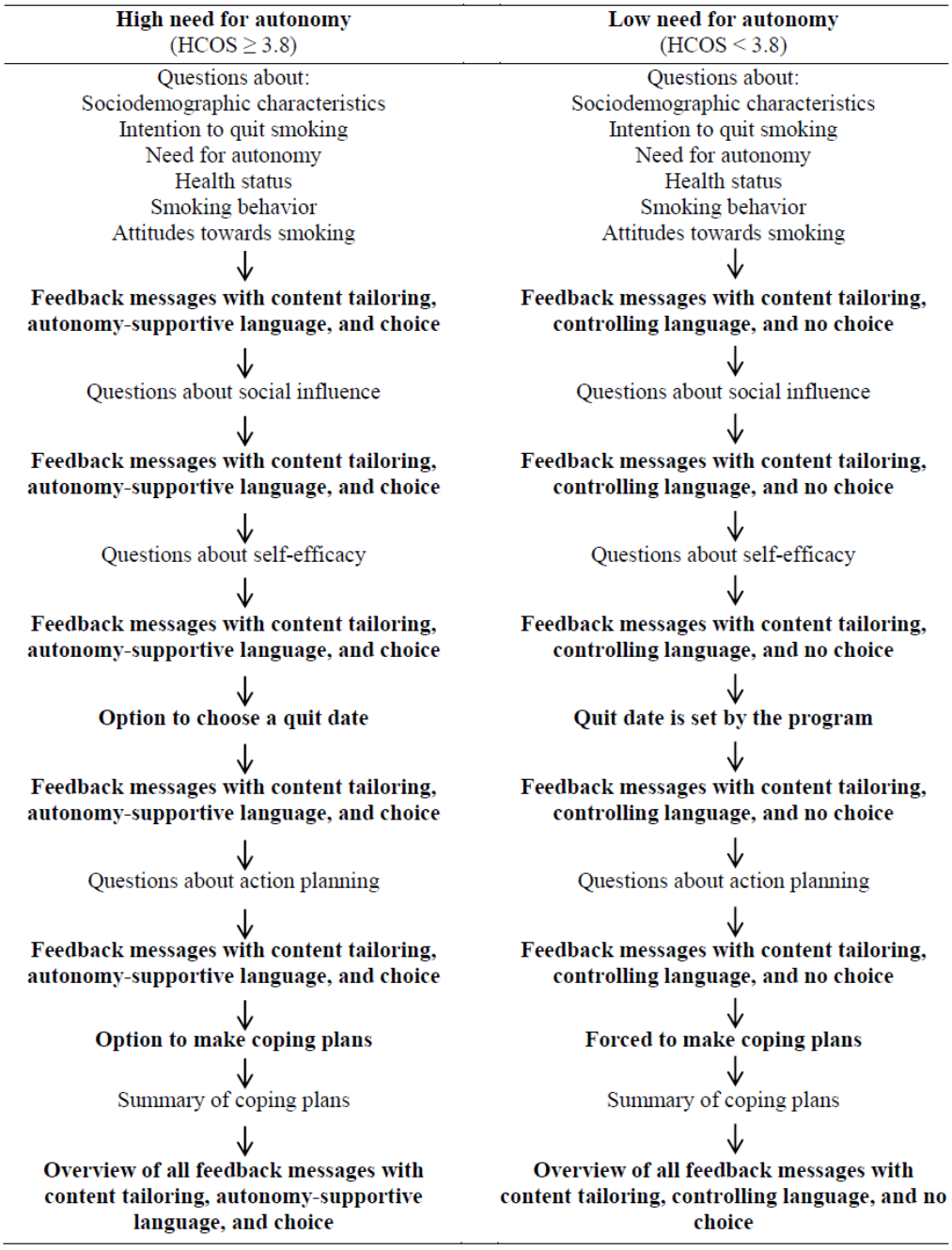
On the basis of the results of the web-based experiment as described in the previous step, the PAS program was developed into a program with message frame–tailoring. The message frame for participants with high need for autonomy (HCOS score ≥3.8) consisted of feedback messages with autonomy-supportive language and choice, and the message frame for participants with low need for autonomy (HCOS score <3.8) consisted of feedback messages with controlling language and no choice. The flow of the redesigned PAS program with content tailoring and message frame–tailoring is presented in Figure 2.

To optimize the PAS program with the tailored message frames, a usability test among experts and smokers was conducted. Regarding user experience, it is argued that, besides the aspect of ease of use, perceived usefulness is also important, which refers to the extent to which the content of the program satisfies the information needs of the participant [38]. Therefore, we aimed to not only identify problems with the use of the program but also to test the content of the program from experts' and smokers' perspectives. Experts were working as professionals or researchers in the fields of health communication, public health, eHealth intervention development, and smoking cessation support.

Both smokers and experts were asked to evaluate the program using the think-aloud method, based on which they were asked to verbalize their thoughts while using the program [39]. As verbalizing one's thoughts while conducting a task is not common, the participants first received a brief task to practice. After completing the usability testing, a semistructured interview was conducted with the smokers to evaluate the program and further explore the problems mentioned. Examples of questions are, "What do you think of the layout of the program?" and "Which are the two most important elements that could be improved?" To identify 80% to 90% of the user issues, 5 to 9 end users were needed [40,41]. The semistructured interviews with experts were based on the heuristic evaluation method [39,42]. The heuristic evaluation method consists of ten heuristic principles, such as simple and natural dialogue, speak the user's language, consistency, and good error messages [42]. To identify most problems by using the heuristic evaluation method, 3-5 experts were needed [39].

As the program will be used on different devices, smokers and experts were instructed to use the program on a laptop, tablet, or mobile phone. The entire procedure took approximately 1 hour to complete, and the participants were rewarded with a shopping voucher worth €25 (US $27.5). Experts and smokers were recruited through the network of the research team. A total of 5 experts (2/5, 40% were men; 4/5, 80% were nonsmokers) and 7 smokers (mean age 31.86, SD 14.15 years; range 20-62 years; 4/7, 57% were men) participated in the usability test. All sessions were video-recorded, which were selectively transcribed and coded using ATLAS.ti 8.0 [43]. The data were analyzed according to the content analysis approach [44]. Deductive content analysis allows us to go beyond general findings and validate theories and models that guided the research. Inductive content analysis allows for inclusion of codes and categories that are derived from the data in an iterative process [45]. First, codes were derived using the heuristic evaluation method [39,42]. Then, the transcripts were thoroughly read and coded. In the next step, categories were identified and ordered into themes that represented the answers to the research questions. When new themes emerged from the collected data, they were added to the analysis [45]. Initially, 2 transcripts were coded independently by 2 coders (ISvSK and MBA). Disagreements were resolved through discussion, and after reaching consensus, 1 coder continued coding the remaining transcripts (ISvSK).

Figure 2. Flowchart of the redesigned Personal Advice in Stopping smoking program that incorporates both content tailoring and message frame–tailoring based on the need for autonomy. HCOS: Health Causality Orientations Scale.



As we aimed to test the content of the program and identify problems with its use, user experience was divided into 2 dimensions: the content of the program and the usability of the program. Modifications that were made regarding the content of the program included the following: replacing difficult words, shortening the introduction and instructions, reformulating questions, changing the labels of answer categories, and adding the quit date to the summary. Modifications that were made regarding the usability of the program included the following: adding a sidebar to show the different parts of the program, modernizing the logo and the colors, displaying only the core messages in bold font, aligning the illustrations on a mobile phone, adding a red frame signaling an unanswered question on the mobile phone, and adding the option to directly add the quit date to a personal agenda. An overview of the codes, subcodes, definitions, examples, and modifications is presented in Table 2.

It is worth noting that participants also wished to receive feedback messages with more illustrations and that some participants wished for shorter feedback messages with more bullet points. However, as the original feedback messages were effective in supporting smokers to quit smoking [19] and making large modifications to this content would mean retesting the effectiveness of the feedback messages, it was decided to stay as close to the original feedback message format as possible.

Table 2. Overview of the codes, subcodes, definitions, examples, and modifications of the usability test.

Code and subcode	Definition	Example	Modifications
1–Language use			
Level and style	Words, concepts, or sentence structures that are unclear or ambiguous. In addition, the use of formal language.	"I don't even know what this is." [smoker]	Difficult words were replaced or explained. Spelling mistakes were corrected.
Amount of information	The amount of information provided in the program, especially in the instruction, introduction, and informed consent.	"Uhm...well...it's a lot of text, I know that a lot of low educated people really hate a lot of text." [expert]	The introduction and instruction were shortened.
2–Questions and answers			
Number and content of questions	The number, relevance, understandability, and topics of the questions in the program.	"I have to read this sentence four times [...] I find it hard to follow. So, I don't know what I have to answer." [expert]	Questions were reformulated.
Answer categories	The answer possibilities, way of answering, and unclarity and inconsistencies regarding scale questions.	"Maybe you also need some kind of range here, don't you? Never, uhm, a few times, very often or I try to do it regularly." [smoker]	The labels of some answer categories were changed. Some answer options were changed from a textbox to a dropdown menu.
3–Feedback messages			
Content and number	The number, length, topics, and content of the feedback messages.	"This is good, good arguments here, especially at the end. With time and money, that is good." [smoker]	A short explanation of the summary of the feedback messages was added. In addition, the quit date was added to the summary.
Credibility and relevance	The concreteness, reliability, and credibility of the feedback messages and whether the messages are perceived as true and suitable to support in quitting smoking.	"They are all things that I have already read and heard, but it is all true." [smoker]	No modifications were made regarding this aspect.
Illustrations	The support of illustrations to the text and the number of illustrations.	"I do indeed see here a picture of someone who gives some kind of support, so that does support the text." [expert]	No modifications were made regarding this aspect.
4–Tailoring			
Content tailoring	The relevancy of the content for a particular participant.	"I think it's good that for each answer category a story is told what really applies." [smoker]	No modifications were made regarding this aspect.
Message framing	The use of autonomy-supportive or controlling language and the provision of choice.	"You must, there is a lot 'must.' I don't feel like quitting smoking anymore." [expert]	No modifications were made regarding this aspect.
5–Program structure			
Structure	The order and structure of the different parts of the program and whether the order is clear. In addition, the feedback that a participant receives via the progress bar and whether it is possible to return to the program.	"Step 3. [...] I don't remember so well that I saw step 2, but those steps are a bit out of the blue. Maybe I should be taken a little more by the hand." [expert]	To make the structure of the program clearer, a sidebar was added, which continuously shows the different parts of the program throughout the completion process, including which part a participant is working on. In addition, the titles of the different parts were made larger.
Instructions	The unclarity of content of the instructions, especially concerning how to complete the program and how to answer the questions.	"How to complete the questionnaire. [...] Well, all basic things." [smoker]	No modifications were made regarding this aspect.
Duration	The duration of the program and time required to complete the program.	"It is long, so maybe people will get bored at some point." [expert]	No modifications were made regarding this aspect.
6–Layout			

Code and subcode	Definition	Example	Modifications
Design	The font size and style, colors, logos, buttons, and illustrations.	"It is very straightforward, so well...there is little...it will be made more beautiful? It is not very inviting." [smoker]	A modern logo was developed and modern colors were used. In addition, the buttons were changed into modern icons. As the print button seemed to appear too often, this was resolved; some inconsistencies in the font size were also resolved.
Readability	The readability of the text, with regard to the layout of the pages, the feedback messages, the summary of the feedback messages, and sentence alignment.	"Shorter sentences, only graphic now in terms of location, you read more easily. This sentence is easier to read than, for example, this sentence, whereby your eye has to go all the way from left to right." [smoker]	The alignment of the sentences was modified. Furthermore, it seemed unclear which information was displayed in bold font; thus, it was decided to display only the core message in bold font.
Layout on various devices	The layout of the program on the various devices (ie, laptop, mobile phone, and tablet).	Someone with a mobile phone: "There is also a picture next to it, that makes the text a bit narrower." [expert]	Changes were made to the alignment of the illustrations on mobile phones.
7–Error messages			
Time of appearance	Whether the error messages appear at the right time.	"I have to give an answer, so that works." [expert]	A red frame signaling an unanswered question was added on mobile phones.
Content	The content of the error messages and whether they are perceived as helpful.	"It was clear that it was about the age question. It was not mentioned that it was about the age question, but I think that's also not possible in an error message." [expert]	No modifications were made regarding this aspect.
8–Features			
Calendar	The appearance and ease of use of the calendar.	"You can also place a link here, or something like that so that it will be added to your agenda automatically." [smoker]	The option to directly add the quit date to a personal agenda was added.
Print or email	The option to print or email the summary of the feedback messages and whether this works. In addition, the layout of the printed summary.	"I like that I can print it because it's a lot to read at once." [expert]	No modifications were made regarding this aspect.

After incorporating the modifications in response to the usability test, the redesign process was completed. The redesigned PAS program—including message frame–tailoring—is shown in Figures 3 and 4. For a comparison with the original interface, refer to the study by Smit et al [19]. This redesigned PAS program has been evaluated in a real-life setting for effectiveness and cost-effectiveness; results of the effectiveness evaluation were recently published elsewhere [46], and the results of the cost-effectiveness evaluation are currently being prepared for publication.

Figure 3. Screenshot that shows the colors, logo, and sidebar of the redesigned Personal Advice in Stopping smoking program.

Figure 4. Screenshot that shows the print button and enlarged titles of the redesigned Personal Advice in Stopping smoking program.

Ethics Approval

This study was approved by the institutional review board of the University of Amsterdam (reference number 2017-PC-7599).

Discussion

Principal Findings

This study aimed to extend the message framing theory, tailoring theory, and SDT by including message frame–tailoring in a digital health communication intervention. In addition to tailoring *what* information is presented (ie, content tailoring), we wanted to improve the effectiveness of a digital health communication intervention by tailoring *how* this information is presented (ie, message frame–tailoring). This paper offers a detailed description of the incorporation of message frame–tailoring in a web-based computer-tailored smoking cessation program, PAS. The PAS is taken as an example to explore the effects of—in addition to the known effects of content tailoring—the promising strategy of message frame–tailoring [10]. The process of incorporating message frame–tailoring was conducted in close collaboration with

experts and smokers, and a usability test was conducted to optimize the redesigned program. An extensive description of the various methods through which experts' and smokers' opinions were included throughout the redesigning process is provided. If the redesigned PAS program is more effective in supporting smokers in their quit attempt than the original PAS program, adding message frame–tailoring to other digital health communication interventions also might be of value.

Potential Strengths

This study has several potential strengths. First, to the best of our knowledge, this study is the first to explore message frame–tailoring in web-based computer-tailored health communication. The existing literature on message framing mostly includes studies on gain and loss framing, focusing on positive (health) outcomes and costs in terms of health loss, respectively. Regarding tailoring, so far, scholars have mainly tailored the content of web-based interventions; that is, adjusting *what* health information is provided based on individuals' current health behavior or their self-reported scores on known predictors of the desired health behavior (change) [9]. To build on tailoring theory, advance the strategy of web-based computer tailoring, and further increase its effectiveness, it has been argued that tailoring *how* information is provided, in addition to tailoring *what* information is given, appears to be a promising strategy [10,32]. To our knowledge, message frame–tailoring based on the need for autonomy and operationalized as differences in the provision of choice and the use of autonomy-supportive or controlling language has not been studied previously. By developing a redesigned PAS program including message frame–tailoring, we were able to test whether message frame–tailoring increases the effectiveness of the PAS program. The results of the effect evaluation were published elsewhere [46]. These results indicated that message frame–tailoring based on the need for autonomy can be an effective additional strategy to include in the computer-tailored interventions in addition to content tailoring, but only for people with high need for autonomy and not for people with low need for autonomy. Regarding cost-effectiveness, the combination of message frame–tailoring and content tailoring in web-based smoking cessation programs seems to have high potential for both cost-effectiveness (ie, considering smoking abstinence as the outcome of interest) and cost-utility (ie, considering quality of life as the outcome), thereby providing good value for money. However, when the willingness to pay for each abstinent smoker becomes high (ie, ≥€5000 [≥US $5500]), the addition of message frame–tailoring might not be worth the effort and only content tailoring is preferred. A manuscript reporting on the results of this economic evaluation is currently in the preparation phase. Given these results, it is plausible that adding message frame–tailoring to other web-based computer-tailored or digital health communication interventions will also increase their effectiveness and cost-effectiveness, at least for people with high need for autonomy. This is important because the overall effect sizes of such interventions are generally positive but small [3], limited evidence suggests that such interventions may be cost-effective [4-6], and the internet is highly accessible [47,48]. This paper provides detailed insight into how to integrate this novel tailoring strategy with more traditional tailoring efforts. Furthermore, the application of message frame–tailoring can support the offering of person-centered care by providing feedback in a manner that matches the individual's preferences and needs, which is one of the key characteristics of person-centered care [49,50]. Moving beyond the tailoring of *what* information is provided to additionally tailoring *how* this information is provided takes into account individual differences in communication style preferences. As such, message frame–tailoring can be considered as the next step in the field of tailored and person-centered health communication. Self-management support interventions, such as the PAS program, have shown to be the most frequent category of interventions with the potential to result in positive health impact for patients with chronic diseases [51]. Therefore, continuation of (research) efforts aimed at the development of improved versions of such programs is warranted.

Another strength concerns the approach taken in developing the redesigned PAS program: scientific and nonscientific experts, smokers, and communication science students were actively involved throughout the process. Involving different types of stakeholders, including end users, in research removes barriers regarding the implementation of research findings and interventions, such as the redesigned PAS program, in practice [52,53]. By describing the process of involving participants in redesigning the PAS program and the valuable insights we have gained as a result, we aim to encourage researchers to involve participants in the development and redesign process of digital health communication interventions.

Finally, we chose to use an existing, already effective intervention [19]. Using an existing intervention as a starting point and adding an additional tailoring strategy to it is a cost-effective and efficient approach because the intervention does not have to be developed from scratch and the time and money that has already been invested are optimally used.

Potential Limitations

This study also has few limitations. First, in the 2×2 web-based experiment, most participants' need for autonomy was moderately high. This may not be representative of the need for autonomy in the general population; therefore, the cutoff point of the need for autonomy, based on which the message frame is tailored, might be very high, resulting in suboptimal message frame–tailoring. In addition, research has shown that the need for autonomy might be different for different groups of people [46]. More research is needed to assess the optimum cutoff point for the need for autonomy and to test whether this point differs between subgroups.

Second, we mainly focused on the communication of information in an autonomy-supportive or controlling manner, especially pertaining to the type of words used; for example, *could* in the autonomy-supportive condition and *must* in the controlling condition. Moreover, in the case of the quit date, we also tried to design the way of responding in an autonomy-supportive versus controlling manner; that is, the smokers in the choice conditions received different types of calendars to enter their quit date based on their individual choices in this regard; for example, a calendar to choose a date from or a commenting section in which they could enter the

date themselves, whereas smokers in the no-choice conditions were given a prespecified date by the intervention. This method of designing could be further explored as a way to make the interface more compatible with the individual's need for autonomy. For instance, more questions can be designed such that individuals with high need for autonomy would receive open entry fields, whereas individuals with low need for autonomy would receive limited multiple-choice answers. In addition, how the program is run can be adapted to an individual's need for autonomy; for example, a fixed order for those with low need for autonomy and a self-determined order for those with high need for autonomy. More attention to the design of the intervention as tailored to an individual's need for autonomy could possibly further increase the effects of this and similar interventions—therefore, such possibilities warrant more attention in future research.

Third, although using an existing, already effective intervention is a cost-effective and efficient approach, it also has limitations. For example, some participants requested shorter feedback messages with more bullet points or more illustrations. However, as we wanted to be able to make a comparison between the effectiveness of the PAS program with and that without message frame–tailoring, it was decided to make no adaptations regarding these aspects. By changing the content of the program, it would not be possible to attribute any differences in effectiveness between the original PAS program and the redesigned PAS program to the effect of message frame–tailoring. When choosing between developing a new intervention from scratch and redesigning an existing effective intervention, we recommend considering both the cost-effectiveness and efficiency of the approaches and the potential limitations of the approaches, such as (not) being able to meet all participants' needs regarding the usability of the program.

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Conflicts of Interest

None declared.

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Abbreviations

HCOS: Health Causality Orientations Scale
I-Change: Integrated-Change
PAS: Personal Advice in Stopping smoking
SDT: self-determination theory

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Original Paper

The Ontario Electronic Consultation (eConsult) Service: Cross-sectional Analysis of Utilization Data for 2 Models

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Abstract

Background: The Ontario electronic consultation (eConsult) service allows a primary care provider (PCP) to access specialist advice through 2 models: the direct-to-specialist (DTS) model, where PCPs select a specialist from a directory, and the Building Access to Specialists Through eConsultation (BASE)–managed specialty service, where PCPs choose a specialty group and are assigned a specialist from a qualified pool based on availability.

Objective: The aim of this study is to examine patterns of use between the 2 models of eConsult delivery.

Methods: We conducted a cross-sectional analysis of utilization data collected from eConsults completed between October 2018 and September 2019. Cases were grouped based on the model used for submission (ie, BASE or DTS). Each model was assessed for the number of cases over time, specialty distribution, proportion resulting in new or additional information, impact on PCPs' decisions to refer, and billing time.

Results: PCPs submitted 26,121 eConsults during the study period. The monthly case volume increased by 43% over the duration of the study, primarily in the BASE model (66% compared to 6% for DTS). PCPs were able to confirm a course of action that they originally had in mind in 41.4% (6373/15,376) of BASE cases and 41.3% (3363/8136) of DTS cases and received advice for a new or additional course of action in 54.7% (8418/15,376) of BASE cases and 56.3% (4582/8136) of DTS cases. A referral was originally contemplated but avoided in 51.3% (7887/15,376) of BASE cases and 53.3% (4336/8136) of DTS cases, originally contemplated and still needed in 19.4% (2986/15,376) of BASE cases and 17.7% (1438/8136) of DTS cases, and neither originally contemplated nor needed in 21.7% (3334/15,376) of BASE cases and 21.9% (1781/8136) of DTS cases.

Conclusions: Both eConsult models had strong uptake. Use patterns varied between models, with the majority of growth occurring under BASE, but survey responses showed that both models provided similar outcomes in terms of new information offered and impact on decision to refer.

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KEYWORDS

eConsult; access to care; utilization; consultation; primary care provider; direct-to-specialist; Ontario; healthcare system

Introduction

Canadians face prolonged wait times for specialist care in comparison to other developed countries. In Canada, patients do not access specialty care directly in most cases. Rather, they must first see a primary care provider (PCP), a family physician or nurse practitioner, who completes an assessment and refers them to a specialist, often one in their professional network or with whom they have had a positive experience [1-4]. Once the referral is complete, patients must wait for an appointment, which for some specialties can take months or even years [5,6]. However, electronic consultation (eConsult) can greatly improve access to specialist advice in many cases by allowing requesting providers, usually PCPs, to communicate directly with specialists electronically regarding a patient's care, often avoiding the need for a traditional consultation. Studies of eConsult services have found that they improve access, lower costs, and deliver high rates of patient and provider satisfaction [7,8].

As early as 2010, regional services in Ontario provided access to specialist advice for PCPs operating in their jurisdictions [9]. However, the availability of these services varied geographically, with some PCPs limited in their ability to access services in their regions. This changed in 2018, when Ontario's Ministry of Health supported the creation of the Ontario eConsult Service, building on existing programs and expanding their reach across the entire province [10].

The Ontario eConsult Service provides access to 2 models of multispecialty provider-to-provider eConsult. In the direct-to-specialist (DTS) model, PCPs select an individual specialist from a directory and send their question to them directly via the eConsult platform [11]. In the Building Access to Specialists Through eConsultation (BASE)–managed specialty service model, PCPs select a specialty group from a menu and the case is then assigned to an individual specialist by the operations team, which has oversight of availability, timeliness, and the specialists added to the pool [9]. To our knowledge, this is the only eConsult service that offers PCPs 2 models of accessing specialist advice on one eConsult platform [12,13].

In this study, we aimed to identify and compare patterns of use between the 2 models of eConsult delivery available through the Ontario eConsult Service. A better understanding of how PCPs use each model will help inform the service's continued expansion and provide insight for innovators looking to establish an eConsult service tailored to their jurisdiction's needs.

Methods

Design

To identify patterns of use between models, we conducted a cross-sectional analysis of utilization data emerging from the Ontario eConsult Service.

Setting

The Ontario eConsult Service operates in Canada's most populous province, with a population of over 14 million people (nearly 40% of all Canadians) [14] served by approximately 15,000 family physicians (ie, those with general practice as their primary or secondary specialty) [15] and 4000 registered nurse practitioners [16]. Like all Canadian provinces, Ontario oversees a federally funded but provincially run Medicare program, which provides health care services to residents free of charge. At the time of this evaluation, the province was divided into 14 health regions known as Local Health Integration Networks (LHINs). Each LHIN coordinated health care services for the needs of its unique population. As of 2020, this model was phased out and the 14 LHINs were reorganized as 5 regions.

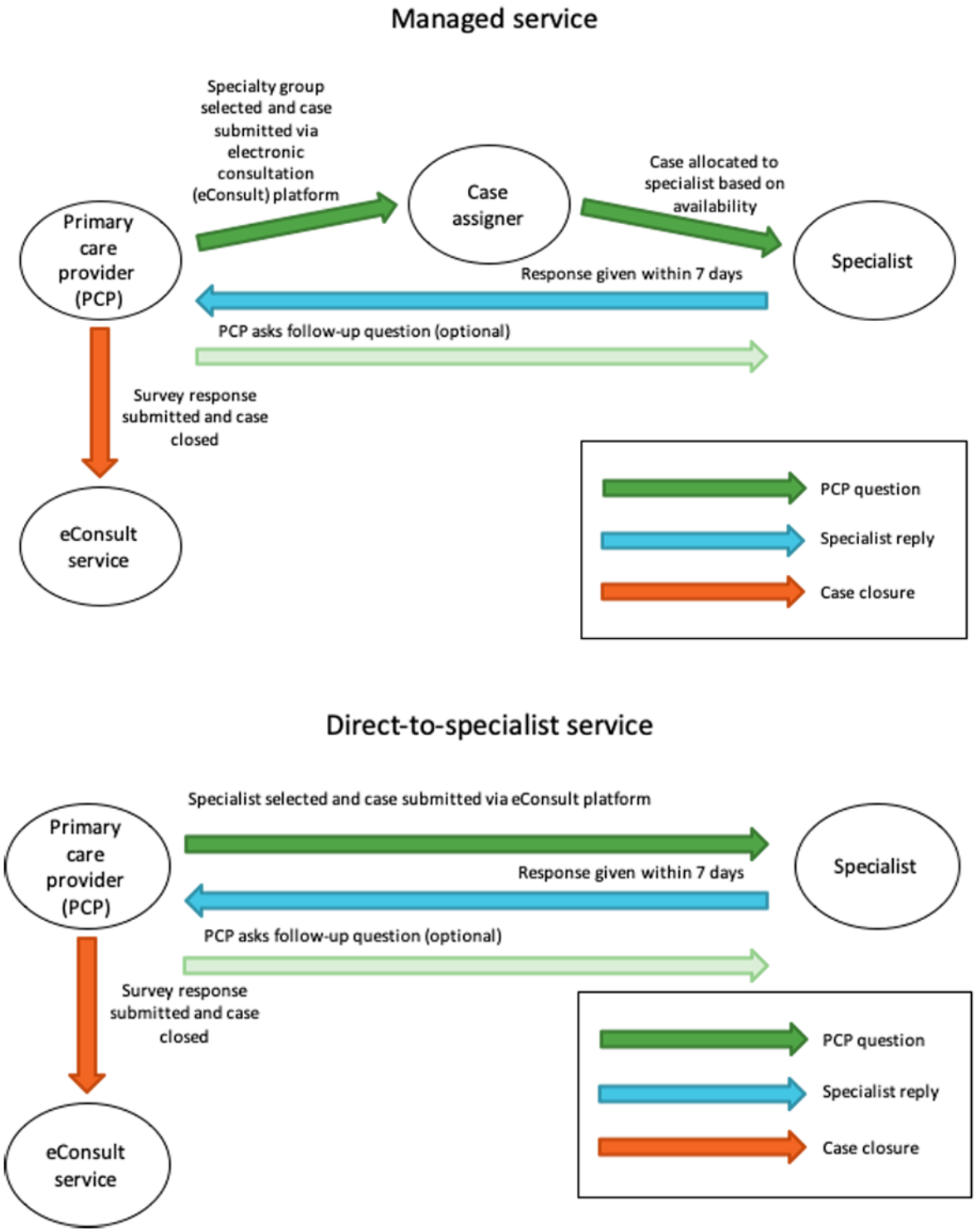
The Ontario eConsult Service

The Ontario eConsult Service was launched in June 2018 and is supported by the province's Ministry of Health. Prior to the launch of the new service, there were 2 provincial services with different models of specialist access. The Champlain BASE service, which began as a regional pilot project in the Champlain LHIN (comprising Ottawa and Eastern Ontario) in 2010 before expanding to other regions, notably the South East LHIN, provides specialist access through the managed specialty service model. The Ontario Telemedicine Network (OTN) was launched in 2012 in Toronto and uses the DTS model. The newly formed Ontario eConsult Service was launched on the OTN and includes both specialist access models. Both services are provider-to-provider, meaning that patients do not use them directly, but PCPs submit questions to specialists concerning their care. It is the PCP's choice which way they access a specialist for each case.

All practicing specialists in Ontario can join the service through the DTS model. BASE operates using a pool of specialists recruited based on need, geographic location, and experience. The number of specialists in each specialty group ranges from 2 to 18 (Multimedia Appendix 1). Specialists in a BASE group may also participate in the DTS option.

The Ontario eConsult Service operates at no charge to PCPs and patients. Specialists are remunerated at an hourly rate prorated to their self-reported billing time. PCPs are also remunerated via the publicly funded Ontario Health Insurance Plan at a flat rate per case. To use the service, PCPs log into the site via an OTN account, select the eConsult model they want to use (DTS or BASE), choose a specialist (DTS) or specialty group (BASE), enter their question, and submit (Figure 1). DTS cases are sent to the specialist; under the BASE model, a case is assigned to a specialist within the chosen group, ensuring cases are evenly distributed among the group's specialists while taking into consideration current availability, desired case volume, and other special factors (eg, specialists who only see patients of a certain age or from a specific region). To build communities of practice, BASE operates regionally where possible, referring PCP questions to specialists operating in their region.

Figure 1. Workflow chart for electronic consultation cases submitted through the Building Access to Specialists Through eConsultation (BASE) and direct-to-specialist models.



In either model, the specialist receives a notification and responds to the question within 1 week by providing guidance, recommending a referral, or requesting more information. Discussion can proceed iteratively back and forth until the PCP is satisfied with the response, at which point they complete a mandatory closeout survey assessing the case's outcome, impact on decision to refer, and educational value. An optional free-text field allows for additional comments.

Outcomes

Cases were grouped based on the model used for submission (BASE or DTS). Each model was assessed for the number of cases over time, proportion of cases resulting in new or additional information, impact on PCPs' decisions to refer, and billing time.

Data Collection

We used routine utilization data automatically collected for each case. This includes user ID, region, billing time, cost, specialty, specialist, and results of the mandatory closeout survey asking PCPs to identify (1) whether the response confirmed their original course of action or provided them with new or additional information and (2) what impact it had on their decision to refer the patient. Our team extracted data from all cases submitted over a 1-year period between October 2018 and September 2019. Subspecialties from both models were grouped into the most relevant specialty (eg, cases sent to pediatric dermatology were grouped as dermatology).

Data Analysis

We conducted a descriptive analysis (eg, mean, median, count, and distribution) to compare metrics between models of care. A time series analysis was conducted to observe growth and changes in the proportion of cases provided to the DTS model compared to the BASE model. Data were grouped by each PCP's LHIN to observe trends in different regions of the province. Additional statistical analyses for time billed and response intervals were performed using the statistical software package SPSS Statistics (version 27.0; IBM Corp). Time billed at or under 25 minutes by specialists (in discrete time blocks of 5, 10, 15, 20, and 25 minutes) and time billed over 25 minutes (continuous variable) were analyzed independently. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to test the normality of the data. Due to the data not being normally distributed, the nonparametric Mann-Whitney U test and Pearson chi-square test were used to assess the differences between groups.

Ethics Approval

This project was approved as a quality improvement initiative by the Ottawa Hospital Health Sciences Network Research Ethics Board.

Results

PCPs submitted 26,121 eConsults to the Ontario eConsult Service during the study period, out of which 24,178 eConsults were responded to by a specialist during the study period. (Table 1). A total of 65% (16,985/26,121) of cases were submitted through the BASE model. A total of 2880 requesting providers submitted at least 1 eConsult, of whom 39.3% (n=1133) used BASE exclusively, 19.1% (n=551) used DTS exclusively, and 41.5% (n=1196) used both. Of the 2880 requesting providers, 27.8% (n=801) submitted 10 or more eConsults during the study period. Among this smaller, high-volume user group, 21.2% (170/801) used BASE exclusively, 5.2% (42/801) used DTS exclusively, and 73.5% (589/801) used both models.

Table 1. Comparison between BASE[a] and DTS[b] models.

Electronic consultation model	Cases submitted (N=26,121), n (%)	Mean time billed in minutes	Response interval in days	Referral avoidance, n (%)[c]	Referral initiation n (%)[c]	Cases cancelled or declined (n (%)[d]
BASE	16,985 (65)	17.5	1.14	7887 (51.3)	494 (3.2)	749 (4.4)
DTS	9136 (35)	21.7	0.99	4336 (53.3)	257 (3.2)	261 (2.9)

[a]BASE: Building Access to Specialists Through eConsultation.

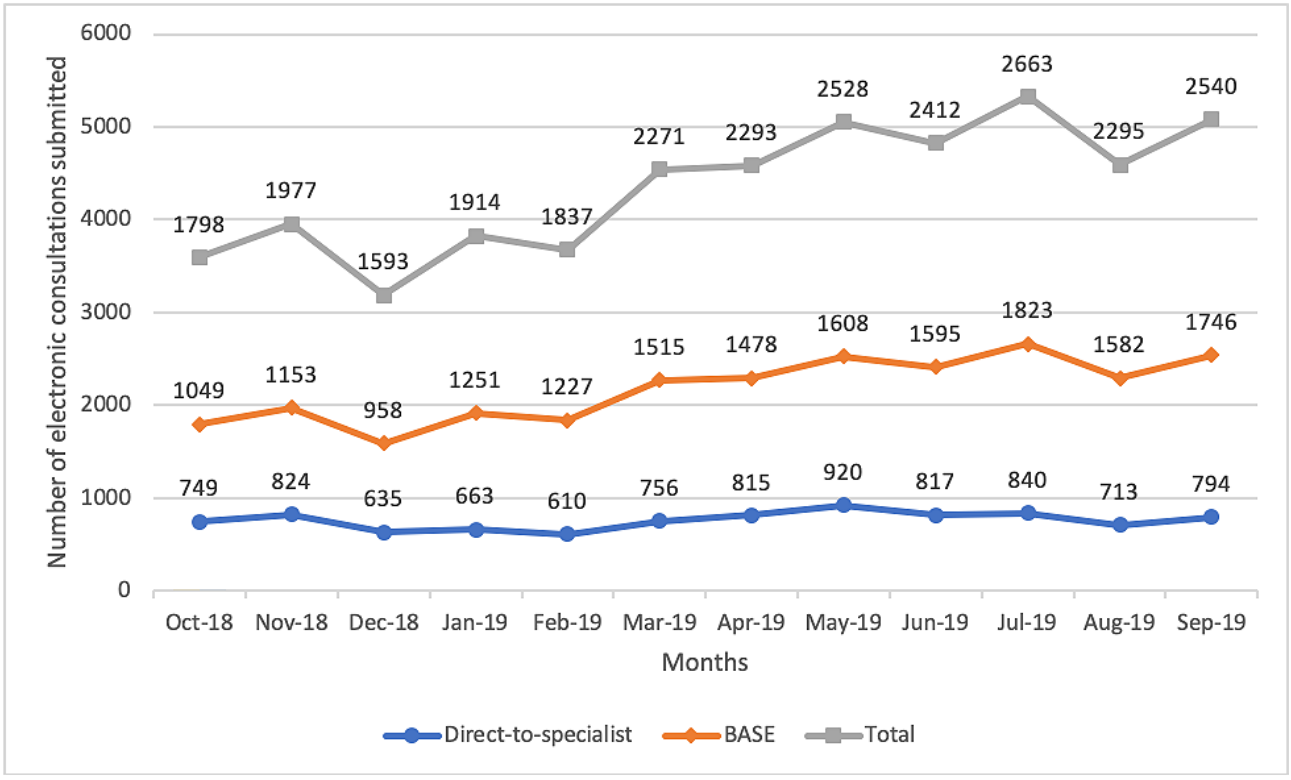
[b]DTS: direct-to-specialist.

[c]For this category, n=15,376 for BASE and n=8136 for DTS; percentages have been calculated accordingly.

[d]For this category, n=16,985 for BASE and n=9136 for DTS; percentages have been calculated accordingly.

The number of eConsult cases submitted increased by 41% over the duration of the study (Figure 2). Most of this increase occurred for BASE, which saw a 66% increase in use compared to a 6% increase in the use of DTS. The service also demonstrated a growth in the number of active users, defined as those who submit or answer 3 or more eConsults in a 6-month period. The service saw a 48% increase in active PCPs and a 28% increase in active specialists.

Figure 2. Historical time series of cases submitted to the Building Access to Specialists Through eConsultation (BASE) and direct-to-specialist models.



The 20 most frequently accessed specialties are outlined in Figure 3. Only 2 of the specialties in this group, psychiatry and internal medicine, had a higher proportion of DTS cases than BASE cases. Figure 4 outlines the proportion of BASE cases in the first and last 6 months of the study period for the top 20 specialties.

Figure 3. Proportion of cases involving the 20 most frequently accessed specialties for the Building Access to Specialists Through eConsultation (BASE) and direct-to-specialist models.

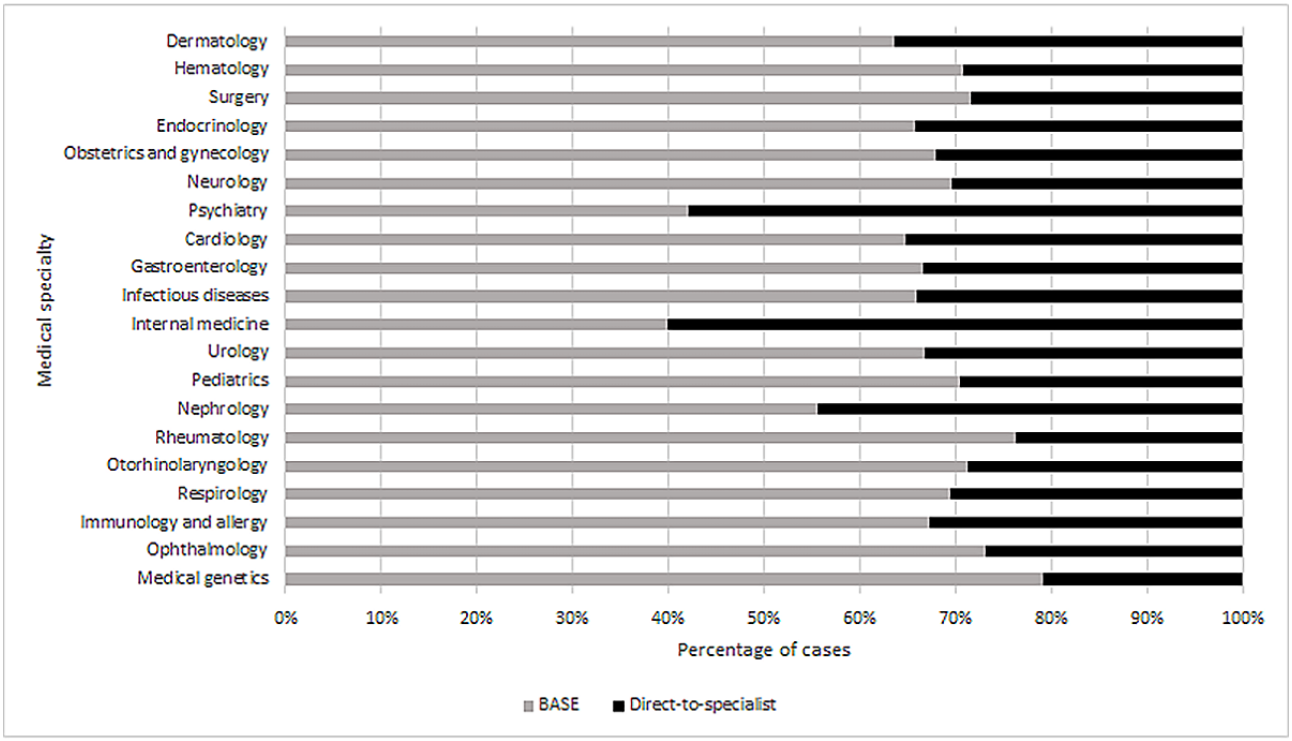
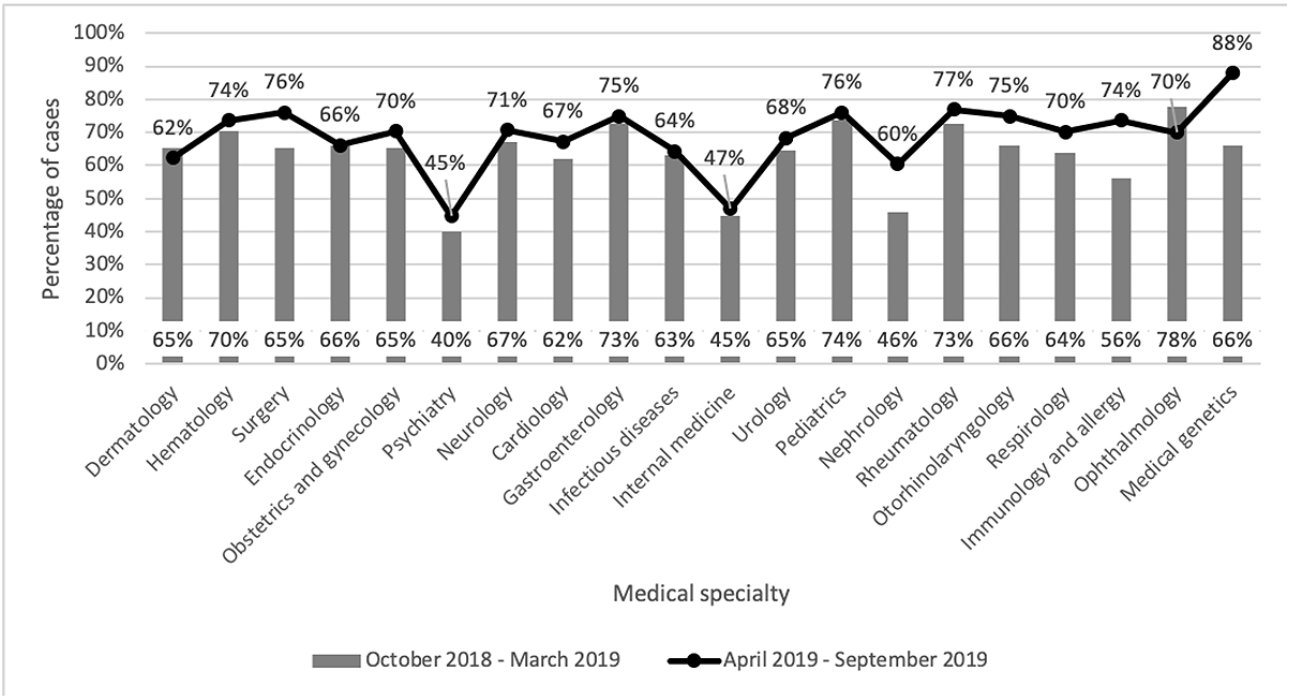


Figure 4. Comparison of the percentage of Building Access to Specialists Through eConsultation (BASE) cases provided for the top 20 specialties in the first 6 months (October 2018 to March 2019) and last 6 months (April 2019 to September 2019) of the study period.



In 12 of the 14 LHINs, requesting clinicians submitted more cases through BASE than DTS. Only 2 LHINs had a greater proportion of DTS cases compared to BASE cases: Erie St. Clair and South West. The Champlain (650/726, 89.5%) and South East LHINs (2575/2972, 86.6%) sent the highest proportion of cases through BASE.

Closeout survey data were available for 23,512 closed cases (Table 1). Based on their responses to the mandatory closeout survey, PCPs had similar experiences across models. PCPs were able to confirm a course of action that they originally had in mind in 41.4% (6373/15,376) of BASE cases and 41.3% (3363/8136) of DTS cases and received advice for a new or additional course of action in 54.7% (8418/15,376) of BASE cases and 56.3% (4582/8136) of DTS cases. When asked about each case's impact on their decision to refer, PCPs stated that a referral was originally contemplated but avoided in 51.3% (7887/15,376) of BASE cases and 53.3% (4336/8136) of DTS cases, originally contemplated and still needed in 19.4% (2986/15,376) of BASE cases and 17.7% (1438/8136) of DTS cases, and neither originally contemplated nor needed in 21.7% (3334/15,376) of BASE cases and 21.9% (1781/8136) of DTS cases.

Among cases with billing times of 25 minutes and under, specialists responding through DTS had a higher mean billing time (14.12 minutes) than those responding through BASE (13.96 minutes; $\chi^2_{5, N=21,768}$=80.471; *P*<.001). Time billed over 25 minutes also differed significantly between models, with cases provided through DTS having a mean billing time of 45 minutes compared to a mean of 37 minutes for BASE (*U*=1,570,925; *Z*=13.326; *P*<.001; *r*=0.24). The response interval of cases provided through DTS (median 0.99 days) was slightly lower than the response interval for cases provided through BASE (median 1.14 days; *U*=63,495,746; *Z*=–9.6; *P*<.001; *r*=–0.06).

Discussion

Principal Results

The Ontario eConsult Service processed over 26,000 cases across 2 models of care, registering growth in the number of monthly cases (41% increase), active PCPs (48% increase), and active specialists (28% increase). Two-thirds of cases were provided through the BASE model. PCPs who used the service frequently tended to use both avenues to access specialty advice. Cases provided through the DTS model had a longer median billing time and a shorter median response interval.

Exploration of Findings

The BASE and DTS models each offer advantages and drawbacks. In the BASE-managed service model, eConsult requires a smaller number of specialists; for some less commonly used specialty groups, 2 specialists are sufficient to handle case volume. As a consequence, the frequency of cases sent to a specialist can be adjusted, ensuring that a given provider does not become overwhelmed by demand but also receives enough cases to keep them in practice with the platform. The BASE model also allows PCPs from underserved areas to gain access to advice from specialists practicing in different parts of the province. This is vital to ensuring equity of access and of particular importance to rural and remote patients, many of whom must travel many hours for in-person specialist appointments. However, a drawback to the model is that PCPs cannot choose which specialist their case will be assigned to, which they may wish to do if they have a past working relationship with a particular specialist or if they know the

specialist is familiar with their patient's condition. In these cases, DTS offers a distinct advantage as PCPs can reach out to a particular specialist in their region when available. This direct connection facilitates collegiality and makes it easier for patients to see a specialist who has already communicated with their PCP about their issue in the event the PCP decides to refer them. For a PCP who does not have a prior relationship with a practitioner from a given specialty, the choice of a particular specialist may actually be more difficult than relying on a central case assigner. Fortunately, the various advantages and drawbacks of each model make them complementary, allowing PCPs to choose the service that best fits their situation. It was this in large part that caused our team to incorporate both models as this allowed users to select the service type that best met their needs.

The proportion of cases sent using BASE compared to DTS varied between specialty groups and regions. In some cases, the discrepancy in use patterns between regions may be structural. For instance, the 2 LHINs with the highest proportion of BASE cases, South East and Champlain, have regional BASE groups that predate the Ontario eConsult Service; the South East LHIN launched eConsult in 2015, while BASE first began as a pilot program in Champlain in 2010 and continues to operate in the region outside of the Ontario eConsult Service. As such, it is perhaps not surprising that PCPs who had already used BASE for years would continue to use that model under the Ontario eConsult Service. However, the broader use pattern goes beyond this explanation and may be affected by how many specialists from a given group practice in the PCP's region. Although all but the most remote communities in Ontario have practicing PCPs, specialists tend to practice in higher-density urban areas, where a larger population size can better support a narrower scope of practice. As a result, PCPs in regions with fewer local specialists may be more likely to use the BASE model as it allows them to access advice through the provincial service in cases where local specialists are unavailable. Additionally, it is worth noting that of the 20 most frequently used specialties, only 2 were accessed predominantly through DTS: psychiatry and internal medicine. This may speak to the importance of established relationships and communities of practice in these specialty groups.

Most of the growth on the Ontario eConsult Service was a result of an increase in the use of the BASE model, which accounted for two-thirds of all cases. We hypothesize the following reasons for the growth of the BASE model: (1) This model eliminates dependency on a PCP having an established network of individual specialists by providing a network of specialty services to access. This promotes equity of access and is especially advantageous for new graduates or a physician who has relocated to a new area. (2) The low resourcing required to launch a BASE group (ie, only 2 specialists are needed to launch a group) allows for a large offering of specialty and subspecialty groups that meet PCPs' wide variety of needs. Finally, (3) BASE has an easy workflow and intuitive user interface, making it simple to adopt and use. Our data indicate that the growth of the BASE models was not accounted for by a specific specialty (Figure 4) or by the cancellation rates (Table 1). Further study to understand the influencing factors on BASE model use, such as a PCP's year of graduation or impacts of promotional activities by the eConsult team on DTS versus BASE use, should be explored.

Limitations

Our study has several limitations. Though focusing on Canada's most populous province across a wide geographical area, our data set nevertheless can account for only one segment of the country, and results therefore may not be generalizable nationally or in other countries. The study relied on utilization data and survey results. Although useful, these data can provide only an incomplete picture of the service's use. Other data, including case logs, patient-level data, or electronic medical record surveys would provide more information and should be sought in future studies.

Conclusions

The Ontario eConsult Service successfully offers 2 models on a single platform. Both models received strong uptake and the service demonstrated growth in cases and levels of adoption by PCPs and specialists during the study period. Use patterns varied between models, with the majority of growth occurring under BASE, but survey responses showed that both models provided similar outcomes in terms of new information offered and impact on decision to refer. DTS and BASE provide complementary benefits, allowing more flexibility for PCPs. Services that are capable of adopting both models should consider offering this option to maximize use and ensure equity of access to prompt and high-quality specialist care.

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Conflicts of Interest

CL and EK are cofounders of the Champlain Building Access to Specialists Through eConsultation (BASE) electronic consultation (eConsult) Service, but they have no commercial interest in the service and do not retain any proprietary rights. As coexecutive directors of the Ontario eConsult Centre of Excellence, they receive salary support from the Ontario Ministry of Health. EK answers occasional eConsults (less than 1 per month) as a specialist through the service, for which she is reimbursed.

Multimedia Appendix 1
List of Building Access to Specialists Through eConsultation (BASE) specialty groups, when they were added on the service, and the number of specialists answering electronic consultations (eConsults) in each group.
[PDF File (Adobe PDF File), 181 KB - formative_v6i4e32101_app1.pdf]

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Abbreviations

BASE: Building Access to Specialists Through eConsultation
DTS: direct-to-specialist
eConsult: electronic consultation
LHIN: Local Health Integration Networks
MOHLTC: Ministry of Health and Long-Term Care
OTN: Ontario Telemedicine Network
PCP: primary care provider

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Original Paper

Feasibility of Using Electronic Health Records for Cascade Monitoring and Cost Estimates in Implementation Science Studies in the Adolescent Trials Network for HIV/AIDS Interventions

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Abstract

Background: One of the most difficult areas in the fight against HIV/AIDS is reaching out to youth aged 13 to 24 years. The proportion of youth living with HIV/AIDS on antiretroviral therapy (ART) and who are virally undetectable is low, highlighting significant challenges for reaching the Joint United Nations Program on HIV targets.

Objective: This study aimed to assess the feasibility of obtaining key clinical indicators and monitoring treatment, viral suppression, and retention components of the youth HIV treatment cascade in Adolescent Trials Network for HIV/AIDS Interventions clinics using electronic health record (EHR) downloads and to provide baseline characteristics for the study participants.

Methods: EHR data were systematically obtained from multiple clinical sites and used to meaningfully capture clinical characteristics, initiation of antiretrovirals, and retention in care, which are part of the Centers for Disease Control and Prevention's 4 continuum of care measures. In addition, this study used standard cost values attached to Current Procedural Terminology codes to estimate the cost per visit.

Results: Only 2 of the 4 Centers for Disease Control and Prevention treatment cascade measures were assessed using routine EHR data. EHR data are not adequate for monitoring HIV testing or linkage to care because denominator data are not available. However, the data work well for measuring ART initiation and adequately for retention in care. The sites were broadly able to provide information for the required data. However, in most cases, these data are insufficient for identifying patterns of missed appointments because such misses are not captured in the EHR system. Sites with good access to data management resources can operate more efficiently for cascade monitoring study purposes.

Conclusions: Data other than EHRs are needed to measure HIV testing and linkage to youth care. EHR data are useful for measuring ART initiation and work moderately well for measuring retention in care. Site data management resources should be part of the selection process when looking for site partners for clinical studies that plan to use EHR data. Study planners should determine the feasibility of additional funding for organizations in need of additional information technology or data management resources.

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KEYWORDS

EHR; HIV; youth; viral load; antiretroviral therapy; treatment cascade

Introduction

Background

We have made substantial progress in preventing HIV infection in the United States during the past decade, and the federal government has recently released a national strategic plan to end the HIV epidemic in the United States by 2030 [1]. However, one of the most difficult areas in the fight against the HIV and AIDS epidemics is reaching youth. In the United States, in 2016, approximately 21% of the 39,782 new HIV diagnoses occurred among youth aged 13 to 24 years [2]. We will not be able to end the HIV epidemic in the United States unless we reach this age group. However, preventing new HIV-positive diagnoses will require a 2-pronged attack, because prevention must reach youth at risk of acquiring HIV and treatment must reach those already living with HIV. The latter is an often-neglected group [3]; however, we cannot conquer the HIV epidemic in the United States without solving the youth *treatment cascade* (ie, HIV testing and diagnosis, linkage to care, and viral suppression) problem.

National-level strategies specify goals related to early HIV diagnosis and effective care. The Centers for Disease Control and Prevention (CDC) HIV care continuum identifies a dynamic series of steps from the time a person receives a diagnosis of HIV through the successful treatment of their infection with HIV medications [4]. The HIV care continuum consists of several steps that are required to achieve viral suppression. Specifically, CDC tracks the following: (1) diagnosed—receives a diagnosis of HIV, (2) linked to care—visited an HIV health care provider within 1 month after learning they were HIV positive, (3) received or were retained in care—received medical care for HIV infection, and (4) viral suppression—their HIV viral load (VL) was at a very low level. Although the HIV care continuum is often presented as a static framework, individuals who are HIV positive often exit and re-enter the continuum at varying steps [5]. Although relatively straightforward conceptually, programmatic implementation to systematically monitor the HIV treatment cascade is quite challenging [6]. Despite the fact that studies have used study coordinator data entry of cascade variables for consented participants [7], this does not adequately reflect the range of youth at Adolescent Trials Network for HIV/AIDS Interventions (ATN) clinics who may not consent to such trials. To date, no studies have been published on multisite youth cascade variables using electronic health records (EHRs). To that end, Scale It Up (SIU), a collaborative program (U19) within the ATN, aims to bring to practice evidence-based self-management interventions via hybrid implementation trials to positively impact the youth HIV prevention and care cascades.

Objectives

The Cascade Monitoring (CM) protocol (ATN Protocol 154) was designed to monitor the cascade within the ATN using EHR and provide longitudinal effectiveness outcomes and cost estimates [8]. The first goal of ATN 154 and the purpose of this report are to assess the feasibility of assessing the youth HIV treatment cascade [9] among those linked to care within the ATN using EHR downloads. To this end, this study aims to assess the feasibility of obtaining key clinical indicators and monitoring treatment, viral suppression, and retention components of the youth HIV treatment cascade in ATN clinics using EHR downloads. In addition, this study will use the first data submissions from 10 study sites to estimate the cost per visit and provide baseline study participant characteristics.

Methods

Ethics Approval

In compliance with ethical standards, the SIU CM study (ATN 154) was approved by an expedited review process by the single institutional review board of Florida State University (approval IRB00000446). All the procedures performed in this study were in accordance with the ethical standards of the institutional review board.

Study Sites

Limited EHR data were collected retrospectively, from 10 clinical sites, also known as subject recruitment venues, participating in SIU: (1) Johns Hopkins University, Baltimore, Maryland; (2) University of Alabama at Birmingham, Birmingham, Alabama; (3) SUNY Downstate Medical Center, Brooklyn, New York; (4) Children's Hospital Los Angeles, Los Angeles, California; (5) St Jude Children's Research Hospital, Memphis, Tennessee; (6) University of Miami, Miami, Florida; (7) Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; (8) University of California San Diego, San Diego, California; (9) University of South Florida, Tampa, Florida; and (10) Children's National Health System, Washington, District of Columbia.

The first data extract requested treatment visits in the full year of 2016 and associated care data for all youth living with HIV/AIDS, aged 15 to 24 years, treated at sites. Subsequently, 1-year data EHR extracts were received from sites annually, with the final year of data uploaded in 2022 for the full year of 2021. Data were requested for a set of variables that were considered invariant for the year 2016 (demographics) and for variables where multiple annual values should be captured to measure the treatment cascade changes. The variables requested included demographics (age, sex, race, and ethnicity), height, weight, International Statistical Classification of Diseases and Related Health Problems–10th Revision (ICD-10) codes, and Current Procedural Terminology (CPT) codes. A complete list of the requested variables has been published elsewhere [8] and is also included in Multimedia Appendix 1.

Study Clinical Measures

EHR data were systematically obtained from multiple clinical sites and used to meaningfully capture clinical characteristics (including viral suppression), initiation of antiretrovirals (ARVs), and retention in care, which are part of the CDC's diagnosis-based HIV care continuum measures (Multimedia Appendix 2) [10]. Two of the four CDC treatment cascade measures—retention in care and viral suppression—were assessed using routine EHR data. For the *retention in care* measure, we used the CDC definition of an interval of >190 days (approximately 3 months) between laboratory visits for CD4 or VL testing to indicate less-than-optimal laboratory visit

patterns. We were able to obtain laboratory visit dates and use data from the subsequent year to determine whether the participant was retained in care. *Viral suppression* was defined as having a nondetectable baseline VL. Laboratories used by individual study sites have varying lowest detectable limits for VL; therefore, this study records undetectable VL as defined by each study site. Additional measures calculated using EHR data included ARV medication percentage and AIDS status. *Antiretroviral medication (%)* was defined as the percentage of patients with at least one recorded ARV therapy (ART) prescription. The data in the EHR did not allow us to estimate patients' adherence to ARV because adherence is not documented in the EHR and only issued prescriptions, not prescription fills, are recorded. *AIDS status* was determined by an absolute CD4 T-cell count of <200.

Feasibility of EHR Data Extraction Process by Study Sites

Multiple EHR platforms are available for the computerized entry of patient medical information. Although a close examination of EHR platforms is important, information on the types of EHR software was not collected because the intent of the CM study was to examine the feasibility of standardized extraction of clinical and cost data of relevance to CM data across multiple EHR systems. Following interviews with study coordinators about the consistency of EHR variable capture, 9 variables were deemed as primary and could be consistently calculated. The following information was provided if available: date of visit, age, sex, height, weight, race, ethnicity, VL, and ICD-10 codes for other diagnoses. Data were requested as comma-delimited files in Excel (Microsoft Corporation). Because the sites have very different access to local technical support for file extraction, the file structure was left to decisions by the sites to ease the workload on the site staff. Data extraction was supported by the provision of an example study data dictionary for each site. This document shows how the variables are optimally defined and delivered. However, the actual extraction files differed for each of the 10 sites in terms of design, organization, variable definition, and completeness. Files had to contain the minimum primary variables, be deidentified with a site-specific patient identifier, and a report provided explaining the reason why any variables were missing. CM study personnel received and approved a variable checklist for each site before the data were approved for uploading. Upon initial receipt of the 2016 data, the data were checked for patterns of variable missingness, congruence with the data request, and the presence of variables for linking relational data by anonymous patient identifiers.

Data Management

Once the data extract was certified for a site, data were cleaned and transformed into a common data model format. Most of the data cleaning and construction of common data model files were performed using SAS (version 9.4; SAS Institute Inc). Once files for all sites were cleaned and variable values were transformed to fit the common data model for the CM study, we constructed a baseline demographics flat-file with one observation per patient and a set of relational vertical files organized by visit (laboratory test or prescription) date. We constructed separate files for visits, laboratory values, ARV medications, and other medications. The visit file contained all CPT and ICD-10 diagnosis codes and formed the basis for the development of a cost value for each encounter.

Data Analysis

Costing information was necessary to evaluate whether it was possible to produce visit cost weights using CPT codes from EHR data in lieu of extracting billing and administrative data, which are often difficult to obtain from a clinic. The ability to estimate cost is important for measuring variations in resource use and efficiency in the process of care at clinical sites. These estimated costs will be examined for validity using a time-driven activity-based costing approach once more data are collected. We used a standard costing approach to assign a cost value to each encounter, because EHR data rarely contain cost data. Cost data for individual sites are usually located in a Charge Master file, which is updated as prices at the site change. The Charge Master files are combined into billing costs for a visit using the clinic accounting data system. Thus, EHR data do not contain cost data per se but can be used to identify costs per event by combining CPT codes with standard cost data. This approach decreases the internal validity of cost estimates for an individual site but greatly improves the validity of estimation of any resource use and cost differences between sites and has greater external validity of economic estimates made using the study costs [11]. The CPT codes in each visit record were used to assign a visit cost based on the median charge for the CPT code published for all medical practices in the United States in 2016 [12].

An exploratory data analysis was conducted to understand the breadth and specificity of the available data. Descriptive statistics, including measures of central tendency, were generated to identify outliers and to track data consistency for future downloads. This study provides the first descriptive analysis performed on the 2016 data as part of the development of a common data model for the study. The analysis was performed using SAS (version 9.4). Groups were compared using chi-square tests for categorical variables and 2-talied *t* tests (normally distributed) or Mann-Whitney *U* or Wilcoxon tests (nonnormally distributed) for continuous variables.

Results

Feasibility of Variable Downloads by Study Sites

The parent SIU study was launched in December 2017 at 10 clinical sites, with 2016 EHR data due on January 31, 2017. Site personnel often reported a lack of consistent access to information technology (IT) and data management specialists as the primary explanation for the delay in data submission. Although the sites varied in the length of time to obtain and prepare data (2-6 months), all sites successfully submitted data to the designated data repository by May 2018. The primary variables requested to monitor the cascade of care included the date of visit, age, sex, height, weight, race, ethnicity, VL, and ICD-10 codes for other diagnoses. In total, 70% (7/10) of the sites provided data for the primary variables via the extraction of electronic records from their EHR system. The remaining

sites provided the primary variables using manual data extraction.

The process of data cleaning and transforming the data into a common data model format was an extremely labor-intensive process that required >400 hours of expert programming and data management work. More importantly, it required extensive consultation between individuals with informatics programming expertise and researchers with HIV-specific treatment data experience. The extent of the work required to transform the data into a common analyzable data model was unexpected. Some of the most time-consuming tasks were needed because the EHR systems for a site did not use clearly defined uniform values for many of the variables. Definitions for some demographic variables (sex, gender, race, and ethnicity) varied within a site's data download owing to the hand entry of variables, and the use of upper and lower cases, codes, and narrative descriptions. Visit variables that contained ICD-10 diagnosis codes and CPT codes were often problematic because they were sometimes extracted as string variables, separated by a mix of spaces and semicolons. Medication files were especially labor-intensive because similar medications had different names, spellings, abbreviations, and patterns of upper cases and hyphens. Laboratory tests had different definitions of VL and CD4 cell counts, and the names of other laboratory tests varied greatly and were sometimes not clearly identified. These difficulties were resolved by querying sites for information and by using site-specific detailed cleaning programs written for this purpose. Laboratories have varying lowest detectable limits for VL; therefore, this study records undetectable VL as defined by each study site.

Baseline Participant Characteristics

A total of 1093 patients were enrolled in 2016 (Table 1). The demographic variables had the lowest frequency of missing values (4%-5%). ARV medication records were not available for 17.75% (194/1093) of the patients. The VL was missing for 6.40% (70/1093) of the patients. This variable was hand-extracted at the site if missing, indicating that some patients did not have a VL record entered as structured data into their EHR system. A CD4 cell count, an important measure of immune status, was missing for approximately 28.81% (315/1093) of cases. However, we did not require this variable to be hand extracted, so it is possible that CD4 cell tests for many patients may have been performed in an external laboratory with results uploaded as a report. It may be important to make CD4 cell count required by hand extraction when electronic extraction is not possible, if we need to use this variable to measure changes in immune status over time.

Table 1. Characteristics of the cascade monitoring study population at baseline (N=1093).

Characteristic	Patient value	Number of patients for whom 2016 data were missing[a]
Age (years), mean (SD)	20.8 (2.5)	41
Height (cm), mean (SD)	169.9 (10.9)	104
Weight (kg), mean (SD)	76.8 (18.5)	84
BMI (kg/m^2), mean (SD)	26.6 (6.6)	106
Male sex, n (%)	730 (70.67)	60
Race, n (%)		50
Black	769 (73.73)	
White	89 (8.53)	
Hispanic	105 (10.07)	
Other	80 (7.67)	
Antiretroviral medication, n (%)	884 (98.3)	194
Patients with AIDS, n (%)	77 (9.9)	315
Site reported sample size, n (%)		
Baltimore, Maryland	94 (8.60)	N/A[b]
Birmingham, Alabama	69 (6.31)	N/A
Brooklyn, New York	115 (10.52)	N/A
Los Angeles, California	85 (7.78)	N/A
Miami, Florida	54 (4.94)	N/A
Memphis, Tennessee	193 (17.66)	N/A
Philadelphia, Pennsylvania	78 (7.14)	N/A
San Diego, California	105 (9.61)	N/A
Tampa, Florida	219 (20.03)	N/A
Washington, District of Columbia	81 (7.41)	N/A
Mean total cost per visit (US $) across CPT[c] codes, mean (SD)	325 (376)	N/A
CD4 Laboratory results, mean (SD)	609.4 (316)	315
Viral load laboratory results, mean (SD)	25,608 (114,184)	70
Visits, mean (SD)	5.4 (4.6)	24
Patients with laboratory visits >190 days apart in 2016, n (%)	84 (8.15)	N/A
Patients in 2016 with no record in 2017, n (%)	202 (18.48)	N/A

[a]Missing 2016 data elements for race, age, sex, height, and weight were extracted from 2017, if available.

[b]N/A: not applicable.

[c]CPT: Current Procedural Terminology.

Patient Care Continuum Outcomes

Only 2 of the 4 CDC treatment cascade measures can be assessed using routine EHR data. EHR data are not adequate for monitoring HIV testing or linkage to care because the denominator data are not available. However, the data work well for measuring ART initiation and adequately for retention in care. The criterion used to indicate less-than-optimal retention visit patterns for CD4 or VL testing is detailed in the *Methods* section. On the basis of this criterion, approximately 82.97% (887/1069) of the patients met the minimum criteria for laboratory visit frequency. On average, our patient cohort had 5.4 (SD 4.6) laboratory visits per year in 2016, with a range of 1 to >150 visit records. All prescribed ARV and other medications were requested for the study participants. A total of 98.3% (884/899) of the patients from sites that were able to extract medication records had at least one record of prescribed ARV medication. This finding is in line with the Joint United Nations Program on HIV proposed target that 90% of all people with diagnosed HIV infection receive sustained ART by 2020 [13].

We compared patients with undetectable baseline VL to those with a VL value above the level of detection used by the VL

test in their center (Table 2). Minority race and ethnicity patients were more likely to have detectable VL (*P*=.03) with 77.9% (313/402) of patients with detectable VL being of Black or African American race compared with 72.6% (355/489) of patients being Black or African American with undetectable VL. The findings showed poorer immune marker values for patients with a detectable VL. A total of 45.6% (194/424) of these patients had a mean VL of >10,000, and 29% (41/141) had a CD4 cell count that classified them as having AIDS. In addition, a small number of patients in the group with suppressed VL at baseline (7/521, 1.3%) also had a CD4 cell count that classified them as having AIDS.

The mean CD4 cell count was 619 (SD 310), indicating that many of the 945 patients with CD4 cell count values had a relatively good immune status. However, 5.7% (54/945) of patients with available CD4 cell count values had a baseline count of <200, which classified them as having AIDS by the CDC. The VL burden was reported to be undetectable in 55.1% (521/945) of the patients. However, a total of 20.5% (194/945) of all patients with a VL record had a baseline (first VL available in 2016) VL of >10,000 copies/mL.

Table 2. Characteristics of patients with undetectable and detectable VL[a] at baseline (N=945).[b]

Characteristics	Patients with undetectable baseline VL	Patients with detectable baseline VL	*P* value
Patients in the study, n (%)	521 (55.1)	424 (44.9)	.002
Age (years), mean (SD)	20.8 (2.6)	20.8 (2.5)	.71
Male sex, n (%)	328 (62.9)	296 (69.8)	.06
Race and ethnicity, n (%)			.03
Black	355 (68.1)	313 (73.8)	
White	46 (8.8)	20 (4.7)	
Hispanic	26 (5.0)	28 (6.6)	
Other	62 (11.9)	41 (9.7)	
VL >10,000, n (%)	N/A[c]	194 (45.7)	—[d]
Log_{10} VL if VL was detectable, mean (SD)	N/A	3.6 (1.2)	—
CD4 cell count, mean (SD)	707 (274)	512 (321)	<.001
CD4 count <200 or with AIDS, n (%)	7 (1.3)	47 (11.1)	<.001

[a]VL: viral load.

[b]A total of 148 patients had no baseline VL measures.

[c]N/A: not applicable.

[d]Statistical testing was not performed.

Discussion

Principal Findings

In preparation for the study, it became clear that some sites that were considered for inclusion were unable to provide specific variables. Therefore, the study team identified 9 mandatory variables for which information must be provided for a site to remain in the study. These mandatory variables (needed to monitor the treatment cascade) included the following: (1) VL, (2) date of visit, (3) age, (4) weight, (5) height, (6) ICD-10 and CPT codes, (7) sex, (8) race, and (9) ethnicity. For the most part, the sites were able to provide information regarding the required data. The use of EHR data is effective in assessing the patterns of completed appointments. However, in most cases, these data are insufficient for identifying patterns of missed appointments because such misses are not captured in the EHR system. Direct electronic download may not be possible in all situations; however, our data management team was able to work with the sites to develop a successful plan for data abstraction. Sites with good access to data management resources can work more efficiently for CM purposes. However, we do not know the IT resources of the study sites. Many clinic site personnel shared with the study investigators that they were not sure who to contact for help or how much help they could expect from their IT service group. Clinical staff members at many sites have little day-to-day contact with IT data specialists. This is an important issue that should be part of the selection process when looking for site partners for clinical studies that plan to use EHR data. Study planners should determine the feasibility of additional funding for organizations in need of additional IT or data management resources because these needs are not always obvious at the planning stage.

A number of barriers to EHR use and lessons learned as part of the CM study have come to light. First, the required variables that are *visible* to clinicians on the EHR user interface may not be readily available for electronic download. A number of important variables are part of the narrative text or are simply not recorded as structured data. VL, height, and weight are examples of information contained within clinic notes or PDF files of the results of tests performed off-site by a vendor and only available as scanned reports. An HIV surveillance study found that differences in estimated care engagement and viral suppression between data sources revealed incomplete laboratory reporting and that patients received care from

multiple providers [14]. Such findings highlight the potential unavailability of information pertinent to treatment CM and make monitoring *dashboard* construction infeasible. Some data require *hand extraction*, and sites cannot easily find the data. Patient height is often not recorded, which makes it difficult to define important measures, such as overweight, obesity, or BMI. Laboratory data extracts may lack important definitions of *normal*. Undetectable VL is especially difficult to standardize in a common data model because the laboratory definition varies according to the type of test used. Some important characteristics of the youth population infected with HIV were not recorded. Sexual partner preference or sexual orientation is not routinely documented in clinics. Sex is sometimes provided as gender and sometimes as biological sex. Missing data are common, and there are few explanations for missing data, but our comparison of data from 2016 and 2017 indicates that variables with missing values in 1 year tend to be within a normal range if present subsequently, so we suspect that they are most likely missing at random. This means that current statistical approaches for dealing with missing data may not be good choices for use in EHR data studies. In addition, there may be a discrepancy between the information provided during a consultation and that reported in the EHR [15], and vital information regarding participation is not captured or readily accessible. Much important information in an EHR for youth infected with HIV is located in unstructured data such as physician, nurse, or social worker notes. Neither data formatting nor hand cleaning will solve this lack of structured data. What may be needed is text recognition software and natural language processing approaches. However, these methods are costly and pose problems with regard to deidentifying data.

The study findings indicate that a substantial disease burden is present in this very young population infected with HIV. However, EHR data can be systematically obtained from multiple clinical sites and used to meaningfully capture the CDC's continuum of care measures. In addition, this study used standard cost values attached to CPT codes to estimate the cost per visit. This approach delineates the differences in prices between sites and proves the internal and external validity of cost estimates. To the best of our knowledge, this is the first EHR study to use this approach.

As previously stated, to fully benefit from advances in HIV treatment, youth must actively engage in each step of the treatment cascade. Although EHRs sufficiently capture pathology and many other aspects of health, obtaining meaningful indicators of health and treatment outcomes regarding patient activity measures of the care continuum (eg, keeping appointments and taking ART medications as prescribed) proved more difficult. Among other recommendations, Newman-Griffis et al [16] suggested specific actions to improve the capture and analysis of activity and participation information throughout the continuum of care, including (1) making activity and participation annotation standards and data sets available to the broader research community and (2) establishing standards for how and when to document activity and participation status during clinical encounters. A data-driven approach leveraging current techniques in health informatics to extract information about function, particularly activity and participation, is needed [16,17].

Conclusions

The work performed as part of the CM study has greatly advanced our understanding of the strengths and weaknesses of using EHR data to monitor the treatment cascade in youth infected with HIV. The analysis of the data from the first year of the study indicates that EHR data can be extracted from diverse sites and converted into analyzable data sets capable of monitoring important variables in the HIV treatment cascade. However, the success of any such effort will depend entirely on a solid collaboration between investigators and staff at the sites and the study team responsible for the cleaning and standardization of the data. The support of clinical investigators at the site has been essential for the success of the project, and the study would not have been possible without the extraordinary level of commitment and willingness to overcome obstacles exhibited by the clinical site staff. The work effort was much greater than expected for the CM study team. However, it appears that the careful programming work performed to transform the 2016 data is paying off because the 2017 data have been downloaded, and early cleaning efforts indicate that much of the work conducted for 2016 is usable for the 2017 data download. This is encouraging and indicates that *up-front* work on a standard data model pays off in terms of efficiency in subsequent years. This study provides pilot data on the use of EHRs to determine who and when youth living with HIV/AIDS disengage from the cascade and a broad, nonintrusive, and efficient way of assessing whether SIU interventions improve cascade outcomes. We conclude that although the use of EHR data for treatment CM for youth with HIV is labor-intensive and not ideal for some measures, it works for much of what we need to know about monitoring retention in care. Thus, it has the potential to become an essential tool for measuring the achievement of the goal of improving access to quality care for youth infected with HIV in the United States.

Future Directions

The longitudinal design of this study will allow for the calculation of cascade measures (ART prescription, viral suppression, and retention in care) throughout the study time fame of 2016 to 2021. In addition, advanced analytic procedures will be used to model care retention based on both patient-related and clinical characteristics, resulting in the creation of patient phenotypes for youth living with HIV/AIDS. Creation of the phenotypes will facilitate the identification of relevant predictors associated with dropout at any stage of the cascade and will be used to estimate the cost per quality-adjusted life year expected from cascade outcomes. As part of the identification of the larger cost-of-illness burden of cascade lapses for youth living with HIV/AIDS, we will use the EHR phenotypes and archival data from Medicaid or privately insured populations to model the extent of cascade interruptions present in other practice settings. The data will be combined with the individual cost weights to estimate the variations in the economic burden that cascade disruptions for youth living with HIV/AIDS place on US communities.

With the development of phenotypes, we will be able to extend our study findings to identify lapses in the treatment cascade for youth living with HIV/AIDS using large national databases. This process will permit the enumeration of these patient phenotypes nationwide and the description of the related annual economic costs of care. This will enable us to identify meaningful variations between communities that can then serve as the basis for targeted interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
List of study variables.
[DOCX File , 15 KB - formative_v6i4e25483_app1.docx]

Multimedia Appendix 2
Summary of Centers for Disease Control and Prevention care continuum measures.
[DOCX File , 14 KB - formative_v6i4e25483_app2.docx]

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Abbreviations

ART: antiretroviral therapy
ARV: antiretroviral
ATN: Adolescent Trials Network for HIV/AIDS Interventions
CDC: Centers for Disease Control and Prevention
CM: cascade monitoring
CPT: Current Procedural Terminology
EHR: electronic health record
ICD-10: International Statistical Classification of Diseases and Related Health Problems–10th Revision
IT: information technology
SIU: Scale It Up
VL: viral load

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Original Paper

Understanding Patient Experiences, Opinions, and Actions Taken After Viewing Their Own Radiology Images Online: Web-Based Survey

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Abstract

Background: The ability for patients to directly view their radiology images through secure electronic portals is rare in the American health care system. We previously surveyed patients within our health system and found that a large majority wanted to view their own radiology images online, and we have since implemented this new feature.

Objective: We aim to understand patient experiences, opinions, and actions taken after viewing their own radiology images online.

Methods: We emailed a web-based survey to patients who recently viewed their radiology images via our electronic patient portal.

Results: We sent 1825 surveys to patients and received 299 responses (response rate 16.4%). Patients reported a favorable experience (258/299, 86.3% agree) viewing their radiology images online. Patients found value in reading their radiology reports (288/299, 96.3% agree) and viewing their images (267/299, 89.3% agree). Overall, patients felt that accessing and viewing their radiology images online increased their understanding of their medical condition (258/299, 82.9%), made them feel more in control and reassured (237/299, 79.2% and 220/299, 73.6%, respectively), and increased levels of trust (214/299, 71.6%). Only 6.4% (19/299) of the patients indicated concerns with finding errors, 6.4% (19/299) felt that viewing their images online made them worry more, and 7% (21/299) felt confused when viewing their images online. Of patients who viewed their images online, 45.2% (135/299) took no action with their images, 32.8% (98/299) saved a copy for their records, 25.4% (76/299) shared them with their doctor, and 14.7% (44/299) shared them with another doctor for a second opinion. A total of 9 patients (3%) shared their radiology images on Facebook, Instagram, or both, primarily to inform family and friends. Approximately 10.4% (31/299) of the patients had questions about their radiology images after viewing them online, with the majority (20/31, 65%) seeking out a doctor, and far fewer (5/31, 16%) choosing to ask a family member about their images. Finally, respondents viewed their images online using 1 or more devices, including computers, smartphones, tablets, or a combination of these devices. Approximately 26.7% (103/385) of the responses noted technical difficulties, with the highest incidence rate occurring with smartphones.

Conclusions: We report the first known survey results from patients who viewed their own radiology images through a web-based portal. Patients reported high levels of satisfaction and increased levels of trust, autonomy, reassurance, and medical understanding. Only a small minority of patients expressed anxiety or confusion. We suggest that patient access to radiology images, such as patient access to radiology reports, is highly desired by patients and is operationally practical. Other health care institutions should consider offering patients access to their radiology images online in the pursuit of information transparency.

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KEYWORDS

personal health records; patient-accessible electronic health records; online radiology image viewing; imaging informatics; patient portals; electronic health records; digital health; mobile phone

Introduction

Hospital systems and providers (health care professionals) around the country have increasingly implemented web-based patient portals, which allow patients to directly access portions of their electronic health record data, including laboratory test results, radiology reports, and pathology reports [1-3]. This new and unprecedented transparency between patients and their health information has been spurred forward by the information-blocking provision of the 21st Century Cures Act, which requires patients to be granted immediate access to clinical information entered into the electronic health record, including radiology reports [4]. The expansion of patient health information availability and obtainability has led to improvements in communication between patients and their providers as well as increased patient-centered care [4-6]. Until recently, however, patients were only able to read their radiology reports and could not view their personal radiographic images themselves. Health systems that have integrated image viewing portals into the patient accessible electronic record have documented up to >7-fold increases in the numbers of patients viewing their images, indicating a strong patient interest in the ability to view images [7]. Such interest has been corroborated by surveys demonstrating patient interest in viewing their radiology images and patient perception that there are potential benefits from doing so [8-10], but they have never before been surveyed about their experiences after viewing their own images though a web-based patient portal.

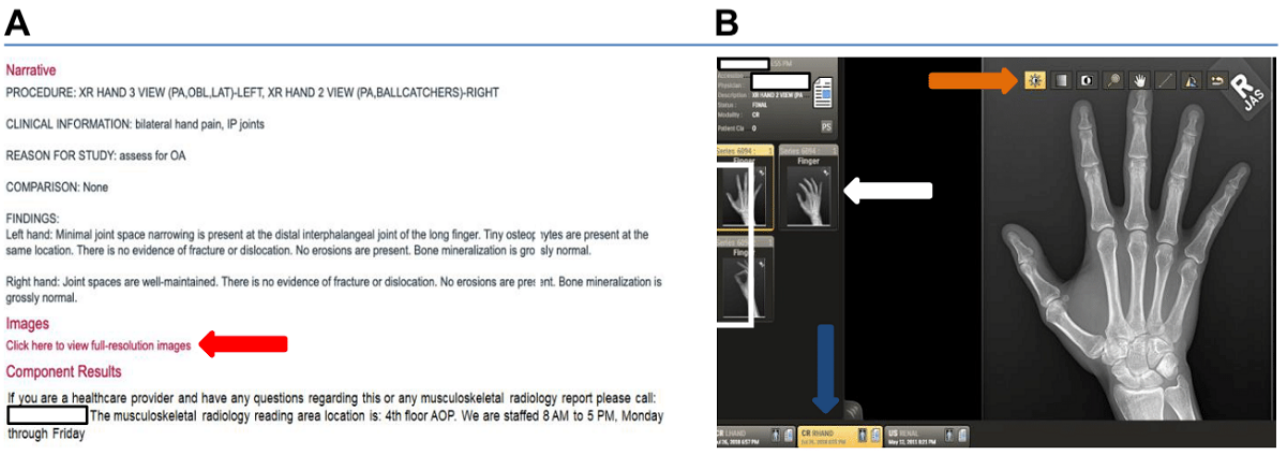
In August 2018, UCHealth launched direct patient viewing of personal radiology images through its My Health Connection (MHC) web-based portal. Prior to the release of this feature, we conducted an independent preintervention survey aimed at better understanding patient attitudes toward viewing their radiology images online. A majority of the surveyed patients felt that the increased transparency far outweighed the associated risks [10]. Following the successful launch of online patient radiology image viewing at UCHealth through the MHC patient portal, we asked patients about their experiences interacting with this new feature. In this report, we present the results of the first known survey of patients who have viewed their own radiology images online.

Methods

Imaging Viewing Implementation

Patients are able to view their images using our MHC patient portal. The MHC patient portal is available for patients to access both on desktop computers using a browser, as well as through tablets and mobile devices using a dedicated application. Upon viewing their report, they are able to click a link to load their images into a viewer originally designed for providers to view images remotely. They can then interact with these images via a series of tools/buttons on touch screen devices and mouse/keyboard on desktop/laptop computers as shown in Figure 1. All radiology imaging modalities are available for review through the portal, including radiography, computed tomography, magnetic resonance, ultrasound, fluoroscopy, and other images obtained during interventional procedures. Images are available immediately as soon as they are uploaded to our radiology picture and archiving communication provider and are not held pending review and released by the care team/doctor.

Figure 1. (A) Shows a sample musculoskeletal radiology report accessible to the patient via the My Health Connection web-based portal with a clickable link to view the associated images (red arrow). (B) Shows the imaging viewer with tabs for navigating all available images (white arrow) and studies (blue arrow), as well as modifying tool buttons (orange arrow) that provide patients with the ability to interact with their images. AOP: Anschutz Outpatient Pavilion; CR: conventional radiography; IP: interphalangeal; LAT: lateral; OA: osteoarthritis: OBL: oblique; PA: posterior-anterior; US: ultrasound; XR: x-ray.



Survey Design and Ethics Approval

This postintervention survey was designed to evaluate patient attitudes about viewing their own radiology images online, and a copy of the full survey is available in Multimedia Appendix 1. This survey had the support of the Chief Medical Officer of our health system and was reviewed by the Colorado Multiple Institutional Review Board (protocol #20-2593) who determined in an expedited review that the survey met ethics clearance guidelines, was deemed "quality improvement," and did not require full review. The survey instrument can be found in Multimedia Appendix 1.

Target Population

We included patients who had undergone radiology imaging and had viewed their images online via the MHC portal. The sample includes patients who underwent imaging both as inpatients and as outpatients.

Recruitment

The surveyed patients were identified by querying our radiology picture and archiving communication provider for the most recent patients who viewed their radiology images within the web-based MHC portal over a 5-day period at the time of our study. There were 1998 patients from this list who could be matched to email addresses in our electronic health record. These patients were emailed a link to the survey. The initial recruitment email garnered 185 responses and was followed by 1 reminder notification 2 days later, after which an additional 114 responses were received.

Statistical Analysis

Survey questions included both open- and closed-ended responses. After reading through all responses, open-ended responses were coded manually, sorting each response into a bucket. Buckets were developed by determining which themes came up most frequently. To ensure that we did not lose any information or make assumptions over implied importance, 1 response could be coded into multiple thematic buckets if multiple themes were present in the comment. For example, "I had to try to bring up the images multiple times before I could successfully bring up the images. It was also hard to navigate between images" was coded as both "Navigation issues" and "Required multiple refreshes/attempts to work." Closed-ended responses were rated on a Likert-like scale. Likert scores were employed to report the survey results as percentages and were reflected as Top 2 Box scores aggregating scores of 4 or 5 from the 5-point scale. All statistical analyses were performed using Q Research Software Version 5.4.5.0 (Displayr).

Results

Target Population

Of the 1998 recruitment emails sent, 173 emails were returned to the sender and 1825 were successfully delivered. We received 299 complete responses, yielding a response rate of 16.4%. This response rate is within the expected range based on previous work completed in our health system. Approximately 69.2% (207/299) were female, 28.7% (86/299) were male, 1.3% (4/299) preferred not to answer, and 0.7% (2/299) identified with another gender. This gender demographic breakdown is in line with what is to be expected from an unweighted convenience sample, and as seen in Table 1, compares favorably with the percentage of patients in our institution who have undergone radiologic imaging. The majority of the respondents were aged 55 years or older (175/299, 58.5%). Regarding education levels, 28.4% (85/299) of the respondents held a bachelor's degree, 23.1% (69/299) held a master's degree, 14.8% (44/299) had some college, and 1% (3/299) did not complete high school. The majority of patients (271/299, 90.6%) had their radiology images taken as part of a clinic or outpatient radiology appointment, while far fewer were taken during an inpatient admission (18/299, 6%).

Table 1. Demographics of the patients.

Characteristic	Study population (N=299), n (%)	UCHealth imaging studies (N=650,843), n (%)
Age (years)		
18-24	4 (1.3)	36,236 (5.6)
25-34	31 (10.4)	79,274 (12.2)
35-44	40 (13.3)	88,348 (13.6)
45-54	49 (16.4)	95,413 (14.7)
55-64	81 (27.1)	127,049 (19.5)
65+	94 (31.4)	224,523 (34.5)
Female sex[a]	207 (69.2)	178,000 (64)

[a]Sex is reported for UCHealth data, as gender identity data were incomplete. The total number of imaging studies in female UCHealth patients was 278,000.

Survey Results

When patients were asked on the postimplementation survey on a scale of 1 to 5 (1=poor, 5=excellent) about their overall experience viewing their radiology images in MHC, 86.3% (258/299) rated it favorably by the Top 2 Box score. Patients were asked to rate the value of viewing their radiology report and images online on a scale of 1 to 5 (1=not at all valuable, 5=extremely valuable), with the results shown in Table 2.

Table 2. Patient responses to the question, "Please rate the value of viewing each of the following within your web-based patient portal" (N=299).

Response	Agreement with statement, scored on a 5-point scale		
	Not valuable (bottom 2), n (%)	Neutral (middle 3), n (%)	Valuable (top 2), n (%)
Report	3 (0.7)	5 (1.7)	288 (96.3)
Images	8 (2.7)	22 (7.4)	267 (89.3)

Of the 299 respondents, 96.3% (288/299) of the patients rated viewing their radiology REPORT as valuable by the Top 2 Box score. Simultaneously, 89.3% (267/299) of the respondents rated viewing their IMAGES as valuable by Top 2 Box score. Surveyed patients rated their level of agreement with various statements regarding online viewing of their images as shown in Table 3. Approximately 82.9% (248/299) of the patients agreed that viewing radiology images would help "better understand my medical condition," 79.2% (237/299) agreed that viewing their images made them "feel more in control" of their health care, 63.2% (189/299) agreed that viewing their radiology images online allowed them to "better follow their doctor's recommendations," and 73.6% (220/299) "felt reassured" that their doctor was doing the right thing. Moreover, 71.6% (214/299) of the patients agreed that viewing images online increased levels of trust. Lastly, 6.4% (19/299) of the patients indicated concerns with finding errors, 6.4% (19/299) felt that viewing their images online made them worried, and 7% (21/299) felt confused when viewing their images online. A total of 174 patients (58.2%) had questions about their radiology images after viewing them; 137 (45.8%) patients discussed their questions with their referring doctor, 14 (4.7%) patients discussed their questions with the radiologist, 23 (7.7%) patients had questions but did not ask anyone, and 30 (10%) patients asked someone else but did not specify who. We asked patients how they used their web-based images and with whom they wanted to discuss their images. As summarized in Table 4, 25.4% (76/299) reported sharing their images with their doctor and 14.7% (44/299) shared them with other doctors for a potential second opinion. Approximately 32.8% (98/299) saved a copy for their records, and 3% (9/299) shared them on social media.

Table 3. Distribution of agreement with statements regarding online viewing of images (N=299).

Statement: Viewing my radiology images online caused me to…	Agreement with statement, scored on a 5-point scale		
	Disagree (bottom 2), n (%)	Neutral (middle 3), n (%)	Agree (top 2), n (%)
...better understand my medical condition.	19 (6.4)	32 (10.7)	248 (82.9)
...feel more in control.	10 (3.3)	52 (17.4)	237 (79.3)
...feel reassured.	19 (6.4)	60 (20.1)	220 (73.6)
...trust my doctors more.	18 (6)	67 (22.4)	214 (71.6)
...better follow recommendations.	28 (9.4)	82 (27.4)	189 (63.2)
...feel confused/have a lot of questions.	229 (76.6)	49 (16.4)	21 (7)
...worry more.	250 (83.6)	30 (10)	19 (6.4)
...find errors in my radiology reports.	239 (79.9)	41 (13.7)	19 (6.4)

Table 4. Patient responses to the question, "Which of the following have you done with your radiology images? Select all that apply" (N=299).

Response	Patients, n (%)
Save a copy for my records	98 (32.8)
Share them with my primary care doctor if they don't have them already	76 (25.4)
Share them with other doctors for a potential second opinion	44 (14.7)
Other (please specify)	31 (10.4)
Share them on social media	9 (3)
None of the above	135 (45.2)

Of the 9 patients who shared their images on social media, their images were posted on Facebook or Instagram, with 2 patients posting on both platforms. In response to asking why they posted their images to social media, the vast majority (8/9, 89%) stated they intended to inform their friends, family, or both. One respondent shared ultrasound images of their pregnancy, and 1 respondent did not answer this open-ended question. Additionally, 45.1% (135/299) of the respondents reported taking no action with their images and 10.4% (31/299) indicated that they did something else with their images but provided no specifics on this. Tables 5 and 6 reveal the breakdown of the electronic devices used by patients to view their images online as well as the technical difficulties experienced, respectively.

Table 5. Patient responses to the question, "Which type of device(s) did you use to view your images? Select all that apply" (N=299).[a]

Response	Patients, n (%)
Desktop/laptop computer	172 (57.5)
Smartphone	154 (51.5)
Tablet/iPad	59 (19.7)

[a]The percentage of each device user sums to greater than 100% because each patient was able to select more than one type of viewing device.

Table 6. Technical issues expressed by the patients in response to the open-ended statement, "Did you experience any technical issues with viewing your radiology images?" (N=103).

Concern	Patients, n (%)
Trouble viewing (image did not load, froze, server down, etc)	43 (40.2)
Navigation issues	25 (24.3)
Required multiple refreshes/attempts to work	15 (14.6)
Phone-specific issue	7 (6.8)
Browser-specific issue	4 (3.9)
Tablet/iPad-specific issue	3 (2.9)
None reported	6 (5.8)

We had 299 patients respond to the survey, but some patients indicated that they used more than one type of device to view their images, which resulted in 385 data points that included patients who used either just a single device or multiple devices. Approximately 44.6% (172/385) of the patients viewed their images on a desktop or laptop computer, with 22.1% (38/172) of the users reporting technical difficulties. About 40% (154/385) of the respondents viewed their images on their smartphone, with 33.1% (51/154) of the users reporting technical difficulties. Approximately 15.3% (59/385) of the respondents used a tablet to view their images, with 24% (14/59) of the users reporting technical difficulties. The total percentage of computer, smartphone, and tablet users sums to greater than 100% because patients commonly view their images on more than one device and could select more than one type of viewing device in our survey. Lastly, we asked patients a series of open-ended questions to better understand their experiences (ie, questions 6, 11-13, and 15 available in Multimedia Appendix 1). We received 231 open-ended responses regarding the question of perceived benefits of viewing radiology images online. Of these respondents, 41.9% (97/231) stated that online viewing of radiological images increased their understanding of their medical issue and 18.6% (43/231) reported access to the images being beneficial for seeing, saving, and sharing their images with family or their doctor. Patients were also asked about their concerns regarding viewing radiology images online, to which we received 197 open-ended responses; 28 of these respondents (14.2%) stated that online viewing of their radiology images caused them confusion, 14 (7.1%) reported feeling that they had no one with whom they could discuss their questions, and 128 (64.9%) respondents reported no concerns with viewing their actual images. Table 7 illustrates representative patient quotations from open-ended questions 6, 12, and 13. Sample responses to question 6 are listed under "General Reactions," sample responses to question 12 are listed under "Benefits," and sample responses to question 13 are listed under "Concerns."

Table 7. Representative patient responses.

Response type	Quote 1 examples	Quote 2 examples
General reaction	*…This is an excellent feature that assists me as a patient in making my healthcare decisions.*	*…The report is more important to me than the images. I really have no idea what I'm looking at with the images.*
Benefits	*…A sense of involvement in my treatment and health. Usually you never get to see your images, so it felt empowering.*	*…I was able to ask my doctor more informed questions when we spoke. As a result, I felt I had fewer unresolved questions later, and worried less.*
Concerns	*…I would like access the report at the same time I get access to the images. Seeing the images without the results is not an effective way to share the information.*	*…I did not have a professional available to explain the results. I had to wait for my appointment with my oncologist.*

Discussion

Principal Findings

As anticipated from our prior work, a majority (258/299, 86.3%) of the postintervention respondents had a favorable experience of viewing their radiology images online [10]. Additionally, the majority of the respondents reported finding high levels of value in viewing both their radiology reports and images online. The perceived value patients experienced viewing their reports and radiology images was higher than that anticipated by the responses in our prior survey, perhaps suggesting that patients may underestimate the value of having access to these until they have the opportunity to do so. This highlights the importance of patient accessibility to their personal health information. For example, 1 patient stated, "I like to be informed on what's going on and this is the best way to do it, where I can see the X-ray or CT scan and then listen to their follow-up on it, which helps me learn about my illness." Other patients reported feeling "empowered," while one stated that viewing their images "made me feel more involved/in control of my injury. 'A picture is worth a thousand words' comes to mind."

It has been theorized that patient fears related to confidentiality, lack of awareness of patient portals, and negative experiences when first accessing portals, as well as numerous socioeconomic factors related to education, limited internet access, and being members of certain racial minorities can lead to significant skepticism regarding patient portals and results in reduced use of these tools [11-14]. Although our study is not designed to assess the myriad of factors that may cause patients to be reticent to view their images online, in all categories regarding patient concerns, postimplementation patient concerns were even lower than those anticipated from our prior work [10]. We suspect that the universally lower rates of adverse experiences reported by our respondents in this study compared to what was anticipated could be a result of assumption-making or insufficient preliminary understanding about the proposed implementation. Our postintervention survey by design samples only those patients who have used and are familiar with the portal. Actually using and being familiar with the portal itself and how it functions may allay wariness or other concerns that a patient may have anticipated before actually being able to utilize such functionality. Nevertheless, there remains ample opportunity to address concerns raised by patients, thus improving overall access and patient experience. Potential solutions include better instructional material on how to access these images on the various desktop, tablet, and mobile platforms, the ability to demo the image viewer to allow patients to practice using them and gain familiarity with their use before using them to access their own images in a higher stress environment, and perhaps target these interventions at specific patient groups more likely to experience such issues (the older adults and certain socioeconomic populations).

Over half of the patients (174/299, 58.2%) reported having questions about their images after viewing them. Although most of these patients discussed their questions with their referring doctor, 7.7% (23/299) of the patients did not ask anyone about their questions. Those that did not ask anyone about their questions indicated a myriad of reasons for this, including "not knowing who to ask," feeling that the "doctor did not have time to answer questions during their visit," that they felt "embarrassed" or did not want to "bother" anyone, or simply that they decided to "wait to ask questions at their next appointment." For those patients who may not know where to direct their questions, possible solutions include an in-application chat-style box, question form, and an easily accessible contact list of providers involved in that patient's care, such as providing contact information of the radiologist at the bottom of every report so that patients can easily contact the radiologist with questions [15].

A significant concern cited by up to 14.2% (28/197) of the respondents was confusion brought upon by viewing the images themselves. Perhaps this confusion is not at all surprising as radiology images are quite complex, and the verbiage used in the dictated reports describing these images are tailored for medical professionals rather than for helping patients understand their images themselves. One possible intervention that may help to reduce this confusion would be to provide reports that are more patient-friendly, either utilizing simplified language that can be understood by patients without medical backgrounds or providing patient-friendly explanations/definitions and diagrams directly within the patient report to allow patients to better understand the reports and their corresponding images [16]. Moreover, some reporting systems allow for hyperlinks within reports that can bring patients to the specific image being discussed, which can help patients correlate between the findings described on the reports and the corresponding images. Additional visual aids such as normal comparisons may be of use and was specifically suggested by 1 respondent who stated "it would be nice to see what a normal image would look like against mine so I can see what's different."

Between a quarter and a third of the patients reported technical difficulties with viewing their images online using their electronic device, with the highest incidence rate for those using smartphones. Many patients reported issues with loading and navigating their images. One patient stated that "enlarging or reducing images is difficult. Tools are not user-friendly for nonmedical people." Another said that image viewing "works more easily on iPad or computer." One explanation for these experiences is that no substantial modifications were made to the provider image-viewer to aid in functionality when it was adapted for patient use. Specifically, no explanations are provided within the image viewer tool as to what individual buttons mean. Although some tools such as a magnifying glass may be self-explanatory to patients, other tools such as Window/Level buttons etc are far less intuitive and are likely to easily confuse patients. Additionally, the image viewer tool is optimized for desktop/browser-based interactions, but a significant proportion of our patients accessed these images via touch screen mobile devices, which make interaction with the image-viewer tool more difficult. A number of potential solutions for these problems should be considered. An in-application help feature explaining the function of buttons within the tool may be of benefit to improve the experience. Additional optimization of image viewing tools for mobile devices/tablets will also make the image viewing experience

far easier. Health care systems should continue investing in their information technology infrastructure and upgrading image-viewing platforms to meet the needs of their patients.

It is notable that patients in our study reported significant lower rates of saving copies of images for their records (98/299, 32.8%), sharing their images with their primary care physician (76/299, 25.4%), or sharing their images with other providers (44/299, 14.7%) than anticipated from our prior work. In fact, 45.2% (135/299) of our survey respondents reported doing nothing with their images, as opposed to only 5.7% of anticipating the same in our prior work [10]. Although this could be due to a multitude of different factors, a significant factor is likely that in our image viewer, no modifications were made to increase the ease of saving and sharing images from their device. Additionally, technical difficulties experienced by patients, especially on mobile devices, likely made such image sharing far more difficult than originally anticipated.

A small percentage of the patients (9/299, 3%) posted their radiology images to social media platforms, that is, Facebook and Instagram. Patients who engaged with social media did so primarily to inform and reassure their friends and family. One patient reported sharing their images "for my family only to keep them better informed, to answer their questions and to reassure them." Another patient expressly used the platforms to share pregnancy ultrasound images: "Seeing prenatal ultrasounds was fun for family members who couldn't be at appointments because of COVID. I also love reviewing the images to see our baby grow."

Limitations

We have refrained from a detailed direct comparison of the results of this study survey to our work prior to the implementation of the image viewer portal owing to differences in the populations sampled. Our prior work sampled members of the UCHealth Insights community, many of whom are patients at UCHealth, but includes other health care decision makers in the community as well. Patients were a sample limited to MHC portal users, as this is the only way to survey patients who had viewed their radiology images. As such, only general comparisons to prior work are discussed here. Although our survey demonstrated a largely favorable experience with viewing their images online, the literature on patient satisfaction surveys does show that the most satisfied patients are more likely to participate in surveys than the dissatisfied, and this tendency produces a positive bias in favorability scores. Additionally, the response rate for our survey is 16.4% (299/1825), which while within the expected range for email survey responses based on previous work in our health system and within the lower end of range of reported response rates in the literature still leads to the possibility that dissatisfied patients may have not responded, and we cannot infer bias or motivation to reply in our analysis [17,18]. Our respondents come from a single center, and the age/sex of the respondents (online image viewers) do not perfectly reflect the age/sex of the patients in our health system in general. Our surveyed patients were selected by sampling those who had most recently accessed their images online over a 5-day period of the study. Given the anonymous nature of the survey, we are unable to consider the severity of patient illness or the cognitive impairment of the survey respondents and cannot assess how these factors may impact survey results. Lastly, as a quality improvement project, our findings are not intended to be generalizable.

Future Directions

As more health care systems move to making online viewing of radiology images available to their patients, our understanding of the associated benefits and risks will continue to grow. Although our respondents largely indicated favorable experiences with viewing their radiology images on MHC, future investigations should determine the reproducibility of our findings in more diverse population groups. A small but significant set of concerns were raised in terms of patient anxiety and worries caused by viewing radiology images before seeing the associated report or being able to discuss the results with a health care provider. Institutions that offer patients the ability to view their radiology images online should consider ways of mitigating these concerns during the implementation of these novel solutions. We also noticed a lower rate of utilization of images (saving copies for their records, sharing with primary care physician and other providers) than anticipated. Further insight into this surprising result is warranted, as it highlights a potential target for improvement.

Additionally, future investigations focusing on user interface, technical improvements, and additional features desired by patients could help to improve the overall patient experience interacting with their web-based portal and image-viewing platform. Although our survey focused on the patient perspective, we believe that a comprehensive understanding of the impact of online radiology image viewing requires the consideration of the provider perspective as well. In the experience of our radiology leaders and clinician leaders, surprisingly few concerns have been raised in the past 2 years. By seeking out both patient and provider attitudes, we would be able to optimize the experience for both.

Conclusions

To our knowledge, this is the first report to describe patients' experience in viewing their radiology images through a web-based patient portal. Patients expressed a high level of satisfaction and a low incidence of negative experiences. Patients who viewed their radiology images reported increasing trust, autonomy, reassurance, and medical understanding, with few expressing concerns such as anxiety or confusion. From these results, we see opportunities to further improve the patient experience with online image viewing. Overall, our experience and that of our patients has been positive with rare concerns. We suggest that patient access to radiology images, such as patient access to radiology reports, is highly desired by patients and is operationally practical. Other health care institutions should consider offering radiology images online in the pursuit of information transparency.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Postintervention survey design that was emailed to our target population.
[DOCX File , 59 KB - formative_v6i4e29496_app1.docx]

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Abbreviations

MHC: My Health Connection

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Original Paper

Computerized Cognitive Behavioral Therapy Intervention for Depression Among Veterans: Acceptability and Feasibility Study

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Abstract

Background: Computerized cognitive behavioral therapies (cCBTs) have been developed to deliver efficient, evidence-based treatment for depression and other mental health conditions. Beating the Blues (BtB) is one of the most empirically supported cCBTs for depression. The previous trial of BtB with veterans included regular guidance by health care personnel, which increased the complexity and cost of the intervention.

Objective: This study, conducted by researchers at a Veterans Affairs Medical Center, aims to test the acceptability and feasibility of unguided cCBT for depression among US military veterans.

Methods: To examine the acceptability of BtB delivered without additional peer or other mental health care provider support, a before-and-after trial was conducted among United States (US) military veterans experiencing mild to moderate depressive symptoms. The feasibility of the study design for a future efficacy trial was also evaluated.

Results: In total, 49 veterans completed preintervention assessments and received access to BtB, and 29 participants completed all postintervention assessments. The predetermined acceptability criterion for the intervention was met. Although the predetermined feasibility criteria regarding screening eligibility rate, number of BtB modules completed, and completion of a posttreatment assessment were not met, the results were comparable with those of other cCBT studies.

Conclusions: This is the first study among US military veterans to demonstrate support for the implementation of cCBT for depression without the assistance of a mental health professional or a peer support specialist, suggesting that stand-alone computer-aided interventions may be viable. Ideas for improving feasibility in future trials based on this study are discussed.

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KEYWORDS

computerized cognitive behavioral therapy; depression; veterans; acceptability; feasibility

Introduction

Background

Depressive disorders are among the most common mental health conditions associated with high morbidity [1]. Compared with the general population, US military veterans are at an increased risk of depression [2]. Approximately 1 in 3 veterans visiting primary care clinics has some symptoms of depression, 1 in 5 has serious symptoms that indicate the need for further evaluation, and 1 in 9 requires psychotherapy or antidepressant treatment for major depression [3].

Although depressive disorders are common and undertreated conditions [4-6], there are effective treatments, including cognitive behavioral therapy (CBT) and pharmacotherapy [7]. Research supports the notion that patients generally prefer psychological therapy to medication [8,9]. However, there is a critical need for trained mental health professionals to treat depressive disorders among individuals in the US, including the US veterans [10]. Although CBT training programs are available for providers within the Department of Veterans Affairs (VA), additional factors can limit individuals' ability to engage in traditional face-to-face therapy, including the resources required to travel to the clinic for repeated appointments, which may not be available at the most convenient time [11]. Alternative methods have been developed to address limitations inherent to traditionally delivered psychotherapy and facilitate efficient, evidence-based, and appropriate treatment [12]. An alternative method for providing evidence-based psychotherapy to a larger population is the use of computer-aided therapies.

In the past 40 years, efficacious computerized cognitive behavioral therapies (cCBTs) have been developed to treat depression and other mental health conditions. Most cCBT programs can be accessed using the internet (eg, from an individual's home or a public library) and are highly interactive (eg, audio, video, and animations) [13]. cCBTs have the potential to address some accessibility concerns related to mental health care, as they can be administered at home during times that are most convenient for the patient, thereby reducing barriers to care, including those posed by geography, transportation costs, travel time, and childcare. Because cCBTs generally require less provider time, they can also be cost-effective alternatives to traditional face-to-face psychotherapy.

Meta-analyses have found that cCBT for depression and anxiety disorders is similarly effective to traditional face-to-face CBT in reducing symptoms of depression and anxiety [14-16]. Posttreatment satisfaction with cCBT in the general population has also been studied [17,18] and is similar to that of face-to-face therapies [19,20]. Patients receiving cCBT reported being as satisfied as those receiving CBT from a clinician [21] and more satisfied than those receiving treatment as usual [22,23]. These findings suggest that cCBT is a viable alternative for treating common mental health symptoms.

One of the most empirically supported cCBTs for depression is Beating the Blues (BtB), an 8-session, self-administered, and interactive cCBT program (see the *Methods* section). Although BtB is self-administered, the program offers a provider portal to track patient progress and facilitate health care provider or peer support to encourage treatment engagement. Participation in the BtB program has been associated with reductions in mild to moderate symptoms of depression and anxiety [24-26], and it has been recommended as the gold standard for treating mild to moderate symptoms of depression in primary care contexts [13,16,27]. In randomized controlled trials, BtB has also been established as a cost-effective intervention [16,28]. In addition, BtB has demonstrated effectiveness in addressing depression in older adults [29].

A recent study has demonstrated the acceptability and feasibility of BtB with peer support for treating mild to moderate symptoms of depression in veterans receiving primary care or outpatient mental health services [30]. However, because the study intervention included an additional component of weekly interactions with a veteran peer support specialist, it is unclear whether the effects observed were associated with the BtB program, the peer support specialist, or the combination.

Some studies have shown that veterans respond differently to evidence-based psychotherapies, including CBT for depression [31]. In terms of variables associated with treatment response, including psychiatric comorbidity and lack of stable housing, Veterans receiving health care from the VA differ from other US cohorts [32]. For example, comorbid posttraumatic stress disorder, which is more common in veterans than civilians, may reduce the effectiveness of depression treatments [31].

Objectives

This study aims to examine the acceptability and feasibility of delivering BtB without additional peer or mental health care provider support among veterans receiving care at a Veterans Affairs Medical Center (VAMC). Acceptability refers to the suitability of an intervention from the perspective of participants [33]. Feasibility refers to the goodness of fit between an intervention and the system in which it is disseminated. Aligned with the guidance provided by Areán and Kraemer [34], our feasibility assessment focused on the ease of implementation of study design elements, which were participant recruitment, enrollment, and retention. Before commencing the study, a set of a priori criteria (see the *Acceptability and Feasibility Criteria and Analysis* subsection in the *Methods* section) was established to measure the acceptability and feasibility per best practices in pilot study designs [35].

Methods

Design

All participants were allocated to receive the BtB intervention following a before-and-after trial design [36]. This study was approved by the Colorado Multiple Institutional Review Board and the local VA Research and Development Committee. A Health Insurance Portability and Accountability Act waiver was granted for the entire study, as all procedures were completed remotely (over the phone with the participant or on the web via a survey link). Data collection occurred between September 2019 and February 2020. After a research team member read

the consent information sheet to the potential participants, verbal consent was obtained. Participants could also download a copy of the consent form via the Research Electronic Data Capture (REDCap; Vanderbilt University) [37] platform, a web-based portal for participants to complete self-report study measures. Following verbal consent, the interviewer conducted a telephone eligibility screening. If the participant was eligible for the study, the interviewer ended the telephone conversation and sent a link to a web-based survey of preintervention (baseline) measures to be completed on the REDCap platform. After completing the preintervention measures, participants were provided a link to register for and access the BtB web-based intervention. All the BtB content, including an introductory session and 8 content modules, could be completed autonomously via an internet browser interface without facilitation by a health care provider, peer, or study staff. Although the core content of BtB can be completed in as few as 8 weeks, participants were given access to the program for 12 weeks. After completing 8 modules or at the end of the 12 weeks, participants were emailed a second link to complete postintervention assessments via REDCap. All participants were compensated for completing the pre- and postintervention surveys.

Participants

Initially, veteran participants were recruited exclusively via referral from a Primary Care and Mental Health Integration (PC-MHI) psychologist. PC-MHI psychologists are embedded in VA Patient Aligned Care Teams within primary care clinics to provide brief mental health assessments, referrals, and interventions. The study team received 45 referrals from the PC-MHI psychologist, and 29 veterans consented to participate in the study. Of the 29 veterans, 18 (62%) did not complete any BtB modules, 4 (14%) were lost to follow-up, and 7 (24%) completed postintervention surveys. Because the study did not meet its targets for recruitment, enrollment, and data collection, the study team implemented a new recruitment strategy that involved identifying potential participants using electronic medical records (EMRs). This paper does not report data from participants recruited via PC-MHI psychologist referral because they might systematically differ from those recruited using EMRs. In addition, we may use the EMR recruitment method in future clinical trials based on this feasibility and acceptability study.

For recruitment using EMRs, potential participants were identified from the VA Corporate Data Warehouse. The records were electronically searched for veterans (1) eligible to receive care at a particular VAMC between August 2017 and July 2019 who (2) were administered the Patient Health Questionnaire-9 (PHQ-9), a brief self-report measure of depression and (3) received a total score between 5 and 15 points, which indicates the presence of mild to moderate symptoms of depression [38]. Considering previous studies supporting the efficacy of cCBT in the treatment of depression and the statistical relationship between depression and suicidal behavior among veterans [39], we chose to recruit veterans based on symptoms of depression instead of other symptomatology. Veterans meeting these criteria were sent a letter inviting them to participate in the study. The letter briefly described the study and instructed interested veterans to call a research team member to be screened for eligibility.

During the telephone screening, potential participants self-reported whether they met the following inclusion criteria: (1) being a US military veteran aged between 18 and 89 years; (2) having a score of 5 to 15 on a verbally administered PHQ-9, which determined whether the veteran currently endorsed mild to moderate depressive symptoms [38]; (3) able to write, read, and speak English; and (4) having reliable access to the internet. The following exclusion criteria were also assessed: (1) inability to complete the assessment sessions or participate in the intervention because of visual or hearing impairment, severe psychiatric symptoms (eg, active psychosis or imminent suicide risk), or severe cognitive impairment; (2) membership in a vulnerable population (eg, pregnant women and prisoners); and (3) self-reported current participation in another mental health intervention study. The telephone-administered PHQ-9 was only used for screening purposes; another PHQ-9 was administered electronically via REDCap along with the other preintervention assessments to collect the data used in the study analyses.

Measures

The measures administered during pre- and postintervention are shown in Multimedia Appendix 1; Table S1.

Client Satisfaction Questionnaire

The Client Satisfaction Questionnaire (CSQ) [40] is an 8-item questionnaire used to assess participants' satisfaction with an intervention. Scores range from 8 to 32, with higher scores indicating greater satisfaction. A score of 24 or higher indicates that the average item rating was in the *mostly satisfied* or better range. The CSQ has good reliability and validity and has been frequently used to evaluate mental health care [41]. The CSQ was administered during the postintervention assessment and was a measure of acceptability.

Generalized Anxiety Disorder Inventory-7

The Generalized Anxiety Disorder Inventory-7 (GAD-7) [41] is a 7-item self-report measure that assesses symptoms related to generalized anxiety disorder. Participants respond to items using a 4-point Likert scale ranging from 0 to 3 (*not at all* to *nearly every day*, respectively). Participants endorse the items based on how they felt in the last 2 weeks. Higher scores reflect greater symptoms of generalized anxiety. The GAD-7 has demonstrated good reliability and validity [41]. As our trial was specifically designed to examine BtB acceptability and feasibility and not as an efficacy trial (eg, it did not include a control condition), only baseline GAD-7 scores are reported in this paper.

Internet Evaluation and Utility Questionnaire

The Internet Evaluation and Utility Questionnaire (IEUQ) [42] is a 13-item measure that examines the participants' experiences of a web-based intervention. The IEUQ was adapted for this study to refer specifically to BtB. The constructs measured included items on ease of use, convenience, engagement, enjoyment, layout, privacy, and overall satisfaction. The IEUQ was administered to gather further information on the

participants' impressions of the aspects of the intervention that were relevant to its acceptability (eg, convenience). Participants responded to items on a 5-point Likert scale from 0 (*not at all*) to 4 (*very*) or rated them as *not applicable*. Previous research indicates that the IEUQ has adequate reliability [42,43].

Internet Impact and Effectiveness Questionnaire

The Internet Impact and Effectiveness Questionnaire (IIEQ) [42] is a 20-item instrument that measures individuals' perceptions of the effectiveness of a web-based intervention. The perceived impact is measured in terms of helpfulness, knowledge gains, treatment effectiveness for self and others, long-term effectiveness, quality of life, mood, physical activity, family and peer relationships, social activity, school or work attendance and performance, treatment implementation, goal orientation, confidence in the ability to manage conditions, relapse prevention, and service reduction. The perceived or actual effectiveness of the intervention is likely to influence patients' perceptions of acceptability [44]. This measure was adapted for this study to refer specifically to BtB. Participants responded to items using a 5-point Likert scale ranging from 0 (*not at all*) to 4 (*very*). There was also a *not applicable* option. Adequate psychometric properties have been demonstrated previously [42,43].

PHQ-9 Scores

The PHQ-9 is a 9-item measure that assesses symptoms of depression. Participants respond to items using a 4-point Likert scale ranging from 0 to 3 (*not at all* to *nearly every day*, respectively), endorsing them based on how they felt in the last 2 weeks. Higher scores reflect greater symptoms of depression. The PHQ-9 has demonstrated good psychometric properties [38]. Similar to the GAD-7, only baseline PHQ-9 scores are reported in this paper.

Reasons for Termination–Adapted

The reasons for termination (RFT) scale [45] assesses 10 common reasons why patients terminate therapy and the impact these reasons have on termination. Thus, the RFT scale gathers information about the elements of a therapy that reduce its acceptability. If a participant completed between 1 and 7 modules of the BtB treatment within 12 weeks of the initial log-in to the BtB treatment website (ie, began but did not finish the therapy within the allotted time), this measure was included with the postintervention measures collected via a REDCap survey link.

Intervention

BtB is a computerized cognitive behavioral intervention program aimed at reducing depressive and anxiety symptoms [23]. BtB was designed explicitly to implement the standard CBT model of depression and anxiety and include the therapeutic elements that make up traditional CBT psychotherapy (eg, thought records [46]). The web-based intervention consisted of a 15-minute introductory session followed by 8 interactive modules, usually taken weekly. Each weekly module lasted approximately 50 minutes, with homework projects to complete between the modules (eg, problem diaries, thought records, and behavioral experiments).

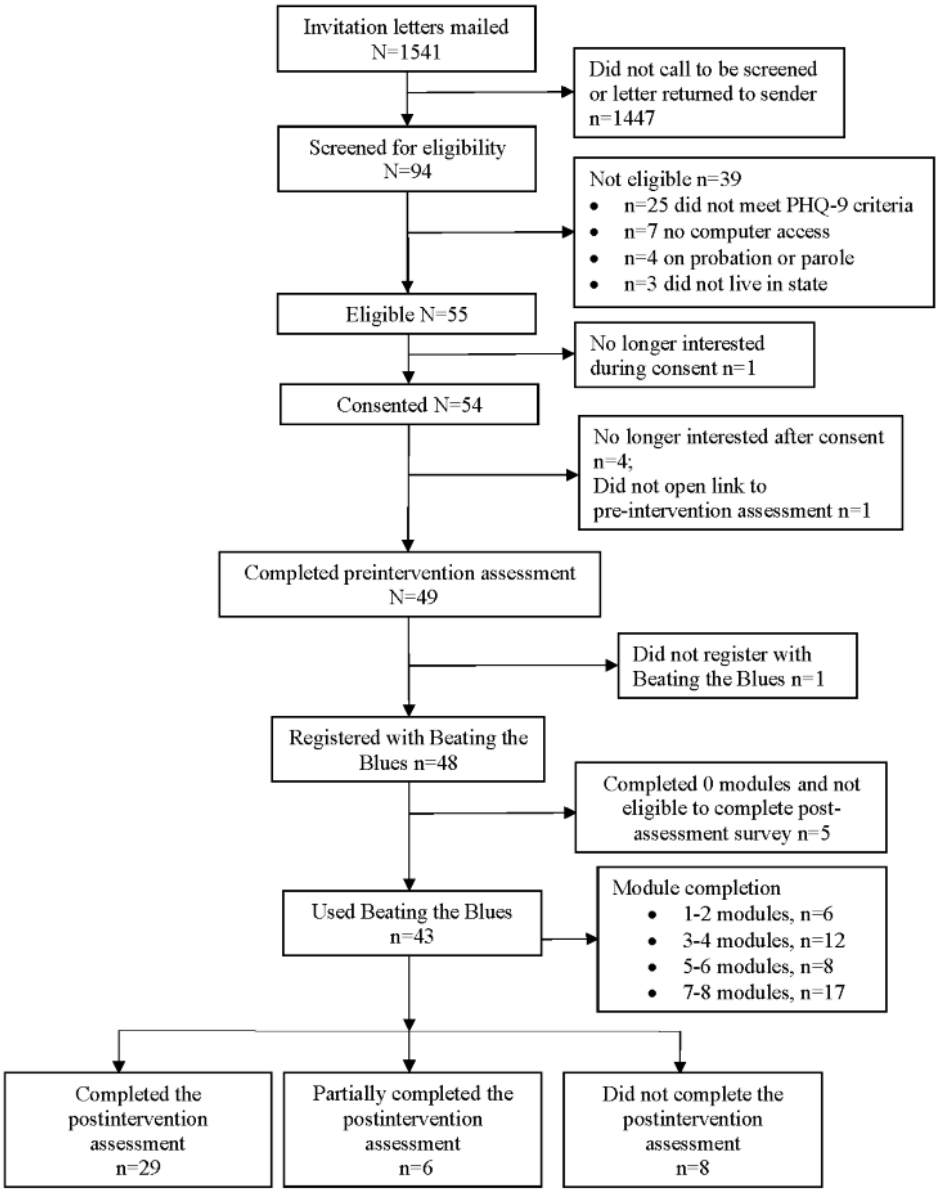
Acceptability and Feasibility Criteria and Analysis

The a priori criterion for assessing the acceptability of the intervention was that ≥70% of the participants had a score of ≥24 on the CSQ. A score of ≥24 was selected as the cutoff because it indicates that the average item rating was in the *mostly satisfied* or better range. Additional acceptability data were collected from the IIEQ, IEUQ, and RFT. The a priori criteria for assessing the feasibility of the study were (1) ≥70% of potential participants would meet the eligibility criteria assessed during the telephone screening, (2) ≥70% of those found eligible would consent to participate in the study, (3) ≥60% of those who completed the preintervention survey would complete all the intervention modules, and (4) ≥75% of those who registered for BtB and completed at least one module would complete the postintervention survey measures.

Study Procedures

Study recruitment, enrollment, and data collection were conducted at multiple time points (Figure 1).

Figure 1. Enrollment flow diagram. PHQ-9: Patient Health Questionnaire-9.



Results

Baseline Demographics

Of the 54 veterans recruited via EMRs who consented to participate in the study, 49 (91%) used the emailed link to complete the baseline assessment measures. The sample was predominantly male (43/49, 88%) and White (37/49, 76%). At baseline, most participants reported moderate depression (ie, a PHQ-9 score in the moderate depression range of 10-14) and mild anxiety (ie, a GAD-7 score in the mild anxiety score range of 5-9). Further details regarding demographic characteristics are shown in Table 1.

Table 1. Baseline demographics (N=49).

Variable	Value
Age (years), mean (SD); range	57.1 (9.9); 35-74
Self-identified gender, n (%)	
Male	43 (88)
Female	6 (12)
Racial background, n (%)	
White	37 (76)
Black or African American	7 (14)
Native American or Alaskan	3 (6)
Asian	1 (2)
Other	1 (2)
Ethnicity, n (%)	
Hispanic or Latinx	7 (14)
Non-Hispanic or Non-Latinx	41 (84)
Refused to respond	1 (2)
Highest level of education, n (%)	
High-school diploma or equivalent	4 (8)
Some college, no degree	18 (37)
Associate's degree	7 (14)
Bachelor's degree	9 (18)
Master's degree	8 (16)
Doctoral degree	3 (6)
Marital or relationship status, n (%)	
Married	28 (57)
Single	10 (20)
Cohabiting	1 (2)
Divorced or separated	10 (20)
Sexual orientation, n (%)	
Heterosexual	49 (100)
Employment status, n (%)	
Employed full-time	13 (27)
Employed part-time	4 (8)
Unemployed, not currently seeking employment	8 (16)
Unemployed, seeking employment	1 (2)
Retired	22 (45)
Refused to respond	1 (2)
Currently a student, n (%)	2 (4)
Currently homeless, n (%)	0 (0)
Ever homeless, n (%)	16 (30)
Branch of military service, n (%)	
Army—active duty	21 (43)
Army reserve	5 (10)
Army national guard	3 (6)

Variable	Value
Air force—active duty	13 (27)
Air force reserve	7 (14)
Air national guard	5 (10)
Navy—active duty	8 (16)
Navy reserve	3 (6)
Marine corps—active duty	7 (14)
Marine corps reserve	2 (4)
Coast guard—active duty	1 (2)
Total months of active duty service, mean (SD)	78.5 (73.4)
Total months of reserve service, mean (SD)	24.4 (54.9)
Service era, n (%)	
Vietnam (August 1964-May 1975)	13 (27)
Post-Vietnam/Peacetime (May 1975-July 1990)	24 (49)
Desert-Storm/Desert-Shield (August 1990-Aug 2001)	22 (45)
OEF[a]/OIF[b]/OND[c] (September 2001-Present)	14 (29)
Other	3 (6)
Highest rank at separation or current rank, n (%)	
Enlisted	35 (71)
Noncommissioned officer	10 (20)
Officer	4 (8)
Number of deployments, mean (SD)	2.2 (3.3)
Number of combat tours, mean (SD)	0.9 (1.2)
PHQ-9[d] at baseline, mean (SD)	12.1 (4.7)
GAD-7[e] at baseline, mean (SD)	9.0 (4.8)

[a]OEF: Operation Enduring Freedom.

[b]OIF: Operation Iraqi Freedom.

[c]OND: Operation New Dawn.

[d]PHQ-9: Patient Health Questionnaire-9.

[e]GAD-7: Generalized Anxiety Disorder Inventory-7.

Acceptability

The CSQ was used to examine whether participants found the BtB intervention acceptable, which was operationalized as a CSQ score of ≥24. Among the 35 participants who completed the CSQ, 26 (74%; 95% CI 57%-88%) received a score of ≥24, which met the a priori criterion of ≥70% (CSQ mean 25.2, SD 4.8).

Acceptability data were also collected using the IEUQ, IIEQ, and RFT. The responses to the IEUQ are presented in Table 2. On the IEUQ, many participants reported liking BtB and being satisfied with the intervention. Data from the IEUQ suggested that BtB was *mostly* or *very easy* to use (23/30, 77%) and generally kept participants' attention. On the IEUQ, most of the participants (21/30, 70%) found that the internet was a *mostly* or *very good* method for delivering CBT. In addition, participants (18/30, 60%) reported they were *mostly* or *very likely* to come back to BtB if depression difficulties continued or returned.

Responses to the IIEQ regarding the perceived effectiveness of BtB are shown in Table 3. On the IIEQ, most participants reported that BtB *somewhat* or *mostly* improved depressive symptoms (18/29, 62%), quality of life (15/29, 51%), and mood (15/29, 51%). Participants felt they *somewhat* or *mostly* gained more knowledge while using BtB (21/29, 72%), and they were *somewhat* or *mostly* prepared to handle depressive symptoms in the future (16/29, 55%). In addition, they were *mostly* or *very likely* to recommend BtB to others with similar problems (20/29, 69%).

Although many participants found the intervention acceptable, some did not complete all the 8 modules of the intervention (Figure 1). The RFT questionnaire was administered to participants who completed between 1 and 7 modules (Table 4). Some participants reported that the barriers to completing

all modules included practical problems (3/14, 21%), time constraints (5/14, 36%), and medical reasons (4/14, 29%). None of the participants who completed the RFT reported that they chose to stop the intervention because they were dissatisfied or wanted a different intervention.

Table 2. Responses to the Internet Evaluation and Utility Questionnaire after the assessment (n=30).

Domain	Response, n (%)					
	Not at all	Slightly	Somewhat	Mostly	Very	Not applicable or no response
Easy to use	0 (0)	2 (7)	3 (10)	9 (30)	14 (47)	2 (7)
Convenient to use	0 (0)	1 (3)	3 (10)	8 (27)	14 (47)	4 (13)
Keeps interest and attention	0 (0)	1 (3)	7 (23)	17 (57)	3 (10)	2 (7)
Liked BtB[a]	1 (3)	2 (7)	4 (13)	10 (33)	10 (33)	3 (10)
Liked how BtB looked	0 (0)	1 (3)	4 (13)	9 (31)	9 (31)	7 (23)
Worried about privacy	17 (57)	5 (17)	4 (13)	2 (7)	1 (3)	1 (3)
Satisfied	2 (7)	2 (7)	4 (13)	11 (37)	9 (30)	20 (7)
Good fit	1 (3)	2 (7)	8 (27)	8 (27)	9 (30)	2 (7)
Usefulness	0 (0)	2 (7)	3 (10)	8 (27)	13 (43)	4 (13)
Easy to understand	0 (0)	0 (0)	5 (17)	3 (10)	19 (63)	3 (10)
Trust the information	0 (0)	0 (0)	2 (7)	11 (37)	13 (43)	4 (13)
Likely to come back	2 (7)	1 (3)	7 (23)	7 (23)	11 (37)	2 (7)
Liked delivery via internet	1 (3)	3 (10)	3 (10)	4 (13)	17 (57)	2 (7)

[a]BtB: Beating the Blues.

Table 3. Responses to the Internet Impact and Effectiveness Questionnaire after the assessment (n=29).

Domain	Response[a], n (%)					
	Not at all	Slightly	Somewhat	Mostly	Very	Not applicable or no response
Improved depressive symptoms	1 (3)	6 (21)	10 (34)	8 (28)	3 (10)	1 (3)
More knowledge	0 (0)	4 (14)	9 (31)	12 (41)	2 (7)	2 (7)
How well it worked	1 (3)	5 (17)	9 (31)	9 (31)	5 (17)	0 (0)
How well it can work for others	0 (0)	2 (7)	6 (21)	7 (24)	6 (21)	8 (28)
Work as long-term cure	2 (7)	3 (10)	11 (38)	7 (24)	4 (14)	2 (7)
Improved quality of life	1 (3)	7 (24)	12 (41)	3 (10)	3 (10)	3 (10)
Improved mood	1 (3)	7 (24)	12 (41)	3 (10)	3 (10)	3 (10)
Improved physical activities	5 (17)	9 (31)	7 (24)	5 (17)	1 (3)	2 (7)
Improved relationships with family	3 (10)	9 (31)	5 (17)	2 (7)	4 (14)	6 (21)
Improved relationships with friends, peers, or coworkers	1 (3)	11 (38)	8 (28)	3 (10)	1 (3)	5 (17)
Improved social life, such as visiting friends and engaging in community activities	5 (17)	7 (24)	8 (28)	5 (17)	1 (3)	3 (10)
Improved school or work attendance	4 (14)	5 (17)	0 (0)	1 (3)	2 (7)	17 (59)
Improve school or work performance	4 (14)	7 (24)	0 (0)	1 (3)	2 (7)	15 (52)
Able to follow through with BtB[b] recommendations	1 (3)	7 (24)	5 (17)	10 (34)	5 (17)	1 (3)
Able to reach goals at beginning of BtB	3 (10)	6 (21)	10 (34)	7 (24)	2 (7)	1 (3)
Help feel more confident to manage depressive symptoms	2 (7)	4 (14)	11 (38)	6 (21)	4 (14)	2 (7)
Likely to recommend BtB to others with similar problems	1 (3)	2 (7)	4 (14)	7 (24)	13 (45)	2 (7)
Prepared to handle depressive symptoms in future	1 (3)	6 (21)	7 (24)	9 (31)	5 (14)	2 (7)
Reduce the number of office visits with a health professional	8 (28)	7 (24)	2 (7)	3 (10)	3 (10)	6 (21)
Reduce the number of phone calls and emails with a health professional	5 (17)	3 (10)	4 (14)	2 (7)	4 (14)	11 (38)

[a]A participant completed the Internet Evaluation and Utility Questionnaire but stopped filling out the postintervention assessments before completing the Internet Impact and Effectiveness Questionnaire.

[b]BtB: Beating the Blues.

Table 4. Responses to the reasons for termination questionnaire at the postintervention assessment (n=14).

Domain	Response, n (%)		
	Yes	No	Not applicable or no response
Practical problems	3 (21)	10 (71)	1 (7)
Time problems	5 (36)	8 (57)	1 (7)
Medical reasons	4 (29)	9 (64)	1 (7)
Problems improved and no longer felt a need for BtB[a]	0 (0)	12 (86)	2 (14)
Not improving as much as wanted to	2 (14)	10 (71)	2 (14)
Dissatisfied with BtB	0 (0)	11 (79)	3 (21)
Wanted a different intervention	0 (0)	10 (71)	4 (29)
Pressured or advised by others (eg, friends, spouse, or other people who criticized participation in BtB or said they did not need it)	0 (0)	13 (93)	1 (7)
Afraid that employer or others would find out about participation in BtB	0 (0)	13 (93)	1 (7)
Other reasons that led to ending participation	6 (43)	6 (43)	2 (14)

[a]BtB: Beating the Blues.

Feasibility

Of the 94 veterans identified via EMRs and screened, 59% (55/94) were eligible for the study, which did not meet the a priori feasibility criterion of ≥70%. Of those eligible, 98% (54/55) consented to participate in the study (Figure 1), meeting the a priori feasibility criterion of ≥70%, and 49 (91%) of them used the emailed link to complete the preintervention assessments. A participant did not register with the BtB program after completing the preintervention assessment, leaving 48 participants in the study. Of these, 33% (16/48) completed all 8 BtB modules, which did not meet the a priori feasibility criterion of ≥60%. Among the other registered participants, 19% (9/48) completed 5 to 7 modules, 38% (18/48) completed 1 to 4 modules, and 10% (5/48) did not complete any module after registering for BtB. Participants were not eligible to complete the postintervention survey if they did not register with BtB and complete at least one module. Of the 43 participants who completed at least one BtB module, 67% (29/43) completed all postintervention measures, which did not meet the a priori criterion of ≥75%, and 6 (14%) individuals partially completed the postintervention survey, meaning that 81% (35/43) of participants completed at least part of it. Of note, based on demographics and preintervention measures, participants who completed this survey did not differ significantly from those who did not (Multimedia Appendix 1; Table S2).

Discussion

Principal Findings

The results of this pilot study indicate that the a priori acceptability criterion for the intervention was met. Veterans generally found BtB helpful and easy to use. Most of the veterans who completed the postintervention assessment reported that they were able to complete the tasks associated with the intervention, that they found the intervention helpful, and that they would recommend it to other veterans with similar problems. The observed module completion rate was similar to the rates found with other unguided cCBT interventions [47] and with BtB in non-Veterans [48]. The completion rate was also similar to that found in a previous study of a peer-supported implementation of BtB in veterans [30]. Among the veterans who completed the RFT measure, the most common reasons for treatment discontinuation were related to external factors (eg, time constraints). None of the veterans reported discontinuing because of dissatisfaction with the treatment.

Concerning feasibility, three of four a priori criteria were not satisfied. We believe that a reason for this outcome is that, in retrospect, the criteria selected before the pilot study were overly conservative. In this study, participant recruitment via EMRs occurred rapidly (within 2 months), which did not allow for larger modifications to aspects of the design (eg, the retention plan) while the study was being conducted. However, in line with the advice of Thabane et al [35], conducting this pilot study has suggested several modifications to the study design that we will implement in future iterations of this research protocol.

One of the initial feasibility criteria was that ≥70% of veterans referred to the study would meet the secondary screening criteria, which included current mild to moderate depressive symptoms. As depression is a waxing and waning condition [49], it is unsurprising that many veterans' symptoms improved or worsened between the initial administration of the PHQ-9 recorded in the EMR and when they were screened for this study. Furthermore, undertaking this pilot trial suggested that only modest experimenter and participant efforts were required to conduct the telephone screening to confirm the presence of current mild to moderate symptoms of depression. Given these considerations, we concluded that the 59% eligibility rate among veterans who received a telephone screening was more than sufficient to demonstrate the feasibility of enrolling this population in future larger efficacy trials. Additional feasibility-related modifications of the study protocol to increase the percentage of veterans with eligible PHQ-9 scores at phone screening (eg, requiring a more recent PHQ-9 administration in the EMR) would not be required.

Another a priori feasibility criterion was that ≥60% of veterans would complete all the 8 modules associated with the treatment. In retrospect, both the percentage of veterans required to complete the modules and the number of modules required by this criterion were overly conservative. Furthermore, we believe that easily implemented changes to the protocol (described below) may further increase the mean number of modules completed. Regarding the number of modules required, a more appropriate number might have been derived from the previous study of BtB in veterans [30], which found that those who completed 5 or more modules of BtB showed statistically significant improvements in symptoms. In our sample, 52% (25/48) of veterans completed 5 or more modules, compared with only 33% (16/48) who completed all 8 modules. Although a higher percentage of veterans met the 5 or more module completion rate criteria, the fact that this 52% completion rate is still less than the 60% rate that we targeted suggests that we should consider modifications to the study protocol to increase the proportion of veterans who complete at least five modules. Of relevance to identifying potentially useful protocol modifications, a previous study found that simple weekly email reminders to complete web-based psychotherapy modules increased the mean number of modules completed by 50% (from 3.7 modules to 5.5 modules) [50]. Researchers have obtained further increases in the efficacy of such reminder emails by adjusting their content (eg, sending emails that inform the user of new content rather than simply reminding them to complete a session) and timing (eg, emailing users after 2 weeks of absence rather than longer periods) [51]. In future iterations of this protocol, we will implement such email reminders to improve the mean number of modules completed. It should be noted that only 40% of veterans completed at least five modules in the previous trial of BtB that used peer support specialists to facilitate the completion of BtB modules [30] compared with 52% (25/48) in our unfacilitated trial, suggesting that the greater investment of resources required to include peer support specialists in the intervention may not necessarily increase the average number of modules completed by participants.

Regarding the criterion for the proportion of participants who needed to complete the required number of modules, we believe that setting this criterion to ≥60% of participants was also too conservative. A core advantage of BtB (and other cCBT interventions) is that it requires less time and resources to be administered to an individual, both from the perspective of veterans and the health care system. Therefore, whereas traditionally implemented treatments might indeed require a low noncompletion rate to justify their research or clinical use, a low-intensity intervention such as BtB probably may not. To reiterate, we believe that the study protocol should be modified to increase the mean number of modules completed. However, we also conclude that a lower minimum completion rate might have been a more useful feasibility criterion given the low veteran and provider burden associated with BtB.

The final a priori feasibility criterion that was not met required that ≥75% of veterans complete the postintervention assessment. In reflecting upon our pilot study, we believe that some small alternations to the experimental design could have improved the observed postintervention survey completion rate of 67%. Previous studies on methods to increase participant retention and assessment completion suggest that using one or more of the following strategies might have increased the rates of postintervention survey completion: a telephone follow-up to the assessment invitation; shortened versions of questionnaires where possible; and, reminders to nonrespondents [52]. We also note that the literature on methods to improve participant retention is growing, and efforts to systematically identify efficacious retention strategies are underway [53].

To our knowledge, this study is the first to demonstrate that a substantial percentage of veterans can complete BtB without the assistance of a mental health professional or peer support specialist [30]. This is important because one of the main virtues of cCBT interventions is the possibility of providing evidence-based CBT interventions to a larger number of individuals [54]. A strength of our study was its broad eligibility and few exclusion criteria, which allowed us to recruit a veteran sample that was relatively representative of the broader population of veterans to whom a BtB intervention might be provided in regular clinical practice (eg, veterans receiving care at a VAMC and reporting mild to moderate symptoms of depression).

Limitations

Our study has several important limitations. First, the relatively small number of veteran participants who were women, non-White, or Hispanic did not represent the entire US veteran population [55] and limited the ability to demonstrate the acceptability of BtB in these important populations. However, other studies have generally shown that cCBT interventions, including BtB, have similar acceptability among women and members of minority groups [56]. Second, veterans with more severe depression (scores >15 on the PHQ-9) were excluded from our study, limiting our ability to draw conclusions regarding the feasibility of the design and acceptability of the intervention among veterans with more severe symptoms of depression. However, this exclusion criterion is consistent with the practice of health care systems where cCBT has already been successfully implemented (eg, in the United Kingdom [57]). In these systems, cCBT (and other less resource-intensive interventions) are initially provided to a larger population of individuals with mild to moderate depression symptoms, whereas a smaller population of high-acuity patients receive more resource-intensive interventions, such as in-person psychotherapy [58]. Finally, 17% (8/48) of the participants who registered with BtB did not complete the postassessment surveys. It is possible that their responses to the CSQ would have suggested that they did not find the intervention acceptable.

Future Research and Conclusions

These findings suggest that further studies on cCBT interventions for treating depressive symptoms in veterans are warranted. Furthermore, the results suggest that unguided implementation of such interventions (ie, those that do not include regular interactions with a health care provider) may be a viable treatment delivery modality, at least for a significant proportion of veterans. Future research is needed to further develop cCBT interventions for veterans. Specifically, research is needed to establish the relative efficacy of cCBTs compared

with standard face-to-face therapy among veterans, as well as with other treatment modalities that improve access to evidence-based psychotherapy for depression (eg, group-therapy delivery formats). Future research could also investigate the differences between veterans who may benefit from cCBTs on their own and those for whom additional support (eg, contact with peer support specialists) could help with successful therapy completion [58]. Finally, future research is required to empirically establish which veterans are most likely to benefit from cCBT interventions and which require other treatment modalities.

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Disclaimer

The views, opinions and findings contained in this article are those of the author(s) and should not be construed as an official Department of Defense or Veterans Affairs position, policy, or decision unless so designated by other documentation.

Conflicts of Interest

LAB reports grants from the Veterans Affairs, Department of Defense, National Institutes of Health, and the State of Colorado, editorial renumeration from Wolters Kluwer, and royalties from the American Psychological Association and Oxford University Press. In addition, she consults with sports leagues via her university affiliation.

Multimedia Appendix 1
Measures and administration and comparison of participants completing the postintervention survey versus not completing postintervention survey.
[DOCX File , 20 KB - formative_v6i4e31835_app1.docx]

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Abbreviations

BtB: Beating the Blues
CBT: cognitive behavioral therapy
cCBT: computerized cognitive behavioral therapies
CSQ: Client Satisfaction Questionnaire
EMR: electronic medical record
GAD-7: Generalized Anxiety Disorder Inventory-7
IEUQ: Internet Evaluation and Utility Questionnaire
IIEQ: Internet Impact and Effectiveness Questionnaire
PC-MHI: Primary Care and Mental Health Integration
PHQ-9: Patient Health Questionnaire-9
REDCap: Research Electronic Data Capture
RFT: reasons for termination
VA: Veterans Affairs
VAMC: Veterans Affairs Medical Center

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Viewpoint

Developing Mobile Health Interventions With Implementation in Mind: Application of the Multiphase Optimization Strategy (MOST) Preparation Phase to Diabetes Prevention Programming

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Abstract

With thousands of mobile health (mHealth) solutions on the market, patients and health care providers struggle to identify which solution to use and prescribe. The lack of evidence-based mHealth solutions may be because of limited research on intervention development and the continued use of traditional research methods for mHealth evaluation. The Multiphase Optimization Strategy (MOST) is a framework that aids in developing interventions that produce the best-expected outcomes (ie, effectiveness), given constraints imposed on affordability, scalability, and efficiency (also known as achieving intervention EASE). The *preparation phase* of the MOST highlights the importance of formative intervention development—a stage often overlooked and rarely published. The aim of the preparation phase of the MOST is to identify candidate intervention components, create a conceptual model, and define the optimization objective. Although the MOST sets these 3 targets, no guidance is provided on how to conduct quality research within the preparation phase and what specific steps can be taken to identify potential intervention components, develop the conceptual model, and achieve intervention EASE with the implementation context in mind. To advance the applicability of the MOST within the field of implementation science, this study provides an account of the methods used to develop an mHealth intervention using the MOST. Specifically, we provide an example of how to achieve the goals of the preparation phase by outlining the formative development of an mHealth-prompting intervention within a diabetes prevention program. In addition, recommendations are proposed for future researchers to consider when conducting formative research on mHealth interventions with implementation in mind. Given its considerable reach, mHealth has the potential to positively affect public health by decreasing implementation costs and improving accessibility. The MOST is well-suited for the efficient development and optimization of mHealth interventions. By using an implementation-focused lens and outlining the steps in developing an mHealth intervention using the preparation phase of the MOST, this study may guide future intervention developers toward maximizing the impact of mHealth outside academia.

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KEYWORDS

text messaging; prediabetic state; telemedicine; telecommunications; exercise; diet; preventive medicine; mHealth; intervention development; behavior change; mobile phone

Introduction

Background

Without effective, affordable, scalable, and efficient interventions to prevent or delay the onset of type 2 diabetes (T2D), >1 billion people will have or be at risk of developing diabetes by 2045, with an estimated annual global health expenditure of US $845 billion [1]. The efficacy of dietary and physical activity behavior change programs on T2D incidence has been shown in several large-scale randomized trials [2-5]. Specifically, these diabetes prevention programs (DPPs) have resulted in reductions in T2D incidence by 28% to 58%. That said, the protective effects of these behavior changes are largest during intensive DPPs, and the relative risk reduction tends to wane over time [6]. This is likely because of the decreased adherence to dietary and physical activity recommendations. For example, the Finnish DPP found that those who engaged in more physical activity during the 4-year follow-up saw larger reductions in T2D risk; however, 38% of participants in the behaviour change intervention group and 54% of participants in the control group did not meet the physical activity recommendations of 150 minutes of moderate to vigorous physical activity during this time [7].

Although the results from DPPs are promising, there is potential for time- and cost-efficient maintenance interventions to improve adherence to long-term behavior changes. Given the wide availability and accepted use of mobile technologies in daily life, mobile health (*mHealth*; defined as health services that are delivered by mobile devices) offers the potential to improve DPP service delivery and patient outcomes by providing the opportunity for patients to leverage the technologies they are already using to learn about their conditions, monitor their health-related behaviors and outcomes, and actively participate in their own health care [8]. Despite this promise, the rapidly evolving landscape of health technologies has resulted in a dearth of evidence-based mHealth interventions used in clinical practice [9]. Furthermore, mHealth tool and service design are often driven by the technology sector (not the health care industry), which prioritizes the rapid development of technologies to reduce time to market, often at the cost of the rigorous development and evaluation processes associated with traditional medical device and intervention design [9,10].

The challenge of developing and translating effective and scalable mHealth interventions into practice to improve public health, preventive medicine, and health communication has been well documented [11,12]. In fact, it has been noted that research findings can take up to 17 years to be integrated into clinical practice [13]. Even more disheartening is the fact that 50% of clinical innovations never reach widespread clinical use [14], and 80% of medical research dollars do not make a public health impact and result in *research waste* [15].

At this pace, technological advances will perpetually outpace research. Furthermore, when technologies are designed for research purposes without clinical implementation in mind, they may need significant modifications to be applicable for use in practice, resulting in increased cost and time—barriers that hinder the delivery of potentially meaningful mHealth programs to those in need [16]. Establishing the effectiveness of an mHealth innovation is insufficient to ensure its uptake in routine practice [17]. The question then remains: how can rigorous, evidence-based mHealth interventions be developed for clinical practice in a time-sensitive manner?

A potential method is to use methodological frameworks to aid in navigating the process from mHealth development to its implementation. This paper provides an example and recommendations for how the *Multiphase Optimization Strategy* (MOST) can be used to develop mHealth interventions and how the implementation context can drive decision-making throughout. Implementation science focuses not on the impact of an mHealth innovation but rather on the factors that influence the adoption of that innovation into routine use [17]. Implementation science has been defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services" [18]. By using the MOST and integrating an implementation-focused lens early in formative mHealth development, mHealth interventions can be developed in a way that will ensure that they are not only effective but also immediately scalable [19].

The MOST Framework

Overview

mHealth interventions are generally a combination of intervention components packaged together and offered to participants (eg, a weight-loss intervention delivered via a mobile phone app that includes diet logging, push notifications providing feedback on the foods eaten, and additional video conferencing with a dietitian to develop and refine a meal plan). Although traditional behavioral trial designs (eg, randomized controlled trials [RCTs]) can provide evidence of whether an mHealth intervention package is better than a control, such designs cannot determine which components contribute most to an outcome and the presence of potentially inert components resulting in inefficient mHealth interventions with unnecessary or possibly detrimental components. The MOST provides a structured, 3-phase, engineering-inspired framework in which intervention development and optimization precede an RCT (or other methods of evaluation). A potential use of the MOST within mHealth is the ability to develop resource-efficient mHealth interventions that include only active components delivered at an optimal dose. Using this strategy, interventions can be developed so that they are not only effective but also efficient, economical, and scalable—all attributes that are necessary for the development of mHealth interventions with implementation in mind. The 3 phases of the MOST include *preparation*, *optimization*, and *evaluation*. The aim of the preparation phase of the MOST is to identify candidate intervention components, create a conceptual model mapping target behaviors to outcomes, and define the optimization objective. Next, optimization trials are conducted to identify the *optimized* intervention, given certain implementation constraints. Finally, optimization may be followed by an evaluation phase, in which the optimized intervention package is evaluated (often in an RCT). This study focuses on the

preparation phase of the MOST. For more information pertaining to the optimization and evaluation phases see Collins [20].

Preparation Phase

Intervention components are defined as any feature that can be manipulated for study by turning it on or off or setting them to be high or low [20] and can include program content (eg, behavior change techniques [BCTs]), fidelity components (eg, provision of additional education to those moderating group chats within an mHealth app to ensure consistent tone and language across all moderators), engagement components (eg, providing badges and rewards to encourage adherence), and delivery components (eg, timing and frequency of contact with a participant).

The *conceptual model* outlines how candidate components are expected to theoretically influence short- and long-term outcomes of interest. Without this forethought, intervention components may be chosen as "it sounded like a good idea at the time," which can limit the utility of an intervention. By creating a conceptual model that identifies the proposed mechanisms of action, the MOST encourages well-thought-out mHealth interventions that can be built on and generalized beyond a single program of research.

The *optimization objective* describes how intervention EASE will be achieved by balancing an intervention's *Effectiveness* against its *Affordability*, *Scalability*, and *Efficiency*. By considering implementation constraints at the onset, the MOST has the potential to create digital interventions that expedite the translation of evidence-based mHealth innovations into clinical practice, thereby maximizing their impact on public health [21].

There is growing interest in applying the preparation phase of the MOST in implementation science [19] and digital behavior change interventions [21], and recent guidelines have been published to ensure transparent and consistent reporting within the preparation phase [22]. Although the MOST outlines these 3 targets within the preparation phase (ie, identification of intervention components and the optimization objective and creation of the conceptual model), little guidance is provided on *how* to conduct quality research within the preparation phase of the MOST, what steps should be taken to decide on what technologies should be used in the intervention, and how to systematically identify potential intervention components, develop the conceptual model, and achieve intervention EASE with the implementation context in mind. This paper provides an example of this by outlining the formative development of an mHealth-prompting intervention to be used within the Small Steps for Big Changes (SSBC) DPP with the aim of improving long-term behavior change adherence.

The SSBC Program

SSBC is an evidence-based, brief diet and exercise counseling program that aims to reduce individuals' risk of developing T2D [23]. SSBC comprises two phases: (1) training and (2) follow-up. The training phase includes 6 one-on-one dietary and exercise counseling sessions and supervised exercise sessions facilitated by a YMCA coach over a span of 3 to 4 weeks. The follow-up phase includes check-ins and measurements for months following program completion. Participants are asked to continue using the strategies they learned in the program to engage in diet and exercise behaviors without any continued coaching support.

The SSBC program has been shown to improve both cardiorespiratory fitness and cardiometabolic risk factors in a university laboratory-based study [23] and has been successfully transitioned from the laboratory into the community [24]. In the laboratory-based randomized trial, accelerometer-measured physical activity significantly increased after program completion when compared with that of baseline measures [23]. Effectiveness data for the community-based program on behavior change outcomes were evaluated using self-report measures 6 months after program completion and showed continued participant engagement in diet and exercise behaviors [24].

Participants in both the laboratory-based and community-based trials, which were conducted in Kelowna, British Columbia, Canada (the province's third-largest metropolitan area, with an approximate population of 152,000) [25], were provided with mHealth platforms in which they were asked to continue to self-monitor their exercise behaviors during both the training and follow-up phases. In the laboratory-based trial, participants were asked to digitally self-monitor daily whether they exercised, took a day off (participants were prescribed 4 days off per week), or did not exercise (if they exceeded their number of days off) on an mHealth platform that is no longer available (Motivation Engine). During the laboratory-based trial, participants were provided with additional BCTs, including mHealth *prompts* (BCT 7.1) sent via push notifications and *rewards* (BCT 10.6), for continued self-monitoring. In the community-based trial, participants self-monitored their activity on a different mHealth platform (HealthWatch360), in which they were asked to log only the days in which they exercised. On this platform, no additional BCTs were used to encourage continued engagement.

Following completion of SSBC, a focus group was conducted to allow SSBC participants to share the challenges they faced while making diet and physical activity changes after the intensive SSBC training phase [26]. Key recommendations from this work include the creation of platforms to communicate information about prediabetes and receive ongoing support from their coaches. Further qualitative work (4 semistructured interviews; before and after training and at 3 and 12 months after completion of the training phase) found that a key facilitator of maintaining long-term behavior changes was the use of mHealth technologies [27]. As such, this study aimed to assess the utility of mHealth prompts within SSBC and develop an mHealth-prompting intervention to provide continued support to clients in their behavior change journey.

Recommendations to Develop mHealth-Prompting Interventions Using the Preparation Phase of the MOST

Overview

The following sections present a high-level overview of the steps taken to develop an mHealth-prompting intervention to be implemented within the follow-up phase of SSBC, situated

within the preparation phase of the MOST. The intended focus of this paper is on the *process of decision-making* involved in choosing possible components and component levels and the development of content within an mHealth-prompting intervention and not the *outcome* of this research. This work was written in accordance with the MOST PREP-REP (Preparation Reporting) checklist by Landoll et al [22] (Multimedia Appendix 1).

On the basis of lessons learned through these steps, coupled with key design considerations posited within the *Person-Based Approach* [28], *agile innovation* [29], and *user-centered design* [10], recommendations are provided for future mHealth developers to promote implementation considerations throughout the preparation phase of the MOST. Specifically, recommendations drawn from these 3 development strategies include a focus on end users throughout, integration of existing research or rapid intervention prototyping, and iterative design and testing [10,28,29]. This presents a single use case of the preparation phase of the MOST; as such, these recommendations may not be generalizable to all applications of the MOST.

Step 1: Select Appropriate mHealth Technology

Recommendation

Although mHealth is wide reaching, the uptake and availability of certain technologies are not equal across all populations. Therefore, researchers *must* consider the contextual factors of the target population before deciding which mHealth technologies will be used or developed to promote feasible implementation [28]. The target population should encompass all potential stakeholders (ie, those using the technology both directly or indirectly) and contextual factors derived from the physical environment or clinical workflow in which the technology is to be implemented [16]. For example, if a researcher develops an mHealth intervention that is inaccessible to the target population in the real-world context but then provides the technology to research participants to prove its efficacy, this mHealth intervention is only effective within the sphere of academia. Such research findings may still have implications in policy (eg, informing health care coverage to include novel technologies) but are unlikely to be translated quickly into practice to improve public health [17].

SSBC Example

As SSBC begins to scale up across Canada, mHealth technologies provide an opportunity to improve long-term behavior change adherence while providing participants with continued support from program providers in an accessible manner. Although much of the mHealth research and development has focused on smartphones and associated apps, such technologies are less likely to reach rural Canadian populations (ie, Canadians at increased risk for developing T2D) [30]. However, cellular phone ownership and SMS text messaging rates are increasing, with 99.7% of Canadians covered by mobile phone networks [30]. To date, SSBC has been implemented within Kelowna, a metropolitan area. However, as SSBC expands to more rural communities, mHealth prompts sent via SMS text messaging have the capacity to reach and engage with the largest number of potential SSBC participants compared with the mHealth prompts sent via push notifications (through an mHealth platform) in the laboratory-based trial.

Step 2: Assess Potential Impact of mHealth Technology Within the Target Context

Recommendation

Before investing resources in developing an mHealth intervention, researchers should first evaluate the intervention's potential to influence behaviors within a given context [16]. Common pitfalls in formative development include spending too much or too little time on this phase [16]. The use of existing data, conducting research using methods that prioritize speed and simplicity (eg, rapid prototyping and innovation sprints), conducting or consulting reviews of the literature, and conducting qualitative research with the target end users can aid in the evaluation of the potential utility of a given technology for the population of interest [29]. Furthermore, agile innovation suggests that creating a clear termination and evaluation plan a priori may avoid continuing to invest resources in an intervention that does not suit the intended users or target context [16].

SSBC Example: Secondary Analysis

To identify the potential utility of mHealth prompts sent via SMS text messaging as SSBC expands to more rural areas, exploratory analyses were conducted to identify how long participants self-reported that they exercised on their respective mHealth platforms during the laboratory-based trial (when they received mHealth prompts sent via push notifications) and community-based trial (when they received no additional BCTs to increase engagement) [31]. We found that 83% of participants in the laboratory-based trial (ie, those who received prompts) self-reported exercise on their mHealth platform for an average of 82 days, whereas only 34% of participants in the community-based trial (those who did not receive prompts) self-reported exercise on their mHealth platform for an average of 43 days.

Following this, a more in-depth analysis of the laboratory-based trial was conducted to determine the acute impact a prompt may have on self-monitoring (ie, any day in which they logged *yes*, *no*, or *day off*) and self-reported exercise (ie, only the days in which they logged that they completed exercise) in the week following compared with the week preceding a prompt [32]. Self-monitoring and self-reported exercise data from the mHealth platform were averaged over 1, 3, 5, and 7 days before and after a prompt for the first and second half of the 12-month follow-up phase and were compared using *t* tests. The impact of the prompt was strongest in the first half of the year, with no significant differences found in the second half of the year. In the first half of the year, self-monitoring significantly increased in the 3 days following a prompt ($P<.001$; $d=0.60$), and self-reported exercise significantly increased in the 3 ($P<.001$; $d=0.37$), 5 ($P=.04$; $d=0.14$), and 7 days ($P=.02$; $d=0.15$) following a prompt.

Together, these secondary analyses provide preliminary evidence that mHealth prompts *may* be useful within the SSBC context, and more comprehensive development of an mHealth-prompting

(to be sent in the future via SMS text messaging to improve scalability) intervention is warranted.

SSBC Example: Consultation of Previous Literature

Once the potential utility of an mHealth-prompting intervention was identified, a scoping review was conducted to identify how existing DPPs develop mHealth-prompting interventions [33]. The results from this review highlight that mHealth prompts are typically delivered via SMS text messaging, followed by push notifications, and that they are generally well-received by participants. However, both the development of prompt content (ie, what BCTs are used and how theory influenced content) and delivery of prompts (eg, frequency, timing, and duration of prompting interventions) are often underreported, highlighting the need for structured development and rigorous evaluation of mHealth-prompting interventions before deployment.

In addition to conducting our own review, previous reviews assessing SMS text messaging interventions were also consulted. To date, many reviews have assessed the impact of SMS text messaging on health behavior change interventions [34-41], and meta-analyses have consistently shown that SMS text messaging interventions have a significant effect on hemoglobin A_{1c} among individuals with diabetes [39,40,42], weight loss [36,37], and physical activity [38,43]. It is widely accepted that behavior change interventions *should* be developed using theory, past evidence, and formative research [20,44] and that sufficient intervention detail be reported to allow for replication [45,46]. However, many SMS text messaging interventions lack rigorous development and thorough reporting, thereby limiting their utility in future intervention development and implementation [47].

In addition to how SMS text messaging interventions are developed, the description of theoretical mechanisms within message content and reporting of delivery characteristics (eg, timing and frequency) are largely unspecified in the literature [48]. With respect to SMS text messaging delivery, the evaluation of weight management SMS text messaging interventions by Skinner et al [36] included subgroup analyses examining intervention duration (<6 months vs 6 months vs 12 months), message frequency (daily vs weekly or biweekly vs personalized), and 1- versus 2-way messaging and found no significant subgroup differences. The authors noted that poor intervention descriptions within publications may have affected their ability to accurately code aspects of intervention delivery. Although a trend was noted that less frequent messaging (weekly or biweekly) was associated with greater reductions in weight (mean −2.88 kg, 95% CI −4.56 to −1.21 kg) than for daily messages (mean −1.56 kg, 95% CI −2.26 to −0.86 kg), the authors concluded that the mechanisms of action by which SMS text messaging programs lead to these effects remain largely unclear, and further investigation into message delivery and content features is warranted. This is mirrored by other reviews that note the heterogeneity in message timing, frequency, and duration within the existing literature and call for future research to determine the optimal message dose for health behavior change [35,49].

Step 3: Select Potential Intervention Components

Recommendation

The selection of intervention components should be performed early in the development process to identify different component levels. Component levels include the different doses of an intervention component one wishes to test (eg, high or low dose or turning a component on or off). By selecting components early, adequate time may be invested in preparatory development work to select appropriate component levels and consider how they will be tested. The detection of key intervention components should be based on theory, evidence, and end users [28,50,51].

Steps 1 and 2 may help to clarify intervention components that are either (1) based on existing evidence or (2) currently under researched and may be studied to move the field forward. In this way, evidence-based intervention components may be incorporated into the intervention package, and where evidence for a potential intervention component does not yet exist, researchers are able to further study the mHealth intervention component of interest (eg, if there is no existing evidence on how the frequency of intervention contact may influence a target population, but previous theory or evidence suggests that it should influence their behaviors, inclusion of that delivery component can allow a new line of evidence to be built for the target population).

The integration of previous research evidence and theory can provide insight into what intervention components have been previously identified as having the potential to be effective; however, unless these studies were conducted with the population of interest, they are unlikely to provide guidance on which intervention components are most important or can be best implemented within a given context [28]. To ground mHealth development within the implementation context, the Person-Based Approach suggests engaging in in-depth qualitative research [28]. Understanding user perspectives and accommodating their priorities within the candidate intervention components can aid in maximizing the acceptability and uptake of interventions when they are at the implementation stage [28].

SSBC Example

Based on qualitative work profiling SSBC participants, participants wanted continued support from their coach and additional information regarding prediabetes after the completion of the training phase, and they found mHealth technologies to be facilitators for maintaining their long-term behavior change [26,27]. From the results of the scoping review, the intervention components to be tested in the SSBC MOST optimization trial included SMS text messaging content and delivery components (ie, timing and frequency of prompt delivery) [33]. By understanding what message content SSBC participants would like to see (and the underlying theoretical mechanisms) and by optimizing SMS text messaging delivery to best facilitate behavior change, this research may reduce intervention costs and promote user engagement, ultimately reducing T2D risk.

Step 4: Place Constraints on mHealth Development to Improve Affordability, Scalability, and Efficiency

Recommendation

The MOST recommends that interventions be developed and optimized to meet resource-related implementation considerations (eg, constraints on personnel time, costs, or complexity of the selected technology). Typically, interventions are developed without considering affordability or the ability to be implemented as designed, which results in considerable research funds and time devoted to establishing efficacious interventions that are not practical in the real-world context [52]. By accounting for implementation constraints at the onset, the MOST aims to achieve intervention EASE by balancing the effectiveness of an intervention against relevant implementation constraints on affordability (eg, can be developed and delivered within certain budgetary constraints), scalability (eg, can be implemented with high fidelity), and efficiency (eg, contains only *active* intervention components).

By considering potential end users when designing mHealth content, researchers can tailor development and delivery based on the intended implementation context, thereby improving translation into practice [10]. Specifically, these constraints can help balance the intervention *EASE* while developing a specific optimization objective. Intervention optimization objectives can be broad (eg, achieving the best outcomes for the lowest price) or specific (eg, improving physical activity by a minimum of 15 minutes per day while keeping the overall intervention cost <US $300), and the level of specificity will depend on the constraints outlined at the onset and the requirements and resources of potential end users.

SSBC Example

When developing the SMS text messaging intervention, constraints were placed on the messages themselves, and the platform that was chosen to deliver the messages. The optimization objective was defined as identifying the SMS text messaging intervention that increases physical activity adherence most during the SSBC follow-up phase, given the identified constraints.

Text Messaging Constraints

Before message development, the following message constraints were put in place to improve the reach and scalability of the current intervention: messages must be written so that they can be sent as automated, 1-way messages (to reduce the burden on SSBC coaches), and they must be <160 characters long (to ensure they fit into a single SMS text message for individuals without a smartphone). These decisions were made so that the development process used in the current program of research could be adapted for any behavior change scientist or health care professional who may not have the resources necessary to create or invest in mHealth platforms that use advanced decision-making algorithms to provide just-in-time adaptive SMS text messaging interventions.

Text Messaging Platform Constraints

To reduce the person-hours required for sending messages and allow for fidelity assessment in future research, the following constraints were identified when selecting the SMS text messaging platform for use in this research program. The platform must be able to schedule and queue messages with rolling start dates; allow for variable timing, content, and frequency within scheduled messages; provide analytics such as audit logs of messages sent, declined, or undeliverable; and provide opt-out reports for participants requesting to unsubscribe from receiving messages.

Step 5: Develop mHealth Content

Recommendation

To improve the implementation of evidence-based mHealth research in real-world contexts, it has been suggested that intervention content should be developed (1) using a dynamic and iterative process including end users, (2) based on existing research evidence and theory, and (3) with the implementation context in mind (eg, clinical workflows) [28,53]. The integration of specific theoretical frameworks such as the Behaviour Change Wheel (BCW) has been suggested to systematically identify candidate intervention components and develop theory-based mHealth content that is underpinned by specific mechanisms of action (note that the use of such theoretical frameworks can also be helpful when developing a conceptual model) [21]. The BCW is a synthesis of 33 behavior change theories that collate the barriers and facilitators needed to change a target behavior.

SSBC Example

The development and refinement of SMS text messaging content for SSBC were split into 3 parts: identification of BCTs, message development, and message evaluation and refinement.

Identification of BCTs

To determine which BCTs were already in use within the SSBC program, 2 coders trained in BCT identification assessed all SSBC program materials and standard operating procedures [54] using the systematically developed taxonomy of BCTs (BCT Taxonomy version 1) [55]. BCTs are the building blocks of an intervention and are defined as the smallest *content components* within an intervention. Depending on the granularity in which a researcher wishes to assess the intervention components, BCTs can be toggled on or off for a more rigorous assessment during the optimization phase of the MOST.

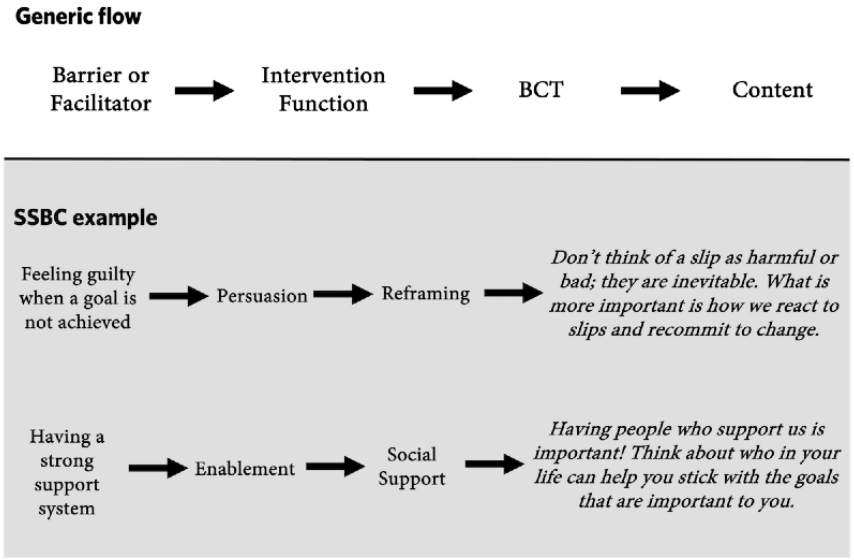
Message Development

The BCW [56] was used to develop a bank of messages [57] linking the relevant BCTs previously identified with theoretical mechanisms by which the messages should influence behaviors. Previous qualitative research profiling SSBC participant journeys in the year following the program [27] was used to identify barriers to and facilitators of maintaining dietary and physical activity behaviors after program completion. These barriers and facilitators were then linked to intended intervention functions (eg, education, persuasion, and enablement) and previously identified BCTs to formulate a bank of 124 theory-based messages based on participant-identified barriers and facilitators (Figure 1). Decisions on which intervention functions and BCTs to use in the messages were guided by the *APEASE criteria*, which may aid in achieving intervention EASE. APEASE represents affordability, practicability,

effectiveness, acceptability, side effects/safety, and equity [56]. By critically appraising each intervention function and potential BCT using the APEASE criteria, only those components likely to elicit changes that are also likely to be implemented in the given context may be included in the development of mHealth content.

Messages were written to target diet or physical activity behaviors or provide more general motivation and education; this was done by tailoring content to target client–identified barriers or facilitators toward improving client confidence in their ability to maintain the diet and physical activity changes made during the SSBC training phase.

Figure 1. Theoretical content development using the Behavior Change Wheel. BCT: behavior change technique; SSBC: Small Steps for Big Change.



Message Evaluation and Refinement

After development using the BCW, key knowledge users (SSBC coaches and past SSBC clients) evaluated the messages on their readability, relevance, and utility for individuals at risk of developing T2D [58]. Overall, messages were rated highly by both coaches and participants (receiving an average score of 13.77 out of a possible 15). General motivational messages (eg, "Your first plan will not work 100% of the time. Continue to change your goals until you find what works best for you!") were generally scored among the highest compared with targeted behavioral messages (eg, "Think about where, when and how you'll get your exercise in today!"). In addition, while evaluating messages, participants were asked if they were to send or receive messages similar to those they evaluated, how many they would like to send or receive weekly, and for how many months. SSBC coaches reported that they would like to send an average of 3 messages per week (mode 3, range 1-5) for 5 months (mode 1, range 1-12), and past SSBC clients reported that they would want to receive an average of 3 messages per week (mode 2, range 2-5) for 7 months (mode 12, range 2-12).

Step 6: Identify Intervention Component Levels

Recommendation

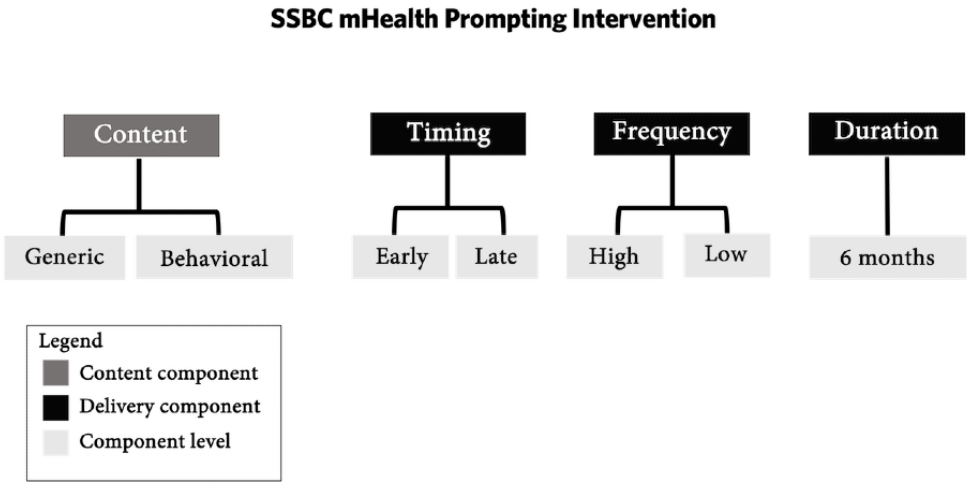
Where previous experimental evidence exists, as identified in the review of existing literature (step 2), it should be used to inform intervention component levels, warranting further testing. If no experimental evidence exists for different component levels or the objective is to further the science of mHealth development and evaluation, different components or component levels may be chosen. At this stage, intervention developers should begin to think about the study design for future intervention optimization trials; these can include factorial, sequential multiple assignment randomized trials (SMART) and microrandomized trials to name a few. The design of the optimization trial is driven by the research questions and available resources. When conducting a factorial experiment, the most efficient way (and the one recommended by the MOST) is to stick with 2 levels for each component (eg, on or off or high or low dose). Once the MOST optimization trial design has been decided, researchers can consider the candidate intervention component levels to be tested. Component levels can be as broad or as specific as needed and often depend on the nature of the intervention and research questions.

SSBC Example

Overview

Our previously identified intervention components included *prompt content* and *message delivery* (ie, duration, timing, and frequency; Figure 2). As this intervention is intended to be implemented by SSBC coaches and potentially other health care practitioners, a factorial experiment with 2 levels for each component was chosen. Although it is likely that the *optimal* (in terms of effectiveness) prompting frequency may change over time and be specific to the client receiving the prompts (thus lending itself better to a SMART or microrandomized trial), health care and public health services are unlikely to have the resources available to tailor prompting delivery to each individual client, making a standard delivery frequency more likely to be implemented into practice.

Figure 2. Intervention components and component levels. mHealth: mobile health; SSBC: Small Steps for Big Change.



Prompt Content

As each message was carefully curated and linked to specific BCTs, it would theoretically be possible to test different BCT categories or compare those messages that include one versus multiple BCTs; however, based on participant feedback in the evaluation and refinement survey, we will test 2 levels in our future optimization trial: general and targeted behavior content.

Message Delivery

Based on secondary analyses showing that prompts were most effective in the first 6 months following the SSBC training phase, coupled with diabetes prevention coaches and past SSBC clients wanting to receive messages for approximately 6 months, we decided not to include another level for this component, thereby defaulting the intervention *duration* to 6 months for all participants. In addition, our review highlighted that prompt *timing* is grossly underreported in diabetes prevention programming; thus, we chose to set the delivery component to *early* or *late* in the day. To identify a specific timing, participant preferences for timing (morning, afternoon, or evening) are being solicited in an ongoing feasibility study (further discussed in the following sections) [59].

For prompt *frequency*, our previous research (ie, secondary analyses assessing the acute impact of a prompt and message evaluation survey) [31,32] suggests that more frequent messages (eg, 6 or 7 per day) are burdensome and are therefore unlikely to positively affect the target behaviors. In addition, none of the past SSBC clients reported wanting only a single message within a week. On the basis of the paucity of data on optimal prompting frequency coupled with these secondary analyses and participant preferences, a frequency between 2 and 5 messages per week is suggested to optimally affect self-monitoring and self-reported exercise. Therefore, we chose to make the weekly prompt frequency a *high* or *low* dose. Again, the specific dose will be identified after the completion of the ongoing feasibility study.

Step 7: Develop a Conceptual Model

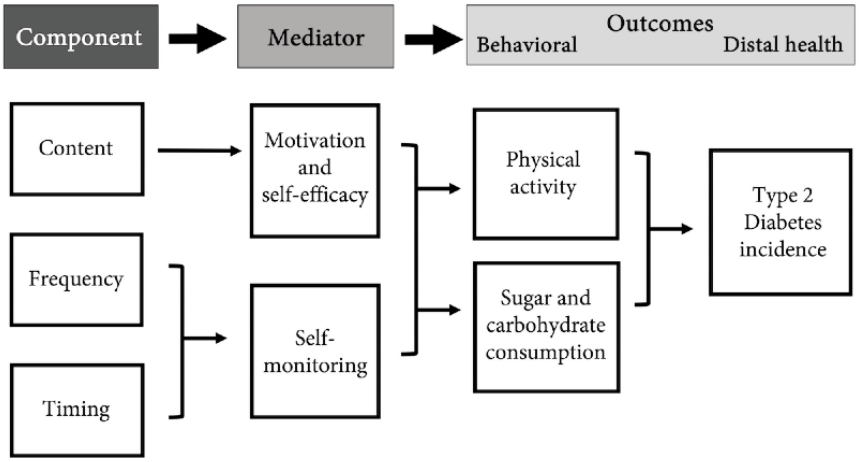
Recommendation

Creating a conceptual model to link intervention components to their theoretical mediators and expected outcomes may improve the ability of an intervention package to be effectively adapted to different contexts or settings [60]. Developing a conceptual model within the preparation phase of the MOST can be completed using a number of potential theories. As pinpointing a specific theory that fits one's needs can be overwhelming, the use of a theoretical framework such as the BCW can aid mHealth researchers in developing a conceptual framework based on theoretical constructs [21].

SSBC Example

Based on the identified intervention components of prompt content and message delivery (timing and frequency), a conceptual model was created (Figure 3) to outline how these components are anticipated to influence target behaviors (dietary and physical activity behavior change adherence). Although each individual message is made up of different BCTs targeting different barriers and facilitators, the content generally aims to increase an individual's motivation and self-efficacy to adhere to the diet- and exercise-related behavior changes made during the SSBC training phase. From our secondary analyses, it appears that the prompting dose may influence a participant's behaviors by encouraging them to continue to self-monitor their behaviors.

Figure 3. Conceptual model.



Step 8: Run a Feasibility Study

Recommendation

Before the optimization phase, Collins et al [20] suggest conducting a feasibility study to establish whether each candidate component and component level can be feasibly implemented as intended. Feasibility studies are a common step in the process of developing and translating social science and public health interventions. Conducting a feasibility study can provide necessary information on participant recruitment, intervention acceptability, and the feasibility of administering an intervention as intended. This information may be used to aid in the decision to (or not to) conduct a fully powered optimization and efficacy trial. Furthermore, this may ensure that resources are not wasted in conducting an optimization trial if the intervention itself cannot be delivered as intended [61]. The primary aim of a feasibility study should be to inform the feasibility or acceptability of an intervention and identify modifications that need to be included within the intervention before a large-scale trial. As feasibility studies are not fully powered trials, conducting inferential statistical tests is discouraged, as *P* values rely on sample size [61]. If a researcher needs to make decisions about the inclusion or exclusion of an intervention component or component level, they should identify a priori how they intend to use the feasibility study data to inform this decision making. It is recommended that participant acceptability and preferences be used instead of *P* values in addition to effect sizes (which are less reliant on sample size).

SSBC Example

To test the feasibility and acceptability of the message delivery platform before optimization, a feasibility study is currently being conducted [59]. In addition to general intervention feasibility (ie, can it be delivered as intended), this study aims to assess participant preferences regarding message timing and frequency to further refine intervention levels. The feasibility study will result in a final set of mHealth-prompting delivery characteristics for further testing in the second phase of the MOST, using a factorial experiment.

Discussion

Given their considerable reach, mHealth interventions have the potential to positively affect public health by decreasing implementation costs and improving accessibility. The impact can be maximized through rigorous development followed by optimization to ensure that candidate mHealth interventions meet the real-world contexts they seek to serve. Transparent reporting should also be prioritized to promote replicability and use beyond the intended scope, where applicable. In addition, these steps may promote intervention packages that are cost-efficient and effective without including unnecessary or potentially detrimental intervention components that could reduce the overall potency of the intervention. The MOST provides an example of a framework suitable for such development. The MOST follows 3 phases to identify components, pinpoint optimal delivery, and evaluate the efficacy of a final intervention package.

This paper provides an example of how the MOST was used to develop an mHealth-prompting intervention for the SSBC program situated within the preparation phase of the MOST. In addition, although this paper may serve as a guide for future mHealth researchers to develop mHealth interventions using the MOST, some of these steps (or the order in which they have been presented) may not be applicable for all mHealth development. Consequently, researchers should adjust their approaches to meet their own contextual needs. Despite the applicability of each individual step, mHealth development using the MOST should consider integrating concepts from agile innovation, the Person-Based Approach, and user-centered design to improve the likelihood that their mHealth development is grounded in the context of those who will be using the intervention and therefore is more likely to be integrated into routine clinical practice following evaluation [10,28,29].

Conflicts of Interest

None declared.

Multimedia Appendix 1
The MOST PREP-REP (Multiphase Optimization Strategy Preparation Reporting) checklist.
[PDF File (Adobe PDF File), 2145 KB - formative_v6i4e36143_app1.pdf]

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Abbreviations

APEASE: affordability, practicability, effectiveness, acceptability, side effects/safety, and equity
BCT: behavior change technique
BCW: Behaviour Change Wheel
DPP: diabetes prevention program
EASE: effectiveness, affordability, scalability, and efficiency
mHealth: mobile health
MOST: Multiphase Optimization Strategy
PREP-REP: Preparation Reporting
RCT: randomized controlled trial

SSBC: Small Steps for Big Change
T2D: type 2 diabetes

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Original Paper

Empowering Patients Through Virtual Care Delivery: Qualitative Study With Micropractice Clinic Patients and Health Care Providers

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Abstract

Background: Prior to the wider adoption of digital health technologies during the COVID-19 pandemic, applications of virtual care were largely limited to specialist visits and remote care using telehealth (phone or video) applications. Data sharing approaches using tethered patient portals were mostly built around hospitals and larger care systems. These portals offer opportunities for improved communication, but despite a belief that care has improved, they have so far shown few outcome improvements beyond medication adherence. Less is known about use of virtual care and related tools in the outpatient context and particularly in rural community contexts.

Objective: This study aims to reflect on the opportunities and barriers for sustainable virtual care through an example of a digitally enabled rural micropractice, which has provided 10%-15% virtual care since 2016 and 70% virtual care since March 2020.

Methods: Three focus groups, 1 with providers (physician and medical office manager) and 2 with a total of 8 patients from a rural micropractice in British Columbia, were conducted in November 2020 and December 2020. Virtual care delivery was explored through the topics of communication approach, mixing virtual and in-person care, the practice team's journey in developing these approaches, and provider and patient satisfaction with the care model. Interviews were transcribed, checked for accuracy against recordings, and thematically analyzed.

Results: Both patients and providers reported ease of communication and high satisfaction. Either could initiate communication, and patients found the ability to share health information asynchronously through the portal allowed time to reflect and prepare their thoughts. Patients were highly engaged and reported feeling empowered and true partners in their health care, although they noted limited care coordination with specialists. The mix of virtual and in-person visits was highly regarded by patients and providers, and patients reported feeling safe and cared for 24/7, although both expressed concern about work spilling into the provider's home life. The physician worried about missed diagnoses with virtual care. With respect to establishing the micropractice, solutions took about 5 years to optimize, with providers noting a learning curve requiring technical support for both themselves and their patients and a willingness to respond to patient feedback to identify the best solutions. Despite a mature virtual practice, patients reported deferred care due to COVID-19.

Conclusions: The micropractice's hybrid care model encouraged patients to be true partners in their care and resulted in high patient engagement and satisfaction; yet, success may rely on the patient population being willing to engage and being comfortable with technology. Barriers lie in gaps in care coordination and provider fear that signs or symptoms more evident with an in-person exam could be missed. Even in this setting, deferral of care in light of COVID-19 was present, and opportunities to address care gaps should be sought.

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KEYWORDS

virtual care; micropractice; focus groups; patient portals; COVID-19; family practice; rural care; digital health technology; telehealth

Introduction

Background

Virtual care represents any nondirect synchronous or asynchronous interaction between patients or members of their circle of care, using any form of communication or information technology. Virtual care encompasses a range of health care activities enabled by technology, including telehealth (the term commonly used for the delivery of care through video or telephone conferencing with a care provider) [1]. Before wider adoption of digital health technologies during the early phases of the COVID-19 pandemic, applications of virtual care were mostly in the form of virtual walk-in clinics using tools enabling communication between health care providers for specialist visits or for phone or video visits between providers and patients in remote settings [2]. These applications were primarily focused on diagnosis, prevention, and public health [3]. However, the COVID-19 pandemic prompted widespread emergency adoption of virtual care models that were haphazardly implemented, with the primary aim of reducing infection risk but also conserving resources including personal protective equipment [4].

Virtual Care Opportunities

Patient engagement has not traditionally been a focus of virtual care applications [3]. While there is no strong evidence that educating health care providers in patient self-management approaches will actually improve outcomes [5], patient empowerment appears to improve medication adherence, and patient engagement may lead to better mental and physical health outcomes [6]. Virtual care tools include interconnected personal health records and tethered patient portals, videoconferencing solutions, remote patient monitoring, and wearable technologies for such things as electronic collection of patient-generated data and delivery of patient education; they allow patients and family members to advocate for their needs, including health and wellness and preventative care services. These tools enhance the potential for participation and bidirectional communication, both asynchronously and synchronously, between patients and providers; hence, they offer a mechanism to increase patient engagement and empowerment [7-9]. While there are limited data supporting change in patient health outcomes, a meta-analysis of patient portals tethered to hospital electronic medical records (EMR) found that patient portals improved patient safety, medication adherence, patient-provider communication, and patient engagement, and both patients and providers believed that portals improved patient care [10]. Less is known about best practices for outpatient and community use of virtual care technologies. Although patient portals are becoming more common, only 20% of Canadians say they have accessed their health information through a blend of channels (mostly lab results and not primary care records) [11-13], and availability and use are far from equitable, leading one author to suggest that the digital divide may be yet another social determinant of health [14]. However, a hybrid approach, combining virtual care with a more traditional in-person approach, might enhance access opportunities.

Access to care has traditionally been a challenge in the Canadian rural setting [15]. The COVID-19 pandemic highlighted the opportunities offered by telehealth and virtual care [16], notwithstanding their current limitations. Given the likelihood that virtual care is here to stay, preparing for transition to long-term sustainable implementations should leverage experiences from stakeholders, both before and during the COVID-19 pandemic. This presents an opportunity for the health system to plan, for providers to learn from their peers in identifying the optimal balance between in-person care and virtual care, and for patients to benefit from advanced digital tools and improved access and patient empowerment.

Micropractice Care Approach

Since the early 21st century, the micropractice model of health care has appeared in the United States, Eastern Mediterranean, and Canada. A clinical microsystem approach advocates for constant communication between health care providers and their patients to understand mutual expectations about care and appreciate the patient's needs and clinician's concerns [17]; it does so by focusing on 6 aims of quality improvement: patient safety, clinical care effectiveness, patient focus, timeliness of care delivery, efficiency in care delivery, and equity of access to care [18]. Micropractices, as a patient-focused, quality-assurance, and data-driven care model, may be an efficient and cost-effective model for primary care delivery that allows health care providers to spend more time with their patients and leverage new technologies and approaches of care more easily than regular (larger) practices [19,20]. In a recent systematic review looking at whether clinical microsystems work, only 3 of the 35 papers included in the review targeted primary care [17]. However, the foci of these studies were highly specific to either a chronic condition [21] or to team effectiveness and care coordination activities [22,23], and neither focused on the patient and provider as a core unit of analysis nor a virtual micropractice delivery model in a rural setting.

Study Aim

The aim of this paper was to explore the opportunities and barriers for sustainable patient-centered virtual care through an example of a rural micropractice, which has provided 10%-15% virtual care since 2016 and 70% virtual care since March 2020. The clinic, as a single-physician, virtually enabled practice pre-COVID-19, offered an opportunity for the researchers to explore a unique model of care during a public health disaster and for community-based providers to learn about digital enablement from the experience of patients and providers in a micropractice.

Methods

Location

This qualitative descriptive study targeted a micropractice as part of a larger mixed methods study examining data sharing and personal health records among rural primary care practices in British Columbia, a province in western Canada. The practice is located in a small rural community with a population of about 11,000 people and was identified as a valuable exemplar in its application of digital health technology deserving of further exploration.

Ethical Approval

Ethical approval was granted by the joint review boards of the University of British Columbia Clinical Research Ethics Board (H19-00958; principal investigator, KLR) and the Interior Health Research Ethics Board. This article follows the Consolidated Criteria for Reporting Qualitative Health Research (COREQ) [24].

Participant Recruitment

The providers of the micropractice were approached to participate through an email invitation from our team's digital health liaison. The micropractice providers then sent a broadcast email advertising the study to all portal-registered patients over the age of 18 years. Interested patients contacted the research assistant who obtained informed consent. Patients received a CAD $25 (US $19.93) gift certificate for their participation, and the physician and clinic manager or medical office assistant (MOA) was remunerated commensurate with provincial guidelines for payment of health professionals participating in research.

Data Collection

A focus group was conducted in November 2020 with the physician and the clinic manager or MOA from the micropractice. Questions asked providers about types of data shared, platforms and tools used for data sharing both pre- and postpandemic, value and trust in patient-generated data, and use of patient-generated data in care decisions. Two focus groups of 4 patients each were conducted in December 2020 following informed consent and completion of a brief survey including demographic information, health status, and use of technology. Focus groups lasted approximately 1 hour and were guided by a semistructured interview guide with questions about types of data or health information shared with their providers; who initiated sharing; problems encountered with electronic data sharing; current and preferred data sharing features, functions, and processes; value of data sharing and sense of partnership with provider; and communication changes since the pandemic. Focus group participants were encouraged to not only address the researcher's questions but also build constructively on the comments made by other participants.

One experienced team member facilitated each focus group (MG, KLR), with at least 2 other research team members present in each group, to cofacilitate as needed. Each focus group was held on Zoom videoconferencing software (Zoom Video Communications, San Jose, CA). All sessions were audio-recorded, with nonmoderating team members taking notes and asking questions to probe for follow-up details or clarification by relaying them to the focus group moderator via a chat function.

Data Analysis

Interviews were transcribed automatically using NVivo Transcription (QSR International, Melbourne, Australia), checked for accuracy against the recordings by a research team member, and thematically analyzed [25]. Initial coding was completed according to a priori categories (eg, electronic communication, selection of tools or platforms, and satisfaction). Through team discussion and consensus, a final schema was generated, with themes emerging from the data, to capture (1) learning and evolving the micropractice model, (2) communicating meaningfully, (3) partnering in care, and (4) transition to (increased) virtual care during the COVID-19 pandemic.

Results

Participant Characteristics

Eight patients participated in 2 patient focus groups. All (8/8) were Caucasian, most (6/8) were female, median age was 60.5 (IQR 35-76) years, most (6/8) were college or university graduates, and participants had a wide range of incomes. Median distance from the micropractice was 3 (range 1-10) km. These patients had also sought health care from a median of 2 (range 0-6) specialists, but only 2 of the 8 patients had required a hospital admission in the past year. Two participants reported poor health, and 5 patients considered themselves in good or excellent health. All used technology at least some of the time, with 7 considering themselves a regular or frequent user. In addition, the 2 providers of the micropractice clinical team, a physician and the clinic manager or MOA who own the micropractice, participated in a separate provider focus group; due to the small sample size, their characteristics are not described here. The micropractice has a panel of approximately 700 patients; most have access to the electronic tools utilized by the micropractice (only 19 patients do not).

Themes

Four themes emerged to describe patients' and providers' experiences with the micropractice. These included learning and evolving the micropractice model, communicating meaningfully, partnering in care, and transitioning seamlessly to an increased virtual care model during the pandemic. The Results section is organized around these 4 themes.

Learning and Evolving the Micropractice Model

Both patients and health care providers acknowledged the need for learning to operate in a technology-enabled virtual care model. Providers described a learning curve for both themselves and their patients. For themselves, it was learning over time, through trial and error in using different systems, what constituted the optimal technology and electronic systems to support their practice. The micropractice providers use Med Access EMR (Telus Health, Montreal, Canada) and have been using a virtual attendant, text messaging, and phone-based appointments (RingCentral, Belmont, CA) with online booking (Veribook, Toronto, Canada) since March 2016. They have used videoconferencing visits since 2017 and used RingCentral (RingCentral, Belmont, CA) until mid-2019. They also have a website that explains how the practice works (eg, restricted phone hours but 24/7 messaging). In mid-2019, they centralized and integrated the virtual care options with their EMR, adding a tethered patient portal (Pomelo Health, Montreal, Canada) for videoconferencing visits, secure messaging, appointment booking and reminders, completion of some forms, and broadcast messaging and information sharing; email is only used as a last resort. Patient communication is supported and, in part, triaged by the medical office manager and ultimately addressed by the physician when needed.

Providers described how important it was for clinic personnel to be very comfortable with technology, to have an open mind to ride the learning curve, and to not resort to going back to "what we know" and how they practiced using these digital tools before making them available to their patients. Providers also set up tools and guidance for patients on using digital tools (eg, video appointments) on their clinic website, including FAQs. If needed, the clinic manager provided tool education before appointments, and providers educated patients to appropriate appointment types (eg, virtual vs in-person) to best support their use. Additionally, providers learned about what was optimal through patients' feedback. Some changes to the practice model were prompted by patient feedback, including negatively perceived online reviews:

> *Because of that feedback, we decided to change things around with the schedule and the paperwork. So now it looks like I'm more available, even though I'm still working the same hours. [...] We do take the feedback seriously.*

It was also noted that some patients may have left the practice as this care model did not suit them. While this practice is located in a small city, access to high-speed internet was not identified as a problem by the providers, who noted that fewer than 3% of their patients were without internet access. Similarly, patients also noted that internet access was not a concern for them.

Providers learned to be proactive and anticipate future challenges and difficulties so they could plan accordingly to remediate them or reduce their negative impact. For example, providers began letting patients know in advance when the clinic would be closed for vacations, and patients spoke of valuing this mass communication to keep them informed and be able to do their own planning. Additionally, providers highlighted the importance of maintaining strong boundaries between personal and work life. Finally, providers highlighted that it was essential to have health care team autonomy and proper compensation for the implementation and delivery of virtual care to make this model sustainable.

The patients in our focus groups speculated that patients likely self-selected for this virtual care model, based on familiarity with technology and a willingness to take an active role in their care. Finally, several patients offered suggestions for improving the technology, for example, to accommodate the visually and hearing impaired (eg, running text beneath a picture) and incorporating additional patient data into clinical care such as step counter (pedometer) results. One patient suggested that use of a dialog box or personal diary between him and the physician might help him decide when a visit is necessary or to avoid putting off needed care. Another patient suggested additional reminders for things like preventive care.

Communicating Meaningfully

Communication was at the heart of patients' and providers' experiences with the micropractice; both described various facets of the communication that characterized their micropractice experience. These included the nature of the communication as promoting dialogue, enhancing data sharing, and including family.

Promoting Dialogue

Unique to this practice was the fluid bilateral dialogue that was both synchronous (eg, virtual visits) and asynchronous (eg, email, secure text, appointment booking) that patients found engaging and empowering. One advantage highlighted by both health care providers and patients was that there were no set rules nor conventions about who would initiate a conversation. Sometimes the patient would begin the exchange, and, with the portal, they were not confined to office hours, such as sending pictures of something painful or making appointments in the middle of the night:

> *The technology is so helpful—it's...all online, and you can book at 2:00 AM—you don't have to wait to call to talk to a receptionist.*

At other times, the practice providers would reach out with reminders, follow up on results of tests, or ask patients to schedule an in-person appointment. Patients did not comment on preferences in communication mode, other than preferring the security of the portal compared with email.

The ability to have more of a dialogue-based communication approach made these patients feel more empowered in their care due to the ability to ask questions and send pictures, compared with a physician-driven exchange:

> *I had booked an in-person appointment for a lump that came up in my back. I was very concerned about that, and so I just added that in the comments because the appointment was so far away. And then I very quickly got a response that was like, we want to talk to you sooner.*
>
> *I got an infected foot, and I wasn't quite sure what it was, but I didn't know how the heck she was going to*

> *decide whether I needed to come in or not unless I took a picture of it.*

Patients who liked the asynchronous communication approach described the time it gave them to rephrase their response, rethink their request, and remember answers instead of having to respond on the spot, as when communicating synchronously. Furthermore, one patient noted that there were things that were more easily expressed in writing rather than face-to-face, such as embarrassing conditions or symptoms:

> *It comes out a lot easier, and I can say more through a message. And then, by the time I get to the face to face, like the embarrassment is all gone.*

In contrast, other participants found a relative lack of ease and candor in the virtual setting.

Patients had reasonable expectations for response times, understanding that they would not get a reply on the weekend but expecting text messages to have a slightly shorter response time than portal messages. Patients were oftentimes surprised to get written responses outside regular office hours:

> *I've gotten replies and emails back like in the middle of the night because she's just kind of up and whatever and she never stops working* [...]
>
> *If there's some sense of urgency, it's not as if she hangs up the computer at 5 o'clock in the afternoon. There tends to be responses at interesting times. So, we feel very safe and comfortable about that.*

Despite the value of dialogue for both patients and providers, there was acknowledgement of the impact on providers. Providers acknowledged that it caused a slight blurring of work and home life for them, but the text messaging system, or the "text line," akin to an office phone line, protected their personal phone number from the patient. Further, patients expressed worry about burdening their physician too much.

Enhancing Data Sharing

The integrated, multimodal system and patient portal allowed for communication of a range of types of patient-generated data. Such data included general intake questionnaires (eg, before a pap smear, COVID-19 screening before a visit, new mother, or new patient intake forms), clinical screening tools (eg, Patient Health Questionnaire-9, Generalized Anxiety Questionnaire-7, chronic pain questionnaires, or attention deficit hyperactivity disorder assessment forms), documentation of patient-recorded measurements (eg, blood pressure, heart rates, daily weights, or blood glucose readings), any clinical notes (eg, lab work, investigations, or consults) that the patient might have, pictures from skin lesions, applications for patient benefits, and any appropriate consents (eg, for treatment, requesting medical records, sharing medical information with a caregiver). Health care providers felt that their relationship with their patients allowed them to trust patient-provided information in all but few cases, such as patients with memory limitations or those seeking specific benefits (eg, in disability applications):

> *If I have an elderly patient with dementia, I'm not going to be asking [that] from that patient—maybe I'm going to be asking their caregiver instead. For the most part, the data that I'm collecting, I feel comfortable trusting it because I know the patient is capable of giving me good information or giving me the right data.*

The clinic manager or MOA was responsible for checking the portal and downloading information into the EMR.

Patients and providers found it challenging that platforms for data sharing did not transfer to other care providers to allow for better care coordination. For example, 1 patient noted:

> *I would love to see more data sharing and more integration. I would love to be able to book an appointment with my specialist the same way but [this particular specialist] doesn't offer eHealth appointments. It would be amazing if it was all integrated; [clinicians would realize] that I haven't had imaging done in a while.*

This might lead to timelier receipt of results:

> *If those results were available online instead of being mailed to my house [...] when moving around for school, I would not have gotten them months later.*

The physician reported frustration over lack of system integration with other providers, resulting in delayed receipt of consult reports from specialists. This caused both patient frustration and resulted in a delayed implementation of specialist recommendations:

> *Many times, we need to go out of our way and "fish" for them so we can get back to the patients with a plan and update their medical records.*

Patients were uniformly positive about this new care delivery system. One patient noted that other health care providers were "way behind" in offering virtual access to care:

> *The way in which I approach my access to the health care system changed before COVID. I'm noticing that other physicians are way behind—my specialist does not have the same ability to provide me care that they had before the pandemic. They aren't up to speed with how to do this electronically...so I can get better care by following up with* [the micropractice provider]

Inclusion of the Family

Patients appreciated that the virtual care approach enabled family members to be involved more easily. This included granting access to information and communication to local family members, children, or carers, but the system also allowed involvement of family members outside the province to participate in their care:

> *What's been fascinating about this approach is that my separated spouse in Ontario can participate as well as I can. And that's been incredibly helpful [...]; it provides a level of foundation, a solidity, that I'm not sure we would have had, had there not been this micropractice.*

Health care providers illustrated an example in which a very complex patient, who required point-of-care testing, was able to make use of the virtual care technology to receive optimal

care with the help of a (distant) family member; this would have been very difficult in a traditional office-based practice setting.

Partnering in Care

Unique to this practice is patients' and providers' shared sense of a partnership and patients feeling empowered to take ownership of their care. Both patients and health care providers liked the micropractice care model:

> *You know, you get your full time with them, and they're on time, and I think I feel more heard than when I was in the clinic.*
>
> *They are simply an amazing team, the two of them.*

Health care providers felt they provided very patient-centered care, recognizing that patients enjoyed this access to their provider and generally did not abuse it, but they also missed some separation of work from home life due to the 24/7 messaging.

Overall, patients felt that there was a true partnership, and health care providers valued their opinions, whether the appointment was conducted in-person or virtually, with the clinician offering them opportunities to make informed choices. Patients unanimously agreed that this practice approach empowered them and forced them to take greater ownership of their own care:

> *I have a couple of chronic conditions that I kind of monitor bloodwork for. And I look after myself, and I can do a lot of that kind of self-monitoring. [...] I have the same access to my bloodwork as my physician, so we can both look at it at the same time. I really appreciate that, and it makes me take more responsibility and feel empowered and not helpless.*

Seamless Transition to (Increased) Virtual Care During the COVID-19 Pandemic

Prior to the pandemic, virtual care was used for a substantial portion of patient visits at the micropractice. Prepandemic use eased the care disruption and confusion that occurred with the pandemic shift to a predominant virtual model of care. Patients recognized that virtual care was often the only way they could seek care during the pandemic and acknowledged the benefit of prior familiarity with virtual care (eg, for some mental health concerns). One patient said:

> *Had we had not been transitioning to this style of medical care when the pandemic hit, I think it would have been way crazy, a lot clumsier, and a lot harder.*

Providers similarly lauded being able to seamlessly respond to the virtual shift in care due to the pandemic:

> *I knew these stories from colleagues having to close the clinics because at the beginning of the pandemic, you couldn't see patients, but we never stopped. We had a video conference. [...] And even though patients were not using it much before, now was the opportunity to really push it and get it to what we envision at some point. And now it's probably past that. [...] We had texting. We had messaging. We have it all in play.*

Both patients and providers expressed concerns about not having in-person visits. The health care providers suggested that they sometimes feared not getting the whole picture and missing problems during virtual visits:

> *Missing like, for example, checking the blood pressure of my patients when they come or maybe looking at moles or maybe listening to hearts. I have found things when they come for some other unrelated issues [...] now that I'm not seeing them that often, how many things am I missing?*

These concerns were echoed in patients' concerns that virtual visits provided fewer opportunities than face-to-face meetings to discuss other issues. These concerns were accentuated during the pandemic. Several patients noted deferring needed care during the pandemic such as follow-up blood tests, with 1 patient mentioning being selective about what to visit the doctor for and not being comfortable in a crowded clinic for minor problems, noting how helpful it was having a virtual care format; 1 patient noted:

> *I don't want to go into the lab. I don't want to wait in a line up at the hospital for anything. If I go there and I see a bunch of people, I come home. I just don't go. [...] having your doctor appointments electronically, amazing, I never have to have that fear of, you know, waiting in a waiting room full of people.*

Patients appreciated not having to spend time sitting in waiting rooms or travelling to a speciality clinic that offers virtual visits, which could be substantial in remote settings (eg, 1 hour to 1.5 hours each way); 1 patient noted:

> *Reflecting on my previous experience with an in-person clinic, I have had to wait over an hour, and when you're already taking an hour off of work to go to an appointment, to then have to take 2 hours off of work. [...] I've missed several appointments where I've waited as long as I can* [and then left]

Discussion

Principal Findings

This study suggests that the micropractice care approach can enable patients to be true partners in their care and have more meaningful communication with their providers. Patients who participated in this study were highly engaged in their care, felt safe, and were able to initiate care when needed. These patients liked the asynchronous communication encouraged by this practice model as it allows both immediacy and having time to formulate their thoughts. Providers in the study were proud of delivering very patient-centered care, although they acknowledged that it caused a slight blurring of work and home life. Having a virtual care system in place proved advantageous during the pandemic, although patients reported some deferral of care, which must be addressed as the pandemic eases. The care model, however, likely depends on self-selected patients who are technology-capable and are willing to initiate communication through the portal. Identified challenges of this virtually enabled care model includes providers' fears of missing symptoms and indicators that they may have otherwise noticed

during an in-person visit and the time and effort needed to train both patients and providers in the use of digital technology.

Learning and Evolving the Micropractice Model

Micropractices may allow health care providers to spend more time with their patients and can leverage new technologies and approaches to care more easily than regular (larger) practices [19,20]. Other reported advantages are increased provider satisfaction with their work, including being able to spend more time with their family, but which may come with reduced scope of practice [26]. In contrast, in this work, both health care provider and patients expressed concerns regarding work-life balance for their provider team. In addition, the micropractice team noted that it takes time to find the right systems and there is a digital health learning curve for both patients and providers (eg, requiring technical support). While not identified as an issue in this study, the chasm between those who have internet access to technologies and the digital literacy to work them and those who don't may to lead to disparities and inequities and warrants further research [27].

Historically, micropractice patients report excellent continuity of care, delivered with high efficiency and low barriers to access, yet their value for enabling patients to manage their care remains less clear [28]. A systematic review of 35 studies evaluating clinical microsystems, of which 18 described general practice clinics, found that implementation of these care models helped develop a patient-centered approach; promoted interdisciplinarity and quality improvement skills; and increased clinical efficiency, patient safety, and patient and clinician satisfaction [17]. A recent UK-based qualitative study of general practitioners practicing in micropractice settings found that, while this care model increased clinician satisfaction, quality improvement efforts focused more on administrative or process metrics than health outcome-focused metrics, and, as such, the value of this approach in improving patient outcomes remains unclear [29].

Communicating Meaningfully

Care coordination is a challenge in health care due in part to communication barriers between primary care providers and specialists; this was no different for the micropractice providers and their patients who participated in our study. Care coordination strategies may improve health outcomes after hospital discharge [30]; for example, using technology to deliver discharge information was the preferred method for both health care providers and patients [31]. While awaiting province-wide integrated EMRs that allow data sharing, suggestions for improving care coordination include use of smartphone apps [32], patient portals as a communication tool for care coordination [33], and developing middleware solutions for transferring data from personal health records to EMRs [34].

Virtual 2-way patient-provider communication was a valued component of the micropractice we studied, which highlighted the dialogical nature of communication between patients and health care providers who are not constrained by traditional office-hour conventions. This contrasts with concerns raised previously by physicians about the obligation of communicating beyond normal working hours [35] and reflects the patient-centric ethos of the micropractice. The ability of the providers in this study to make themselves more available while working the same number of hours through use of multiple communication modalities allowed patients to share their data and questions at times that were relevant to them (ie, when they were experiencing concerns). The timeliness of the responses contrasts with the long patient waiting times typical of traditional primary care providers [36,37].

Partnering in Care

Personal health records may increase health-protective behaviors and facilitate a more patient-focused health partnership and social care system [38]; yet, evidence indicates that uptake of patient portals and personal health records is low [39,40]. The majority of studies, however, used patient portals as a supplement to in-person visits, making the portal seem more peripheral to care and potentially discouraging its use. In the micropractice we studied, portal use was patients' primary mode for accessing care and interacting with their providers; this appeared to facilitate high patient engagement, a behavior also observed in patients in rural New Zealand [41]. Supporting this idea, authors of a systematic review reported patients' interest in using portals for patient-clinician communication as one of the areas with strongest evidence [42]. Recommendations for patient-provider partnerships in care and to build lasting digitally enabled care models include the use of low-threshold technologies, security and privacy regulations, reimbursement and liability policies, training and awareness of the technology's limitations, and not completely replacing the role of in-person medicine [9].

Seamless Transition to (Increased) Virtual Care During the COVID-19 Pandemic

Although the decision for scheduling mostly virtual visits during the pandemic was made by the micropractice team, patients expressed great satisfaction with the virtual care received, in part because they were already familiar with virtual visits and also likely due to their underlying relationship with, and trust in, the micropractice team. A survey of 420 patients attending virtual visits before the pandemic found that over 80% of patients agreed or strongly agreed that their virtual visit was as good as an in-person visit by a clinician [43]. While having a prior relationship with their virtual visit clinician was associated with less comfort and ease with virtual technology [43], here the opposite was found, possibly due to enhanced digital data sharing experienced by micropractice patients. Patients expressed hopes that such health data sharing systems would increase ownership in their care, improve timeliness and efficiency of care delivery, increase care personalization, and lead to safer care [44].

The fear about missed diagnoses during virtual care expressed by the micropractice physicians was also seen in a recent media review, in which health care providers worried that less frequent care, or more impersonal virtual care, might worsen health outcomes [45]. Missed diagnoses during virtual care have not been widely reported; in contrast, a report of tele-ophthalmology during the COVID-19 pandemic indicated appropriate triage and what appeared to be reasonable patient safety, with only

1.5% of virtual visits resulting in an in-person visit within 1 day or 5.4% in a visit within 2 weeks [46].

Despite the value of virtual care, the micropractice team in this study expressed concern that care had been missed. This is consistent with evidence of deferral of primary care in the United States, Canada, and the Netherlands during the COVID-19 pandemic, including concerns about missed referrals and routine care, increasing risk for morbidity and mortality [47,48]. As the acute phase of the COVID-19 pandemic subsides, this issue may resolve; however, health care providers may need to strategize ways to address this issue for future emergencies [49] and plan for catching up on preventive activities such as immunizations [50,51] and cancer screening [52,53].

Limitations

In this study, we focused on only 1 micropractice and its patients and health care providers, which limits transferability of the results, including the potential to adapt its success to other practices. There is also the possibility of selection bias, whereby those more enthusiastic about the virtual care approach volunteered to participate in focus groups. Yet, this in-depth exploration provides unique insights that might be lost by pooling results with other practices that adopted virtual care during the pandemic. Another limitation might be that the health care providers owned the micropractice; however, the providers were not involved in the study design, collection of patient data, nor the analysis of results. Additionally, they might be more invested in its success and be willing to tolerate hardships more than if they had been employees. As such, additional insights from micropractices that are not owner-operated may be useful to inform the feasibility and utility of larger-scale implementation.

Future Work

Additional study is needed regarding implementation of digital solutions in primary care practices with respect to different stages of practice and technology readiness for implementation, number of features added separately or together, and the influence on patient outcomes and team-based care. A comparison of the experiences of patients and health care providers in this rural micropractice with rural practices that only adopted virtual care as a response to the COVID-19 pandemic might be insightful to identify additional barriers and opportunities for long-term sustainable implementation of virtual and technologically enhanced care.

Conclusions

Using focus groups of health care providers and patients of a virtually enabled micropractice, we identified that opportunities of this hybrid care model lie in patients being true partners in their care. This can result in high patient engagement and satisfaction. Yet, the virtual care model needs to take account of less technology-engaged or technology-comfortable patients. Barriers lie in gaps in coordination of care with other practices that are less technology-enabled and provider fear that signs or symptoms more evident with an in-person examination could be missed. Finally, even in this setting, deferral of care occurred during the COVID-19 pandemic, and opportunities to address care gaps, including prevention, should be sought.

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Authors' Contributions

All authors contributed to the study design. All authors contributed to the collection of data, and MG, KLR, LB, and MAS analyzed the data. MG drafted the manuscript. All authors critically revised and approved the manuscript for publication.

Conflicts of Interest

PRE and LSH own the Kootenay Micro Practice, Nelson, BC.

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Health Research
EMR: electronic medical record
MOA: medical office assistant

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Original Paper

Using a Virtual Community of Practice to Support Stroke Best Practice Implementation: Mixed Methods Evaluation

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Abstract

Background: Successful best practice implementation is influenced by access to peer support and knowledge exchange. The Toronto Stroke Networks Virtual Community of Practice, a secure social media platform, is a knowledge translation tool supporting dissemination and adoption of stroke best practices for interprofessional stroke stakeholders.

Objective: The aim of this study is to evaluate the use of a virtual community of practice (VCoP) in supporting regional stroke care best practice implementation in an urban context.

Methods: A mixed methods approach was used. Qualitative data were collected through focus groups and interviews with stroke care provider members of the VCoP working in acute and rehabilitation settings. Thematic analysis was completed, and the Wenger Value Creation Model and developmental evaluation were used to reflect practice change. Quantitative data were collected and analyzed using website analytics on VCoP use.

Results: A year after implementation, the VCoP had 379 members. Analysis of web analytics data and transcripts from focus groups and interviews conducted with 26 VCoP members indicated that the VCoP provided immediate value in supporting user networking, community activities, and interactions. Skill acquisition and changes in perspective acquired through discussion and project work on the VCoP were valued by members, with potential value for supporting practice change. Learning about new stroke best practices through the VCoP was a starting point for individuals and teams to contemplate change.

Conclusions: These findings suggest that the VCoP supports the early stages of practice change and stroke best practice implementation. Future research should examine how VCoPs can support higher levels of value creation for implementing stroke best practices.

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KEYWORDS

stroke; rehabilitation; knowledge translation; implementation; quality improvement; evidence-based practice; evaluation; continuing education; social media; internet; web-based learning; allied health

Introduction

Background

In Canada, stroke care is guided by the *Canadian Stroke Best Practice Recommendations* [1], a resource for health professionals to bridge the gap between scientific knowledge and clinical practices in stroke care. Best practice guidelines are effective in increasing the performance of care processes identified as best practices and in improving patient outcomes [2]. Although best practices can support the consistent delivery of evidence-based care throughout a health system, the implementation of best practices can be challenging because of environmental barriers including organizational constraints, resource allocation, and social and clinical norms that vary among professions, organizations, and regions [3]. To address the challenge of implementing best practices in diverse contexts, a variety of approaches to tailor programs to meet the needs of regional settings and target groups have been developed [3]. Implementation success is influenced by individual factors such as educational interests and motivation [4]. Social factors, such as communication within a social network, accessibility of local opinion leaders, and availability of knowledge exchange with peers, also influence the success of initiatives aiming to achieve practice change in health care [5-8].

Communities of practice (CoPs) are groups of people "sharing a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis" [9,10]. CoPs are knowledge translation (KT) tools that have the potential to support the implementation of practice change initiatives by addressing the communication and social network factors affecting implementation success. Research on CoPs shows that they can contribute to best practice implementation in a variety of health care contexts, including stroke care [11-14]. Virtual CoPs (VCoPs) are a type of CoP that combines the value of traditional face-to-face CoPs in supporting peer-facilitated learning with the value of social media networks to overcome geographical and temporal boundaries to knowledge sharing and continuing education in health care [15]. VCoPs have typically provided a closed, virtual group environment to share knowledge, address professional isolation, network, foster peer collaboration and mentorship, and improve clinical practice through KT [15].

Rationale

VCoPs are a potentially valuable tool for supporting the implementation of stroke care best practices, as they provide a mechanism to share knowledge among stakeholders across geographical and organizational boundaries. VCoPs also provide a virtual space for care providers from different disciplines to connect. VCoPs provide stakeholders with a platform to share strategies and outcomes of best practice implementation initiatives in different contexts, allowing them to leverage learning from others to make the process of quality improvement more efficient.

The Toronto Stroke Networks (TSNs) work collaboratively with stakeholders to implement high-quality stroke care and have an established education and KT infrastructure grounded in the *Knowledge to Action* (KTA) Framework [16]. Following TSNs stakeholder meetings with clinicians, researchers, managers, and system leaders across 17 regional acute and rehabilitation organizations, the TSNs established a stroke-specific VCoP to support the system-wide implementation of stroke best practices [17]. VCoP membership is largely constituted by regional stroke care providers in a large urban setting; however, there are also members from outside this region. As an ongoing KT initiative, the TSNs VCoP supports stroke best practice implementation by providing discussion forums, organizing working groups, housing a directory of local stroke care stakeholders, and curating a central repository of stroke care resources. In addition to housing passive resources (eg, educational and implementation resources for stroke best practices and members directory), the VCoP was designed to support active engagement and interaction among members through discussion groups and forums. Members may join any open public groups based on specific topics (eg, mood and cognition), in which multiple discussion forums may be housed about different subtopics (eg, depression screening as a subtopic of mood and cognition). Members have the capability to start new discussion threads within a forum or respond to existing threads by posting. Posts can include plain text responses, links, or uploaded resource documents. Documents can also be uploaded to groups as a general resource not associated with a specific post. Members may also request the creation of private groups, which have the same functionality as public groups, but require members to submit a request to join them.

The aim of this study is to evaluate the use of the TSNs VCoP by members and the value created in supporting regional dissemination and implementation of stroke care best practices using a mixed methods approach. This study adds to the small existing body of literature on the use and value of VCoPs to support best practice implementation in health care contexts.

Methods

Overview

A mixed methods approach was used in this study to evaluate the TSNs VCoP using both quantitative data on site use and qualitative data on value created through the use of the VCoP. Developmental evaluation [18,19] and the Wenger Value Creation Model [10] were used as foundations to inform the development of the evaluation framework for the VCoP.

Evaluation Framework

Developmental evaluation seeks to enhance the "understanding [of] the activities of a program operating in dynamic, novel environments with complex interactions" [18] by asking evaluative questions and gathering data to inform ongoing decision-making. Developmental evaluation poses a useful approach for assessing the value and impact of CoPs for supporting best practice implementation because of the complex, social nature of CoPs as an educational strategy. For VCoPs, developmental evaluation is an appropriate approach for assessing the challenge of tailoring implementation for varying contexts identified by individual VCoP members, teams, organizations, and the region.

Although developmental evaluation provides a structured method of assessment, the Wenger Value Creation Model [9] provides a complementary conceptual framework for contextualizing the results of this evaluation. The Wenger Value Creation Model [9] consists of five cycles: cycle 1, *Immediate Value—Activities and Interactions*; cycle 2, *Potential Value—Knowledge Capital*; cycle 3, *Applied Value—Changes in Practice*; cycle 4, *Realized Value—Performance Improvement*; and cycle 5, *Reframing Value—Redefining Success*. The Wenger Value Creation Model [9] supports the evaluation of CoPs by assigning value to the processes and outputs of a network that result in learning enabled by community involvement and networking [10]. The use of this model requires the integration of quantitative indicators and qualitative themes to build a picture of how a CoP creates value for its members [10]. To support data analysis, a framework based on developmental evaluation [18,19] and the Wenger Value Creation Cycles [9,10] was constructed by the authors (MD, EL, and SQ; Table 1).

Data Collection

Data on VCoP use were collected 1 year after implementation of the VCoP by 2 university students supervised by a member of the TSNs team (JF), including quantitative, aggregate web analytics data (eg, number of members and number of site visits), quantitative user-level data (eg, number of discussion posts), and qualitative user-level data (eg, questions asked in discussion forums and replies to discussion posts). Quantitative data were collected manually from the VCoP and using Google Analytics. Qualitative user-level data were collected manually from the VCoP and did not contain any identifying characteristics of users.

VCoP members were contacted with a request to participate in a focus group or semistructured interview via email and through the VCoP by a member of the TSNs team (JF). Semistructured interviews and focus groups were conducted by a member of the TSNs team (JF) with support from 2 university students following an interview guide with prompts based on the Wenger Value Creation Model [9,10]. Interviews and focus groups were audio recorded and transcribed.

Data Analysis

To analyze the data collected using web analytics, descriptive analysis of quantitative data on VCoP use was completed using Microsoft Excel (version 2015, Microsoft) to determine the total numbers of page visits, posts, VCoP members, and other indicators of VCoP engagement within 1 year following implementation. Narratives from VCoP discussion forums were analyzed using the analysis framework for this study based on the Wenger Value Creation Model [9,10] (Table 1).

To analyze the data collected from interviews and focus groups with VCoP members, transcripts from audio recordings of interviews and focus groups were generated and analyzed using thematic analysis [20]. Although an interview guide based on the Wenger Value Creation Model [9,10] was used, the analysis was inductive, in that themes developed in the analysis were based on what emerged from discussions in interviews and focus groups, not a predetermined thematic or coding structure.

The analysis was conducted individually by two university students and two authors (MD and EL) with expertise in KT. Manual coding of transcripts was performed to create frameworks by each individual. Subsequently, individual coding frameworks were compared manually to reach a consensus and develop a preliminary coding framework. This framework was then applied in recoding the transcripts. The resulting themes were collectively reviewed for validation through consensus. The trustworthiness of the findings was supported by review and validation of themes by authors who did not participate in the interviews and focus groups (MD and EL). An audit trail of coding changes was created to document the process of analysis and ensure consistency between coders.

Quantitative and qualitative data from web analytics and interviews and focus groups with participants were integrated using the evaluation framework developed for this study (Table 1) to identify broader themes of value creation stories generated from VCoP use.

Ethics Approval

Ethical review and approval for this study were provided by the Sunnybrook Health Sciences Centre Research Ethics Board before the collection of data (approval number 123-2013). Quantitative data on VCoP use were anonymous, and qualitative user-level data were anonymized and deidentified at the time of collection. Informed consent to participate in interviews and focus groups was provided by VCoP members interested in participating in the study. Any identifying details presented in interviews were omitted from transcripts.

Table 1. VCoP[a] evaluation framework using the Wenger Value Creation Cycles.

Cycle and cycle indicator	Quantitative data (web analytics)	Qualitative data (interviews and narratives from VCoP)
Cycle 1: Immediate Value—Activities and Interactions		
Level of participation	Number of threads, total number of members, number of members in a group, number of members in discussion forums, and number of discussion forums	Questions or statements related to joining a discussion forum
Quality of interaction	Frequency of responses to inquiries, frequency of citing one's own experience, post length (words), number of debates or differing points of view, and number of suggestions made to a problem	Questions or statements about a clinical issue and sharing of a case example
Networking	Number of group memberships	Question or statement about a need that can be met by the expertise of another member and request connection with a member's particular knowledge
Collaboration	Number of joint projects and timeliness of responses	Question or statement about a collaborative project and statement about length of time a member waited for response to a question
Cycle 2: Potential Value—Knowledge Capital		
Skills acquired	Number of documents	Question or statement about a document on the VCoP that was used or shared with colleagues
Change in perspective	—[b]	Statements indicating a shift in understanding or opinion
Confidence building	—	Questions or statements indicating disagreement or challenging posts of other members
Cycle 3: Applied Value—Changes in Practice		
Implementation of advice, solutions, and insights	—	Questions or statements about successes or challenges related to applying new learning from the VCoP
Use of social connections	—	Questions or statements about networking with other VCoP members
Cycle 4: Realized Value—Performance Improvement		
Personal performance	—	Statements about personal goals
Organizational performance	—	Statements about organizational goals or accomplishments
Organizational reputation	—	Statements about organizational performance relative to other benchmarks (eg, Ministry of Health and Long-Term Care and Health Quality Ontario)
Cycle 5: Reframing Value—Redefining Success		
Community aspirations	—	Questions or statements that indicate new purpose for the VCoP or improvements and/or additions to the community
Relationships with stakeholders	—	Questions or statements about relationship building or with others external to the VCoP (eg, patients or other organizations)

[a]VCoP: virtual community of practice.

[b]No quantitative data identified.

Results

Overview

A year after implementation, 379 members had joined the VCoP from 22 organizations in the TSNs representing several professional backgrounds: nursing, occupational therapy, physical therapy, speech-language pathology, medicine, academic research, and other health system stakeholders. Of these 379 members, 26 (6.9%) provided informed consent and participated in 14 interviews and 2 focus groups. Participants included nurses, occupational therapists (OTs), physicians, physiotherapists (PTs), and speech-language pathologists (S-LPs) from 4 rehabilitation and 8 acute care organizations. Overall, 19 participants provided data for number of years in practice, with the mean number of years practicing being 15.6 (SD 8.7; range 2-29.5) years.

Quantitative Results

The data collected from the VCoP through web analytics reflecting cycles 1 and 2 of the evaluation framework are summarized in Table 2.

Table 2. Quantitative data summary.

	Value
Descriptive web analytics	
Virtual community of practice members, n	379
Groups, n	24
Discussion forums, n	21
Discussion forum descriptive analytics	
Threads initiated in each discussion forum, mean (SD)	1.04 (1.4)
Discussion threads in each group, mean (SD)	1.0 (1.4)
Posts in each thread, mean (SD)	2.5 (5.1)
Prompts and questions per discussion forum, n	28
Responses to inquiries, n	27
Instances own experience cited, n	6
Debates about a topic, n	0
Length of posts (number of words), mean (SD)	67.2 (65.1)
Members in each group, mean (SD)	17.0 (41.2)
Members in a discussion forum, mean (SD)	1.9 (1.7)
Member behavior descriptive analytics	
Documents shared, n	117
Suggestions made to a problem, n	31
Joint projects, n	9
Timeliness of responses (number of days), mean (SD)	18.6 (14.2)

Qualitative Themes

The subjective value of the VCoP and use patterns were collected using interviews and focus groups with VCoP members. Through a qualitative thematic analysis of interview and focus group transcripts, the research team identified 5 themes discussed in the next sections.

Theme 1: Effective Networking

Participants noted that a primary function of the VCoP is to provide a more effective platform for contacting individuals and building networks within and across disciplines. This enhanced connectivity was primarily achieved through the use of the VCoP as a mechanism to find members' organizational contact information and directly message them through this platform. Participants noted that they leveraged the VCoP network to assist colleagues who were not VCoP members, suggesting the spread of VCoP value beyond the immediate member network:

> *...I helped a colleague here who needed to contact somebody...and you know, through the VCoP I knew exactly who she needed to contact. I got her number through the member directory.* [Participant 17, OT]

> *What is meaningful to me is directly messaging other members, I can network with people in the same discipline.* [Participant 2, S-LP]

Theme 2: Value for Project-Based Work

Participants also discussed how they leveraged the VCoP to support collaborations within and between professions on ongoing stroke projects. Members also used the VCoP to collaborate with individuals on posters for conferences, which contributed to knowledge transfer outside the VCoP:

> *We've been using [the] VCoP for the development of posters...to share ideas & information about the process, and then post the actual creation of posters on VCoP...that was our only means of communication at that point...I was able to liaise with different [colleagues] about different practice concerns...the two posters I worked on.* [Participant 10, OT]

This project-based collaboration on the VCoP was noted to provide additional educational opportunities. For example, individuals not directly involved in he projects benefited from observing the collaborative process in public groups, leading to the development of conference posters. In addition, VCoP members identified that conducting project-based work on the VCoP led to the development of practice resources:

> *I have learned things from reviewing the other posters that I haven't been involved in because I was part of the online group and saw what was posted.* [Participant 6, nurse]

> *[The] VCoP was the means of communication for a group project...afterwards, I created additional assessment checklists...and shared it with my team.* [Participant 19, OT]

Theme 3: Resource Sharing Supports Application of Knowledge to Practice

Participants identified that access to up-to-date information and resource sharing improved with VCoP use. The VCoP was noted as beneficial for identifying topic-specific resources more easily and providing a central location for resources. This increased accessibility saved members' time that would otherwise have been spent searching for these resources:

> *Now with the VCOP, I will not have to go back to my desk to refer to the assessment checklist as it is all online now.* [Participant 16, nurse]

> *I printed the triage tool that someone uploaded to the VCoP and gave it to new people on my team for reference.* [Participant 17, PT]

VCoP members also noted that these resources had an impact beyond their immediate use. Resource sharing on the VCoP provided a catalyst for in-person knowledge sharing about best practices across institutions. Although a direct link to changes in practice was not identified, participants noted that VCoP resources started discussion about changes in practice that could lead to future changes:

> *I shared information with a group that sparked discussion about [specialized] assessments, the comparison between hospitals prompted discussions here with our [professional group] about whether we should change our ways of doing things.* [Participant 13, OT]

Theme 4: Enhancing Understanding of Stroke Best Practices and Stroke Care Priorities

Participants identified that the VCoP helped them understand the broader picture of stroke best practices within their region beyond their disciplinary boundaries. Participants noted that the VCoP helped them access information to support learning about stroke Quality-Based Procedures (QBPs) [21], which are stroke care procedures associated with improved outcomes and reduced financial cost to the health care system:

> *Looking up the information about the QBP is very helpful to get someone new to understand how it impacts the [stroke] program...it gives them a leverage point of how they can advocate for the stroke patients.* [Participant 17, PT]

Multiple participants noted that the information shared on the VCoP went beyond what was available from other web-based sources and was more regionally relevant. Learning about activities and concerns outside one's practice was made possible through a diverse membership on the VCoP from across professions, sectors, and organizations within the region:

> *So if you really want to find out what's happening across the stroke community, you have that opportunity more at your fingertips than what you did before.* [Participant 8, PT]

> *It's information that you're not going to necessarily find on the internet because it's about current practice.* [Participant 12, OT]

> *I have a better awareness of the best practices and what the bigger picture is. When you work in one area (e.g. rehab) you don't really have a big sense of what was going on in acute care, what they were looking at for outpatient services, community service...being a part of the community and through looking at some of the resources.* [Participant 8, PT]

Theme 5: Barriers to Use

Although themes of benefits were identified, challenges with accessing resources were also recognized as barriers to VCoP use. Members noted that the navigation path to certain resources was too long, making them difficult to find. Frustration over inability to find resources and time spent searching for them was noted as a deterrent to future use:

> *If it takes less time to find it, right, it's like you're spending like 10 minutes and you're like, "Okay, I'm not going to do this again," right?* [Participant 2, S-LP]

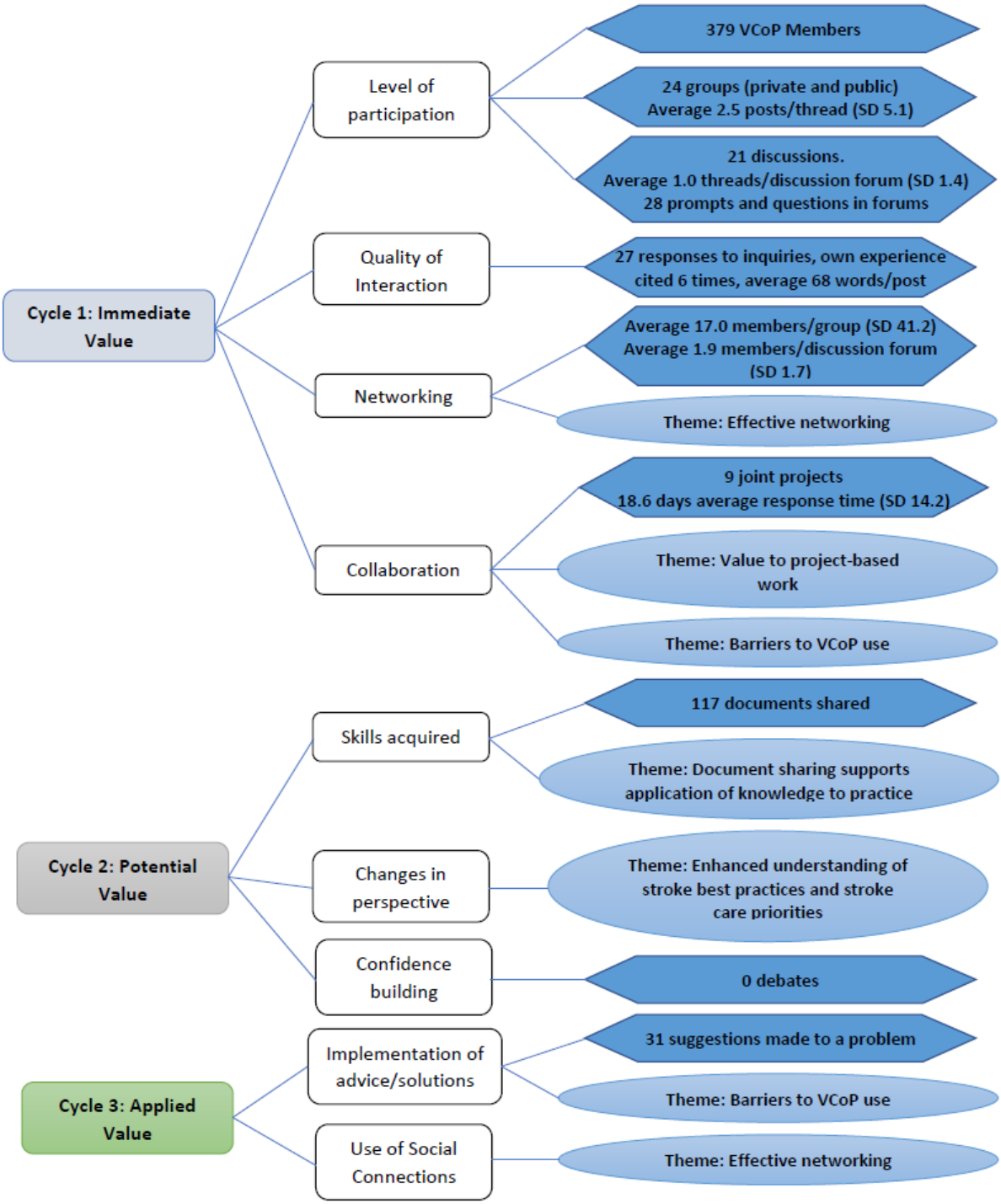
Email notifications were suggested as a strategy to increase engagement in preferred topics and previous discussions in which individuals had participated. This suggested that improvement may decrease the time spent searching the site for information and challenges with navigation:

> *...if there was a new tag or a new thing, something pops up into my e-mail, to, kind of, go answer it...what about an option to receive updates via email, or notifications based on individuals' interests?* [Participant 9, physician]

Integrating Quantitative Data and Qualitative Themes

The results from both quantitative and qualitative analyses were applied to the evaluation framework. These results provide evidence for value creation associated with VCoP reflective of cycles 1 to 3 of the Wenger Value Creation Model (Immediate Value, Potential Value, and Applied Value, respectively; Figure 1).

Figure 1. Mapping of quantitative data and qualitative themes to an evaluation framework reflecting the Wenger Value Creation Model (cycles 1-3). VCoP: virtual community of practice.



Discussion

Principal Findings

The results of this evaluation strongly support the creation of *Immediate Value—Activities and Interactions* (cycle 1) and *Potential Value—Knowledge Capital* (cycle 2), with some evidence provided for creation of value in *Applied Value* (cycle 3) in a VCoP to support stroke best practice implementation [9]. Support for the creation of immediate value in activities and interactions is evidenced by value creation stories identified in this study that described networking, collaboration, and acquiring skills and perspectives through document sharing as meaningful forms of VCoP use for members. Several groups and discussion forums were created during the evaluation period, providing a platform for networking and collaboration. Evidence supporting the creation of value in knowledge capital was evidenced by the number of resources shared by VCoP members during the evaluation period and participants' narratives about using resources from the VCoP to initiate conversations with

their teams about best practice change. Participants frequently cited this as a starting point for team discussions and questioning of current practice that could lead to practice change. The number of responses to inquiries and suggestions made by members demonstrates the responsiveness of the community to one another.

Although evidence for value creation reflective of cycle 3 was weaker than that of cycles 1 and 2 in this study, some narratives and data on the number of projects, number of resources shared, and number of solutions to problems offered by members support the initial steps toward best practice implementation. Several VCoP member narratives described sharing of resources as helping individuals and teams make progress toward changes in practice. For example, VCoP members interacting in a group (cycle 1) supported the generation of knowledge capital such as an educational poster (cycle 2). In the process, members learned from each other and brought information back to their teams, prompting discussions about practice changes (cycle 3).

Evidence of the value created by a VCoP to support stroke best practice implementation in this study aligns with existing KT frameworks that identify the importance of increasing awareness of best practices and identifying practice gaps. For example, the KTA Framework [16] outlines the importance of becoming aware of best practices before determining the gaps, which, in this study, was achieved through interactions between VCoP members and collaboration to create new knowledge products addressing identified gaps. In another framework, Pronovost et al [22] described a collaborative model for integrating theory into practice that engages staff in understanding the current best practice gap and the potential negative consequences of the gap. The KTA Framework [16] and the Wenger Value Creation Model [9] both identify the need to build awareness and prompt collaborative thinking about practice gaps as foundations for successful implementation, which aligns with what was observed in this evaluation.

This evaluation found few instances of members sharing their experiences or debating issues, suggesting that this community is still in the process of building social capital. Social capital is created in social networks [23] through relationship formation and is supported by mutual confidence and trust [24,25]. Members may be hesitant to challenge others or share experiences that could be perceived as organizational or personal shortcomings in a web-based forum such as a VCoP. Previous research has suggested that developing social capital requires more time [26]. This may also explain why this study found evidence for the creation of value in cycles 1 to 3 but less evidence of value created in cycles 4 and 5. It is possible that a data collection period of 1 year may have been too brief, for this growing community, to capture VCoP value in cycles 4 and 5. As the VCoP builds and becomes more deeply integrated into the TSNs' initiatives, more evidence for cycles 4 and 5 may emerge. Research should continue to evaluate mature VCoPs, as this technology is increasingly being adopted to support KT and interprofessional collaboration.

The patterns of and reflections on VCoP use identified in this study may pose challenges to value creation on the VCoP. Web analytics data indicated slow response times for users to address questions posed by others on the VCoP and instances of as few as 2 individuals having web-based exchanges in some discussion forums, whereas other forums had extensive resource sharing. Slower response times and inconsistent engagement across different discussion forums could challenge value creation on the VCoP by discouraging members from posing questions if they do not think they will receive a timely response or any response at all. Although some VCoP members identified that the VCoP saved them time in the long run when it came to finding resources, others, as supported by previous literature [15,27], also identified the amount of time required to navigate the VCoP as a potential challenge to use. A shorter click path required to access sections of the site, active facilitation of the VCoP (eg, prompting responses and connecting members to answer each other's questions), and more notifications for personally relevant site activity, as suggested by participants, may lead to a greater number of responses and sharing of experiences.

The self-selection of VCoP members to participate in the focus groups and interviews, rather than random sampling, creates a potential sampling bias that could impact the generalizability or transferability of this work to different regional contexts or KT applications. Additional insights provided by less active members could improve understanding of VCoP value, as active members outweighed nonactive members participating in focus groups and interviews.

Participants included health care providers in acute and rehabilitation hospital settings, which represents VCoP membership demographics at the time of data collection. Membership has since expanded to include more VCoP members from nonhospital settings. Although the VCoP has an interprofessional membership, most participants in focus groups and interviews were allied health professionals. A more diverse group of participants may affect the value expressed by VCoP members for health professions involved in stroke care.

In addition, this study was conducted to evaluate a regional best practice implementation tool. Study participation included users in a large metropolitan area. Although there are existing face-to-face opportunities to build social capital in this region, challenges for stroke care providers to access these opportunities exist (eg, taking time away from care provision to commute to in-person events) [28]. This feedback from stakeholders prompted the development of the TSNs VCoP as a virtual KT resource. Previous research has shown that VCoPs are an effective tool for addressing geographical boundaries to collaboration among health care providers [15]. Some studies have suggested that individuals in more rural areas, where stroke teams are more isolated, may be more motivated to engage in alternate ways to learn and decrease isolation [29,30]. This virtual KT resource was developed to address geographical challenges to in-person engagement in an urban setting; however, they are potentially relevant to both urban and rural settings. Future research should compare the value of VCoPs as a tool for KT in different regional contexts.

Conclusions

Through a developmental evaluation approach, the value of a VCoP in supporting the initial phases of stroke best practice

implementation was demonstrated in this study. Members reported enhanced networking, more efficient identification of resources, and enhanced collaboration on joint projects to build and maintain professional relationships. VCoP use contributed to a broader understanding of the stroke continuum of care and a better understanding of the priorities in stroke care that supported individuals and teams to contemplate best practice change. Future VCoP design changes to improve functionality and user experience were suggested to increase collaboration and the quality of engagement. The evaluation framework used in this study will continue to be used to collect evidence of the value created by the TSNs VCoP as an ongoing KT initiative. The use of a VCoP in other care networks and regions should be investigated to gauge the potential value of this educational strategy for health professionals working with other populations seeking to enhance best practice implementation.

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Conflicts of Interest

None declared.

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Abbreviations

CoP: community of practice
KT: knowledge translation
KTA: Knowledge to Action
OT: occupational therapist
PT: physiotherapist
QBP: Quality-Based Procedure
S-LP: speech-language pathologist
TSN: Toronto Stroke Network
VCoP: virtual community of practice

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Original Paper

Live Video Mind-Body Program for Patients With Knee Osteoarthritis, Comorbid Depression, and Obesity: Development and Feasibility Pilot Study

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Abstract

Background: Knee osteoarthritis (KOA) is the most common joint disorder in the United States and a leading cause of disability. Depression and obesity are highly comorbid with KOA and accelerate knee degeneration and disability through biopsychosocial mechanisms. Mind-body physical activity programs can engage biological, mechanical, and psychological mechanisms to improve outcomes in KOA, but such programs are not currently available.

Objective: This mixed methods study aims to adapt a mind-body activity program for the unique needs of patients with KOA, depression, and obesity (GetActive-OA) delivered via live video.

Methods: Participants were adults (aged ≥45 years) from rural Kentucky with obesity (BMI≥30 kg/m^2), idiopathic KOA with mild to moderate radiographic changes, and elevated depressive symptoms (9-item Patient Health Questionnaire ≥10) recruited from 2 orthopedic centers. In phase 1, we developed GetActive-OA and the study protocol using qualitative focus group feedback from the study population (N=9; 2 focus groups, 90 minutes) and multidisciplinary expertise from clinical psychologists and orthopedic researchers. In phase 2, we explored the initial feasibility, credibility, and acceptability of GetActive-OA, live video delivery, and study procedures via an open pilot with exit interviews (N=5; 1 group). This research was guided by National Institutes of Health (NIH) model stage IA.

Results: Phase 1 qualitative analyses revealed nuanced information about challenges with coping and increasing activity, high interest in a mind-body activity program, program participation facilitators (flexibility with technology) and barriers (amotivation and forgetfulness), and perceived challenges with data collection procedures (blood and urine samples and homework). Phase 2 quantitative analyses showed that GetActive-OA met most a priori feasibility markers: acceptability (80%), expectancy (100%), credibility (100%), clinician adherence (90%), homework adherence (80%), questionnaire data collection (100%), program satisfaction (100%), and safety (100%). Adherence to ActiGraph wear (80% baseline, 20% posttest) and collection of blood samples (60%) were low. Participation in GetActive-OA was associated with signals of improvements in general coping (Cohen *d*=2.41), pain catastrophizing (Cohen *d*=1.24), depression (Cohen *d*=0.88), anxiety (Cohen *d*=0.78), self-efficacy (Cohen *d*=0.73), pain (Cohen *d*=0.39), and KOA symptoms (Cohen *d*=0.36). Qualitative exit interviews confirmed quantitative findings and provided valuable information to optimize the program and protocol.

Conclusions: Patients with KOA, depression, and obesity from rural Kentucky were interested in a live video mind-body activity program. GetActive-OA shows promise; however, the program and protocol require further NIH stage I refinement before formal efficacy testing (NIH model stage II).

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KEYWORDS

knee osteoarthritis; depression; obesity; mind-body; physical activity; mixed-methods; mobile phone

Introduction

Background

Symptomatic knee osteoarthritis (KOA) is the most common joint disorder in the United States and is projected to affect >67 million Americans by 2030 [1,2]. Approximately one-third of patients with KOA experience rapid progression of cartilage degradation, knee pain, and disability [3], leading to greater health care use [4,5]. Depression and obesity, which are highly comorbid among patients with KOA [6-8], place individuals at a greater risk for these poor outcomes.

Depression, obesity, and KOA exacerbate one another through biopsychosocial pathways. Specifically, these conditions share a common pathophysiology [9-11] that involves a cycle of increased proinflammatory cytokine interleukin 1-beta (IL-1β) and Toll-like receptor 4 (TLR4) [3,12,13] activity, which, in turn, leads to inflammation-induced knee cartilage degradation [14]. KOA, depression, and obesity also exacerbate one another though a *disability spiral* that involves reduced physical activity [15], more pain, low mood, higher weight, and further knee cartilage degradation [16]. Current treatments (eg, medications, injections, and knee arthroscopy) are costly [17] and have limited efficacy [18], likely because they do not address the aforementioned biopsychosocial pathways that reinforce knee cartilage degradation, disability, and obesity. Novel treatments are needed to target the biopsychosocial processes involved in the KOA, depression, and obesity comorbidity.

Physical activity can improve depression, obesity, KOA pain, and cartilage breakdown [19]; however, uptake and adherence are challenging [20,21]. Indeed, there are barriers to engaging in physical activity in this population, including pain intensity, misinterpretation of pain signals as threats, and programs that are too challenging or incompatible with patients' lives [22-25].

Walking is a promising, safe, and patient-preferred method for improving physical function in populations with chronic pain, particularly when it is gradually and strategically increased (ie, quota-based pacing regardless of symptoms) [22,26-32]. In addition, mind-body programs, which incorporate a range of complementary practices (eg, meditation, relaxation, breathing, and body movement) [33], can decrease depression, obesity, and pain in osteoarthritis (OA) [34-36], which are additional barriers to engagement in activity in this population. Combining mindfulness with walking is promising for improving mood and coping with KOA [35], and trials of this approach are ongoing (eg, NCT03064139). Multimodal programs that teach a variety of mind-body, walking, cognitive behavioral, and resiliency skills are needed to address depression, obesity, and pain as barriers to physical activity in OA and to target the biopsychosocial pathways of this comorbidity [37-42].

We have previously developed a multimodal, evidence-based program [43-46] for adults with chronic pain (GetActive) that combines mind-body skills with walking. GetActive has demonstrated high feasibility, acceptability, and satisfaction as well as statistically significant improvement in pain and physical and emotional function outcomes when delivered in person to adults with chronic pain [28,32]. Adapting this program for live video delivery would be an attractive option for patients with this comorbidity, including those living in rural areas. Depression, pain, and stigma associated with obesity can make weekly travel for clinic appointments challenging. Furthermore, live video delivery bypasses several barriers to care, including the lack of skilled providers in remote areas, missed work, and the burden of travel (cost and reliance on family and friends). This is particularly relevant for our patients in Kentucky with this comorbidity, who are underserved and prefer telehealth as a treatment modality. GetActive may be a solution to the problem of comorbid KOA, depression, and obesity, but it requires adaptations.

Objectives

Here, we followed the National Institutes of Health (NIH) stage model [47] and conducted a mixed methods study aimed at adapting the original GetActive program for live video delivery and meeting the unique needs of patients with KOA, depression, and obesity (GetActive-OA) from rural Kentucky (NIH stage IA). In phase 1, we developed the live video GetActive-OA program and protocol through qualitative feedback from patient focus groups and multidisciplinary experts. In phase 2, we explored the initial feasibility, credibility, and acceptability of the program and preliminary signals of improvement in pain, multimodal physical function, emotional function, coping, and KOA biomarker outcomes. Individual exit interviews were then conducted to assist in further optimizing the programs and methodology before conducting a subsequent efficacy trial (NIH stage II).

Methods

Overview

Our methodology followed our previously published study protocol [48]. A total of 7 physicians at the University of Kentucky (UK) Healthcare Hip & Knee Center and the UK Healthcare Orthopedic & Sports Medicine Center referred eligible patients with mild to moderate KOA, using standard diagnostic criteria, during regularly scheduled office visits. The

standard diagnostic criteria included clinical examination, patient-reported symptoms or functional limitations, and radiographic assessments. We also circulated an institutional review board–approved study flyer at the UK, Massachusetts General Hospital (MGH), and patient advocate groups such as the Arthritis Foundation.

Ethics Approval

The institutional review boards at the UK and MGH approved all study procedures (approval number 53457 for the focus groups [Phase I] and 62256 for the open pilot [Phase II]).

Participant Recruitment and Enrollment

Our eligibility criteria are consistent with those of other clinical trials in KOA or mind-body interventions [43,47]. The inclusion criteria were as follows: (1) obesity (BMI ≥30 kg/m^2), (2) idiopathic KOA [49] with mild to moderate radiographic changes (Kellgren or Lawrence grade 2 or 3 [50]) or Knee Injury and Osteoarthritis Outcome Scores (KOOSs) consistent with KOA [51], (3) elevated depressive symptoms with a 9-item Patient Health Questionnaire (PHQ-9) score ≥10 [52,53], (4) aged ≥45 years [54,55], (5) history of concurrent psychotropics for <2 weeks before initiation of treatment or on stable doses for >6 weeks, (6) access to an internet-enabled computer or smartphone, (7) willingness to comply with the study protocol and assessments, and (8) physician's clearance to participate. We selected the PHQ-9 because it is widely used and validated as a screener in health care settings [56], including orthopedic clinics [57], and for patients with KOA [58]. Given the tendency to underreport emotional symptoms of depression in our rural population, particularly among men, the PHQ-9 is also more likely to detect physical manifestations of depression that overlap with KOA (eg, slow movement and sleep disturbance).

The exclusion criteria were as follows: (1) any disorder requiring the use of systemic corticosteroids; (2) rheumatoid arthritis; (3) history of cancer within 5 years of screening; (4) inability to walk or use of a wheelchair; (5) previous surgical fixation of a femur or tibia fracture; (6) taking high doses of opioid pain medication (>50 mg of morphine equivalent per day); (7) diagnosis of a medical illness expected to worsen in the next 6 months (eg, malignancy); (8) active suicidal ideation or past-year psychiatric hospitalization; (9) non-English speaking; (10) lifetime history of schizophrenia, bipolar disorder, or other psychotic disorder; (11) current substance abuse or dependence (or a history within the past 6 months); (12) practice of yoga or meditation or other mind-body techniques once per week >45 minutes within the last 3 months; and (13) engagement in regular moderate or vigorous physical exercise for >30 minutes daily.

To reduce the travel burden for participants in rural Kentucky, we enrolled and collected baseline data (self-report questionnaires, blood draws, and urine samples) during the patient's office visit with their referring physician whenever possible. After providing verbal consent, potential participants met with a trained research coordinator for study screening. Eligible participants provided written informed consent and Health Insurance Portability and Accountability Act authorization owing to the sensitive data collected. Trained clinical psychologists from MGH conducted the focus group and open pilot sessions via secure Health Insurance Portability and Accountability Act–compliant Zoom. After enrollment, the research coordinator either assisted participants with installing the Zoom app on their smartphone or emailed participants the Zoom installation instructions. The research coordinator also emailed the invitation link and appointment reminders to participants, offered Zoom test calls, and was available to solve technical difficulties in real time during the focus group and open pilot sessions.

Phase 1: Development of GetActive-OA

The goal of phase 1 is to identify the treatment needs and preferences of patients with comorbid KOA, depression, and obesity from rural Kentucky via focus groups.

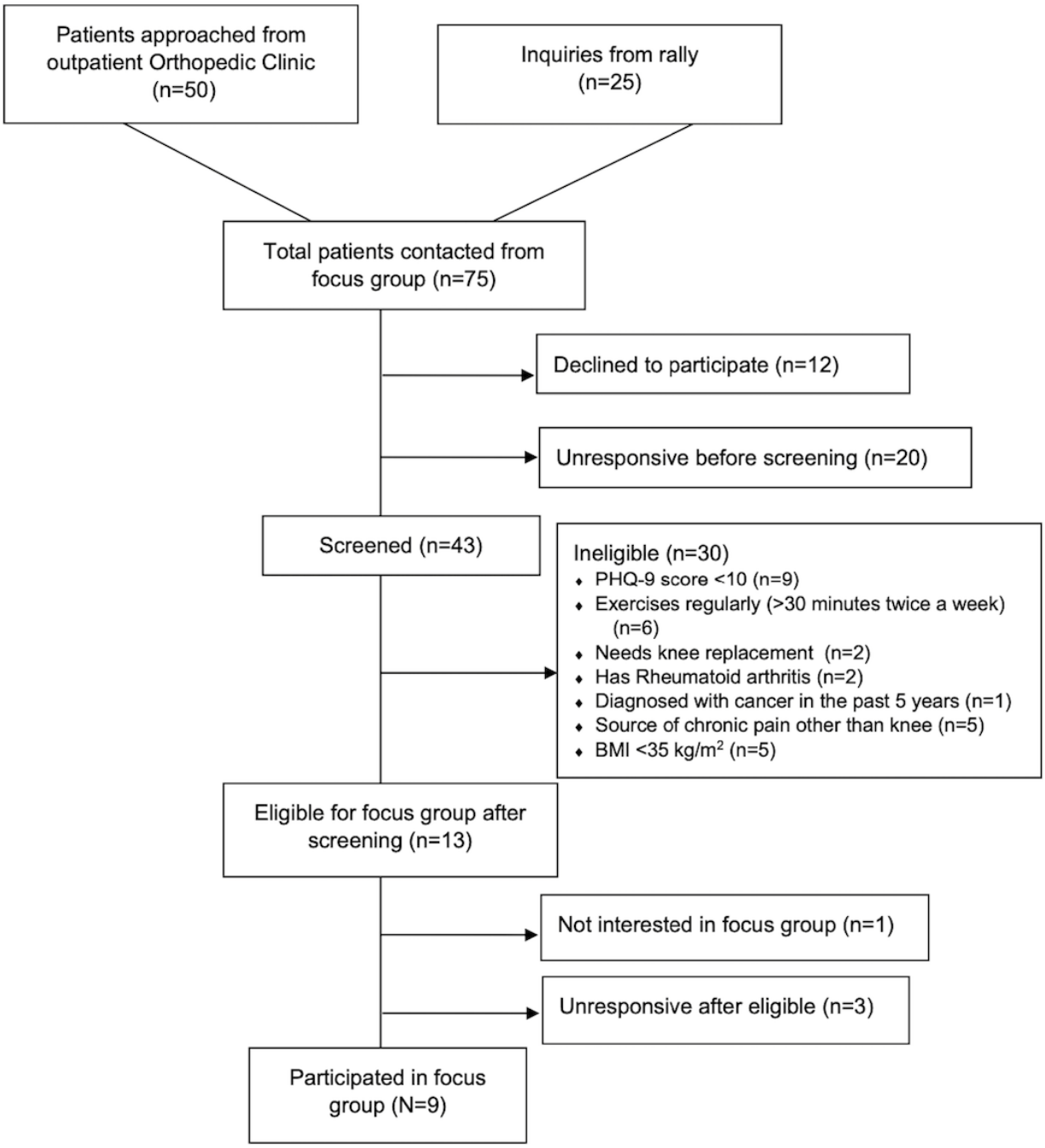
Focus Group Procedures

Figure 1 depicts participant flow in phase 1.

Enrolled participants completed a one-time 90-minute focus group (N=9; a total of 4 groups). Clinical health psychologists with expertise in heterogeneous pain conditions and qualitative methods moderated the focus groups via Zoom. Our interdisciplinary team developed a semistructured qualitative interview guide to elicit feedback on the following a priori set themes: (1) experiences living with comorbid KOA, depression, and obesity (challenges, causes, and connections between conditions); (2) patients' previous experiences with medical and complementary treatments; (3) perceptions of increasing walking; (4) perceptions of the GetActive-OA program, including barriers to program adherence (challenges with live-video delivery, group participation, homework completion); and (5) perceptions of data collection procedures (self-report assessments, ActiGraph, and blood and urine tests). The research coordinator transcribed the audio recordings of the focus groups.

We used rapid assessment procedures to analyze the focus group data, consistent with established qualitative frameworks [59-61]. Rapid assessment is a valid alternative to in-depth qualitative methods and is ideal for delivering timely results to guide multiple phases of intervention development [62,63]. We used rapid assessment to identify actionable suggestions to modify the GetActive-OA program and the study procedures for the phase 2 open pilot. First, the researchers created neutral domains that corresponded to each of the a priori set interview themes. Next, the moderators (RAM and JG) created a summary template to take notes during focus groups and reflexively summarize the main ideas directly afterward. The summary template was piloted with 1 focus group and modified, as necessary. The senior authors (CAJ and AMV) conducted a secondary review of the summaries to ensure consistency. In addition, the study team held regular meetings to collaboratively discuss any discrepancies in the summaries until a consensus was reached. Finally, we consolidated the summaries with a matrix to compare the focus groups, identified common themes, and reported the results in the next section [64].

Figure 1. Participant flow for the focus groups (phase 1). PHQ-9: 9-item Patient Health Questionnaire.



Focus Group Results

Multimedia Appendix 1 reports detailed qualitative results by semistructured interview topic.

Theme 1: Experiences Living With Comorbid KOA, Depression, and Obesity

Participants attributed KOA, depression, and obesity to significant challenges across the domains of physical, emotional, and social functioning. Participants identified physical discomfort, pain flare-ups, and swelling as the primary sources of disability. Some participants were worried about deteriorating knee health, and a participant expressed further concerns that OA would negatively affect other parts of their body. Participants endorsed a variety of depressive symptoms, including low mood, amotivation, and feelings of hopelessness. Because of these emotional challenges, they described feeling socially isolated, lonely, stigmatized, embarrassed, and having low self-esteem. Most participants were knowledgeable about the range of psychological (eg, sedentary and dietary habits and life stressors) and biological factors (eg, heredity and aging) that contribute to KOA, depression, and obesity. However, some participants were unable to identify risk factors or endorsed misconceptions about KOA, such as activity causing knee flare-ups or being "too active" when young.

Participants described the co-occurrence of KOA, depression, and obesity as a "vicious cycle" of worsening disability. Many participants believed that depression led to unhealthy eating habits, subsequent weight gain, and knee pain. Other participants

explained that KOA or pain flare-ups made it harder to move, resulting in weight gain and depression. Participants reported noticing themselves withdrawing from both physical and social activities and becoming more depressed over time. They reported frustration and discouragement by the lack of available or effective treatments.

Theme 2: Previous Experiences With Medical and Complementary Treatments

All participants reported a history of 1 or more medical treatments for KOA and knee pain including injections, surgery, pain medication, and steroids. The medical treatments were described as providing mixed results. Some participants reported that they had short-term relief, but the benefits wore off and they experienced negative side effects. Some participants were informed that they were ineligible for surgery because of their weight. One person reported having a *botched surgery*. Similarly, many participants reported prescriptions for antidepressant medication with modest benefit and negative side effects (eg, *brain fog*). Participants felt that their physicians commonly focused on 1 comorbidity and did not view them as a whole person.

Participants were knowledgeable about nonpharmacological interventions for pain (eg, physical therapy and mind-body activities) and depression (eg, psychotherapy and self-care) and weight loss interventions (eg, weight loss programs, personal trainers, and dietitians). Participants endorsed high interest and motivation in these approaches, as evidenced by initial lifestyle changes and help-seeking behaviors (eg, contacting physicians for referrals, removing junk food from pantry, and purchasing walking shoes). However, participants reported struggling to follow through because of lack of time, poor planning, distractibility, negative coping strategies (eg, withdrawal and avoidance, and overeating *comfort foods*), weather, and lack of insurance.

Theme 3: Perceptions of Increasing Walking

Overall, participants shared positive views of a program that encourages increased walking. Most identified walking as their preferred and primary source of physical activity. Some participants expressed an interest in walking more, whereas others reported that they already walk a lot for work. Participants recognized a bidirectional relationship between increasing walking and healthy eating or losing weight, which motivates them to continue positive habits (*building momentum*).

Participants identified several personal facilitators for walking, including setting gradual and feasible goals, pacing, creating reinforcements, and prioritization. Participants valued encouragement from others or having a *walking buddy*. Several participants used technology to promote walking, such as listening to music or using guided smartphone apps. Warm weather and having access to safe places to walk and exercise equipment were identified as environmental facilitators of physical activity.

Participants acknowledged several personal barriers to walking, including fear of further pain or injury, lack of motivation, procrastination, and time. A participant expressed concerns that walking is unsafe for patients with KOA and preferred to use a stationary bike. Several participants also identified a lack of access to safe walking areas (eg, few sidewalks and uneven surfaces) and COVID-19 restrictions as environmental barriers to walking. A participant noted that after overcoming these initial barriers, they were typically able to sustain their momentum and continue walking.

Theme 4: Perceptions of the GetActive-OA Intervention Components

Participants expressed a high interest in a program that combines increased walking with mind-body skills. Many participants agreed with the program's rationale for addressing the 3 comorbidities. They believed that the mind-body skills would help them overcome the barriers to walking and healthy eating identified in theme 3. Participants also liked that the program did not include medication. Many participants noted the importance of balancing intervention components targeting KOA, obesity, and depression in every session. To reduce stigma surrounding obesity and depression, participants recommended the use of sensitive language in the treatment manuals and that the study clinicians speak about these issues in positive ways ("do not force dietary information"). Some participants expressed a fear of increasing walking because of the possibility of falling. Few participants had previous mind-body experience and were unsure if mindfulness would help but were open to trying it. Participants explained that reassurance from trusted sources, including medical clearance from their physicians or patient testimonials, would reduce their ambivalence about walking and mind-body skills.

With respect to format and delivery, participants were in support of participating in a live video group setting. Participants shared positive impressions of Zoom during the focus group, including that it was feasible, they enjoyed learning the features, and it enabled flexible attendance. Many participants were familiar with live video to stay connected with friends and family during the COVID-19 pandemic. Barriers to attending a live video group program included a lack of privacy at home, scheduling conflicts, and internet connectivity. Participants also noted several factors that would facilitate participation, such as support from the group and clinicians, regular reminders for walking and attendance, calendar appointments, and easy access to readings and program materials.

Participants also agreed that 5 to 10 minutes of home practice per day was feasible and constructive. They believed that home practice could encourage them to track progress in their walking goals and mind-body practice. Participants reported that a smartphone log would be easier and faster than paper and pencil. A participant noted that they might need assistance with using the smartphone log. Additional barriers to home practice include distractions, low motivation, forgetfulness, and schedule conflicts. A combination of reinforcements, such as reminders to log their home practice, check-ins from clinicians, and identifying family support, could prevent nonadherence.

Theme 5: Perceptions of Data Collection Procedures

There were no major concerns regarding the biological data collection of blood and urine samples. A few participants noted previous experience with phlebotomists who had difficulty locating a vein for blood collection. Several participants noted

the inconvenience of traveling to the clinic, including long commutes, transportation costs, and difficulty finding parking. Nevertheless, participants confirmed that the biological data collection could not deter them from participating. Participants recommended combining the biological data collection with physician appointments to reduce this burden. Many participants also expressed an interest in receiving the results to learn about their inflammation levels and other markers of knee health.

Similarly, most participants had no concerns about ActiGraph or self-report assessments. Participants expressed a preference for a small, unobtrusive, and well-fitting device. A participant was concerned about privacy and wanted more information on whether ActiGraph could track the geographical location. Several participants had experience with self-reports for research or medical appointments and preferred to complete them via a web-based survey. A participant noted the importance of explaining the purpose of the self-report assessments so that they "don't feel like an exam."

Phase 2: Preliminary Feasibility of the GetActive-OA Program

Overview

The goal of phase 2 is to conduct an open pilot study of the newly developed GetActive-OA with individual exit interviews to explore preliminary credibility, acceptability, satisfaction with treatment, feasibility of recruitment, instruments, biological data collection, and adherence to homework (exercise and mind-body skills). Here, we describe modifications to the GetActive-OA program and the phase 2 procedures informed by our phase 1 qualitative focus group results. Our published protocol [48] contains remaining details of procedures that were not influenced by the focus groups, including clinician adherence, depression severity and suicide risk assessment, and the GetActive-OA makeup session.

GetActive-OA Program and Procedures

Table 1 presents the program outline and skills for each session.

GetActive-OA also provides educational information on the biopsychosocial interactions among KOA, depression, and obesity that comprise a population-specific *disability spiral*. Participants learn that inflammation is the biological tie among the 3 conditions and physical activity is a modifiable factor that can decrease inflammation, improve the biology and function of the knee, and decrease both depression and obesity [7-9,16,38-40,65-67]. GetActive-OA teaches 5 core skills that target the comorbidities: (1) setting weekly activity goals that are personally meaningful (eg, walking with kids instead of forcing a gym workout); (2) quota-based pacing to gradually and safely increase activity that is noncontingent on pain (eg, walking for 15 minutes twice per day); (3) mind-body skills to elicit relaxation and cultivate mindfulness (eg, deep breathing and mindfulness meditation) and minimize negative reactivity to pain and reduce activity avoidance; (4) cognitive behavioral skills (eg, behavioral activation and adaptive thinking) to challenge pain-specific cognitions such as catastrophizing and fear avoidance that interfere with program goals; and (5) resiliency skills including self-compassion, gratitude, acceptance, and social support to enhance coping, given that discouragement is common in this population.

We also added several novel components based on the focus group results. First, we added patient-friendly educational information on the interconnectedness of KOA, depression, and obesity (eg, reduced activity can exacerbate pain and disability). Second, participants were encouraged to apply mindfulness to facilitate healthy eating and dietary changes (eg, noticing hunger or fullness urges and mindful eating). Third, our multidisciplinary team reviewed all skills for patient-sensitive language and to reduce stigma. Fourth, we provided all participants with a stationary peddler. This was intended to serve as an alternative to walking for participants with concerns about starting a walking program or with limited access to sidewalks in rural Kentucky. It may also address other environmental barriers to walking, such as bad weather, as identified in the focus groups or participants who live in neighborhoods with high crime rates.

Finally, given the positive impressions of technology and to reach patients in rural areas, we optimized the program and study procedures for live video delivery. We have successfully adapted mind-body programs for live video similar populations with chronic pain [45,68]. We considered other approaches to live video, such as asynchronous web platforms, but decided against it because telehealth delivery is preferred by this population and fostering peer contact can directly target stigma and isolation common in this comorbidity. To offset the weaknesses of live video groups (eg, scheduling), we created a website that contains program materials and audio recordings of mind-body skills that participants can access at any time.

A clinical psychologist from MGH led the 8 weekly GetActive-OA group sessions (90 minutes) via Zoom with the support of a clinical psychology fellow. The first session of GetActive-OA oriented participants to program expectations for participation. In each weekly session, the study clinician introduced the core GetActive-OA skills and problem-solved adherence issues. Participants' home practice involved daily walking or stationary pedaling according to their activity goal, daily mind-body skills (5-10 minutes, via clinician-guided audio recordings available on the program website), and logging in the GetActive-OA manual at least three examples of gratitude. Participants who achieved their activity goal from the previous week were encouraged to increase their goal by 10% to 20%, according to the guidelines for quota-based pacing [69]. Participants also logged their mindfulness minutes and skills practiced each day using a smartphone log. The research coordinator sent reminders (via SMS text messaging, phone call, or email based on participant preference) to remind participants of the homework and sessions.

Table 1. GetActive-OA session overview informed by the focus group results.

Topic	GetActive-OA skills
1. Break the disability spiral by exercising	Myths about pain, disability spiral, and quota-based pacing
2. Smart ways to exercise more	Exercising with enjoyment, self-compassion and gratitude, and diaphragmatic breathing
3. Mindfulness	Mindfulness, mindful breathing, body scan, and mindful moments
4. Everyday mindfulness	Leaning into difficulty, mindfulness of pain, mindful exercising, and noticing the benefits of exercising
5. The benefits and barriers to exercise	Mindful eating, overcoming barriers to exercising, stop and breathe, reflect, and choose
6. Coping with negative thoughts	Negative automatic thoughts, changing our perspective, and acceptance
7. Strengthening social support	Social support and the disability cycle, effective communication, social walking, and loving kindness
8. Staying on track and maintaining your progress	The powerful self; working with pain, your emotional well-being, and unhealthy weight; and resiliency plan

Measures

Feasibility Markers

We evaluated a priori appropriateness, acceptability, feasibility, and fidelity based on established benchmarks, consistent with our prior feasibility pilot studies [31,32,70] and protocol for GetActive-OA [48].

- Program credibility and expectancy were determined by the percentage of participants with Credibility and Expectancy Questionnaire–6 [71] scores above the scale's midpoint.
- Program satisfaction was determined by the percentage of participants with Client Satisfaction Questionnaire–3 [72] scores above the scale's midpoint.
- Feasibility of recruitment was determined by the percentage of patients who agreed to participate from the total patients approached.
- Program acceptability was determined by the percentage of patients who attended at least six of the eight of the GetActive-OA sessions.
- Adherence to ActiGraph wGT3X-BTLink was determined by the percentage of participants with valid accelerometer data for at least five of seven days for a minimum of 10 hours per day during the baseline and postintervention testing.
- Adherence to the home practice was determined by the percentage of participants who completed mind-body and walking skills at least four of seven days or one of these skills at least five of seven days.
- Feasibility of assessments was determined by the percentage of participants with no missing outcome data.
- Study clinician adherence was determined by the percentage of content delivered based on an independent audit of audio recordings and progress notes for all sessions by the senior authors.
- We assessed program safety based on the absence of adverse events (eg, swelling soreness and stiffness) and stable medication use reported to the study staff.

Quantitative Assessments

Our assessments aligned with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, Osteoarthritis Research Society International, and Outcome Measures in Rheumatology recommendations [73,74]; our conceptual model [48]; and recommendations for feasibility trials [75,76]. In addition, 1 week before and after the GetActive-OA program, participants traveled to the UK to receive their ActiGraph activity monitor (model wGT3X-BTLink) and collect biological data. Participants completed the self-report assessments on the web via REDCap (Research Electronic Data Capture; Vanderbilt University).

The Numerical Rating Scale (NRS) [77] assessed pain intensity at rest and with activity on an 11-point scale. Higher scores indicated greater severity of pain (0, no pain; 10, worst pain). The minimum clinically important difference (MCID) for the NRS was 1 [78].

The KOOS [79] assessed KOA-specific pain (9 items), KOA symptoms (7 items), activities of daily living (17 items), sport and recreation function (5 items), and knee-related quality of life (4 items). Items were scored on a scale from none (0) to extreme (4) or never (0) to always (4). Subscale scores were transformed to a scale of 0 to 100, with lower scores indicating more severe knee problems. Of the 5 subscales, 4 (80%) were used in this study's analyses, as the Sport and Recreation Score was not applicable to this population, and MCIDs for the 4 subscales were as follows: pain=9.3, symptoms=8.4, activities of daily living=9.0, and quality of life=10.3 [80].

The ActiGraph wGT3X-BTLink accelerometer assessed the average step count over a 7-day period at the baseline and postintervention time points. Our published protocol contains full details of the accelerometer procedures [48]. Participants had to wear ActiGraph on their nondominant wrist for a minimum of 10 hours per day for a minimum of 5 days for their data to be considered valid during the baseline and postintervention testing [32,48]. Participants did not wear the ActiGraph wGT3X-BTLink during the program and did not have access to their step count data, as the device itself does not have a display screen. We opted to use the *blinded* ActiGraph so that any change in physical activity would not be confounded by the feedback provided by the device. We processed the accelerometer data using the ActiLife software [81] according to established guidelines [82-84]. The MCID

for the accelerometer was 800 steps/day, which is consistent with that used in other clinical populations [85].

The Physical Activity Scale for Individuals With Physical Disabilities (PASIPD) [86] assessed self-report of disability on a 13-item scale. Lower total scores, calculated based on the average hours per day and metabolic equivalent values, indicated higher disability across leisure, household, and work-related activities. The MCID for the PASIPD is not available.

The Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety (v1.08a) and PROMIS Depression (v1.08b) [87] both assessed emotional functioning on separate 8-item scales. Participants were asked about the frequency of their anxiety and depression symptoms (1, never; 5, always). Higher *T* scores indicated greater severity of anxiety and depression. The MCID was 4.28 for the PROMIS Anxiety and 5.19 for the PROMIS Depression [88].

The Pain Catastrophizing Scale (PCS) [33] assessed hopelessness, helplessness, and negative rumination about pain on a 13-item scale. Higher scores (range 0-52) indicated greater pain catastrophizing (0, not at all; 4, all the time). An MCID was not available for the PCS.

The Arthritis Self-Efficacy Scale (ASES) [89,90] assessed arthritis-specific self-efficacy on a 20-item scale. The ASES contains pain (5 items), function (9 items), and other symptoms (6 items) that are scored on a scale from very uncertain (1) to very certain (10). Scores ranged from 1 to 10, with higher average scores indicating greater arthritis-specific self-efficacy. The MCID for the ASES was not available.

The Measure of Current Status–Part A (MOCS-A) [91] assessed general coping skills on a 13-item scale. Participants rated their ability to use relaxation, awareness of tension, ability to express needs, confidence in coping, and assertiveness skills on a scale from 0 (I cannot do this at all) to 4 (I can do this extremely well). Higher total scores (range 0-52) indicated greater use of coping skills. An MCID was not available for the MOCS-A.

The Modified Patient Global Impression of Change (MPGIC) [92] assessed patients' perception of improvement using the scale from 1 (very much improved) to 7 (very much worse) on 5 questions related to the following: pain, level of physical activity, physical function, emotional function, and resiliency.

We assessed KOA biomarkers of cartilage breakdown and systemic inflammation. Urinary CTXII (Urine Cartilaps, CTX-II; Immunodiangostic Systems Inc) was used to assess cartilage degradation, which was normalized to creatinine levels to account for differences in hydration [93] (Parameter Creatinine Assay; R&D Systems Inc). Enzyme-linked immunosorbent assays were used to assess the proinflammatory cytokines IL-1β and interleukin 6 (IL-6; Proinflammatory Multiplex 1; Meso Scale Diagnostics) as well as TLR4 (Invitrogen Human TLR4, Life Technologies Corporation). The selected biomarkers have been shown to predict inferior clinical outcomes and cartilage thinning [93,94] and are responsive to changes over a 3-month follow-up [95-97]. Our published protocol contains full details of the biological data collection [48].

Quantitative Analysis

This open pilot study was designed in accordance with the NIH stage model intervention development pilot studies to explore feasibility and *not* to test efficacy [47,98,99]. We reported the frequency and percentage of each a priori benchmark set in our previously published protocol [46]. We rated each benchmark as *good* if the criteria were met in at least ≥80% (4/5) of the open pilot study participants. The benchmarks allowed us to evaluate readiness for a subsequent efficacy trial and determine whether further modifications to GetActive-OA and study procedures are needed. Exploratory analysis for each quantitative measure included descriptive statistics, baseline and postintervention comparisons using paired 2-tailed *t* tests, and Cohen *d* effect sizes (0.20, small; 0.50, medium; and 0.80, large; [100]) to cautiously explore preliminary before and after improvement associated with participation in GetActive-OA.

Exit Interviews

We conducted group exit interviews via Zoom using the same rapid assessment procedures as in phase 1. Our goal is to gather impressions about the GetActive-OA adaptations and technology enhancements. We performed rapid assessment procedures on the exit interview transcripts to identify actionable suggestions to optimize GetActive-OA for the subsequent randomized controlled trial (RCT) [59]. Integrating the qualitative exit interviews with the quantitative results also allowed us to corroborate the feasibility markers, contextualize the findings at both the group and individual participant levels, and begin to understand *why* changes in outcomes may have occurred [101].

Results

Participants and Feasibility Markers

Figure 2 shows the flow diagram, and Table 2 reports the demographics of the open pilot study participants.

GetActive-OA had *good* feasibility on nearly all of the a priori benchmarks (Table 3) [31,32,48,70].

Of the 10 patients who were approached, 9 (90%) were eligible after screening. Of these 10 participants, 6 (60%) were enrolled after 4 (40%) declined to participate owing to disinterest in the study and lack of time (*poor feasibility of recruitment*). All but one of the enrolled participants, who was removed because of neurological symptoms that were not present at the time of enrollment, completed baseline testing and started the open pilot. The sample was majority White, non-Hispanic, women, married, and fully employed. More than half of the participants were prescribed psychotropic medication for depression or anxiety (3/5, 60%) and had bilateral KOA (3/5, 60%).

GetActive-OA was viewed as highly credible, and participants expected their knee health to improve during the program (5/5, 100% above the Credibility and Expectancy Questionnaire–6 scale midpoint, *good program credibility and expectancy*). Of the 5 participants, 4 (80%) attended at least six GetActive-OA sessions (*good program acceptability*), and 4 (80%) completed the smartphone homework logs (*good adherence to homework*). The study clinicians delivered 90% of the manual content (*good*

study clinician adherence). Participants completed all self-report measures at the baseline and postintervention assessment time points (no missing data, ie, *good feasibility of quantitative measures*). At baseline, of the 5 participants, 4 (80%) met the adherence benchmark of a minimum of 10 hours of ActiGraph wear time for a minimum of 5 days (*good ActiGraph adherence*). However, of the 5 participants, only 1 (20%) met this benchmark at the postintervention time point, with 1 (20%) patient not meeting the minimum wear time for even 1 day (*poor ActiGraph adherence*). All participants were highly satisfied with the program (5/5, 100% above the Client Satisfaction Questionnaire–3 scale midpoint, *good satisfaction*). No adverse events were reported (*good program safety*).

Figure 2. Participant flow for the live video open pilot study (phase 2). OA: osteoarthritis.

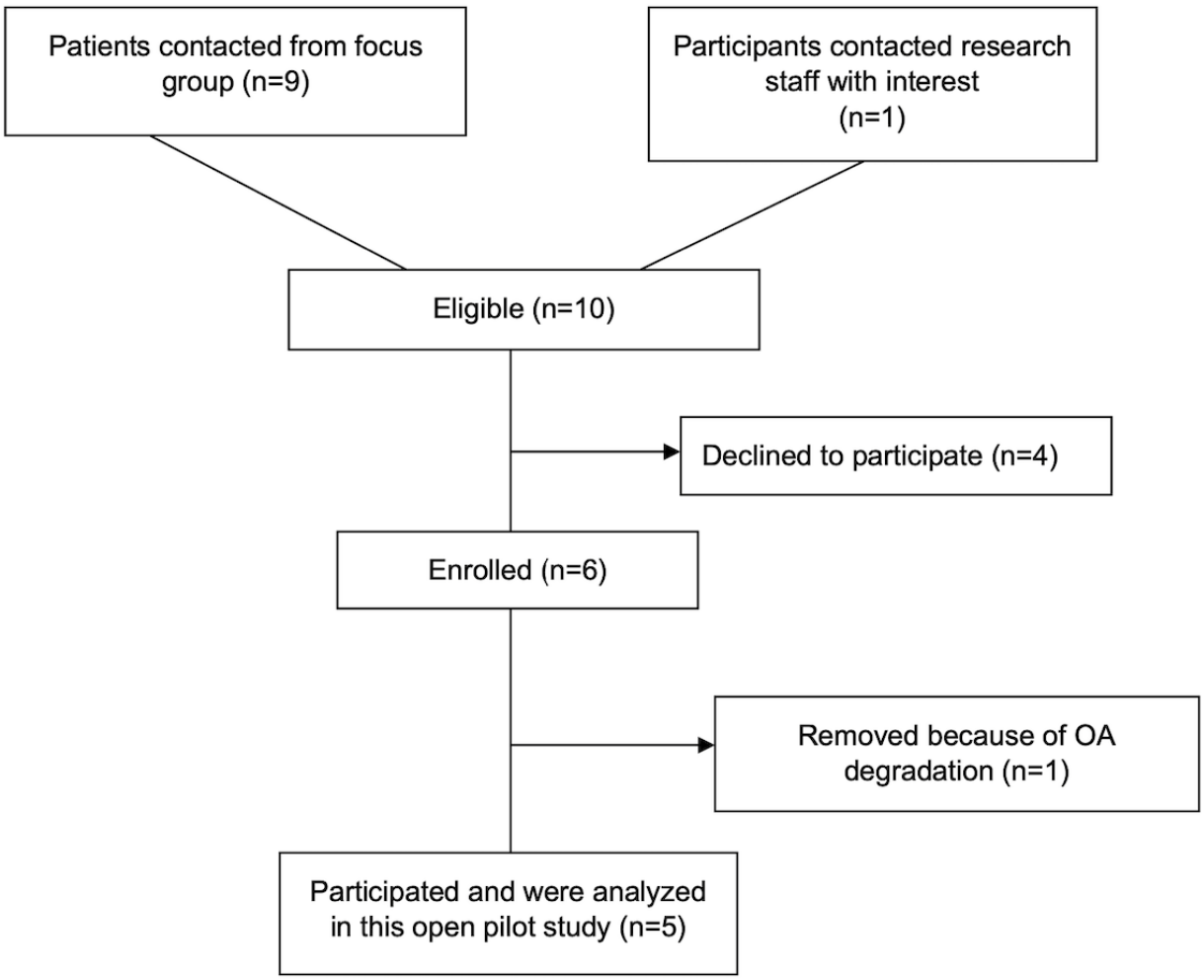


Table 2. Demographics and clinical characteristics of open pilot study participants (N=5).

Characteristics	Value
Age (years), mean (SD; range)	53.2 (6.64; 49-65)
BMI (kg/m^2), mean (SD; range)	39.8 (6.68; 32.6-50.8)
Sex, n (%)	
Male	0 (0)
Female	5 (100)
Ethnicity, n (%)	
Hispanic or Latinx	1 (20)
Not Hispanic or Latinx	4 (80)
Race, n (%)	
White	4 (80)
African American	1 (20)
Marital status, n (%)	
Single, never married	1 (20)
Widowed	1 (20)
Married	3 (60)
Education, n (%)	
Completed high school or GED[a]	2 (40)
Associate's degree	2 (40)
Some college	1 (20)
Employment, n (%)	
Employed full-time	3 (60)
Homemaker	1 (20)
On disability	1 (20)
OA[b] symmetry, n (%)	
Bilateral	3 (60)
Unilateral	2 (40)
Depression or anxiety medication, n (%)	
Yes	3 (60)
No	2 (40)
Opioid medication, n (%)	
Yes	1 (20)
No	4 (80)

[a]GED: graduate equivalency degree.

[b]OA: osteoarthritis.

Table 3. A priori feasibility markers.

Marker	Criteria
Feasibility of recruitment	Of 10 eligible patients, 6 (60%) successfully contacted agreed to participate (poor)
Program acceptability	Of 5 participants, 4 (80%) attended ≥63% (≥5/8) of group or make-up sessions (good)
Credibility and expectancy	Of 5 participants, 5 (100%) scored above the scale midpoint for expectancy (good), and 5 (100%) scored above the scale midpoint for credibility (good)
Study clinician adherence	The study clinicians delivered 90% of the manual content across the 8 sessions (good)
Feasibility of quantitative measures	Of 5 participants, 5 (100%) were not fully missing questionnaires on quantitative measures at baseline (good), and 5 (100%) were not fully missing questionnaires on quantitative measures at the postintervention time point (good)
Adherence to homework	Of 5 participants, 4 (80%) completed mind-body and walking skills at least four of seven days or one of these skills at least five of seven days (good)
Adherence to ActiGraph	Of 5 participants, 4 (80%) who received ActiGraph at baseline wore it for ≥5 of 7 days (good), and 1 (20%) who received ActiGraph at the postintervention time point wore it for 5 of 7 days (poor)
Client satisfaction	Of 5 participants, 5 (100%) scored above the scale midpoint (good)
Program safety and adverse events	0 adverse events

Quantitative Outcomes

Table 4 reports the results for the quantitative outcomes.

Baseline ActiGraph step count varied widely (mean 8832, SD 4083; range 5548-16,410). Participants endorsed moderate to high levels of pain intensity (mean 7.0, SD 1.5) [102]. The levels of pain catastrophizing were higher than the norms for chronic pain samples (mean 39, SD 12.5). Participants had more severe knee problems than previous samples with OA across all KOOS measures [103]. Participants reported elevated levels (PROMIS+1 SD) of both depression (mean 60.6, SD 7.5) and anxiety (mean 60.8, SD 9.0).

As a group, participants exhibited small to moderate improvements in KOA pain, KOA symptoms, and KOA physical function on the KOOS. Participants reported large improvements in general coping on the MOCS-A, arthritis self-efficacy on the ASES, and reductions in pain catastrophizing on the PCS. Participants also showed large reductions in depression and anxiety on the PROMIS. Changes in KOA-related quality of life on the KOOS, pain intensity on the NRS, and disability on the PASIPD were minimal. Among the 4 patients with pre- and posttest ActiGraph data, there was a small decrease in the average step count. The 1 participant who met the adherence benchmark at the postintervention time point increased by 310 steps. Only 1 participant reported that their emotional functioning had improved on the MPGIC. Participants did not report improvements on the remaining MPGIC items: pain, physical function, and resiliency.

Table 4. Quantitative outcomes.

Measure	Baseline, mean (SD)	Postintervention, mean (SD)	Mean difference from the paired sample *t* test (2-tailed)	*P* value	Cohen *d*
KOOS[a] pain	33.6 (5.5)	38.0 (14.9)	4.4	.36	0.39
KOOS symptoms	32 (16.8)	39.4 (22.8)	7.4	.18	0.36
KOOS ADL[b]	34.4 (6.7)	39.6 (14.8)	5.2	.54	0.45
KOOS QOL[c]	14 (6.8)	14 (15.7)	0	.99	0
NRS[d] pain	7.0 (1.5)	7.2 (1.4)	0.2	.82	0.13
PASIPD[e]	36 (19.3)	37.6 (33.8)	1.6	.93	0.05
PROMIS[f] Depression	60.6 (7.5)	52.6 (10.4)	−8.0	.08	0.88
PROMIS Anxiety	60.8 (9.0)	52.6 (11.7)	−8.2	.11	0.78
PCS[g]	39 (12.5)	24.4 (10.9)	−14.6	.10	1.24
ASES[h]	3.8 (0.8)	4.8 (1.7)	1.0	.30	0.73
MOCS-A[i]	22.8 (3.7)	33 (4.7)	10.2	.004	2.41
Step count[j]	8763 (3813.9)	7887 (3131.9)	−766	.37	0.22
IL-6[k]	3.10 (0.48)	1.97 (1.75)	−1.13	.38	0.87
TLR4[l]	24.27 (33.49)	16.58 (10.12)	−7.69	.74	0.34
CTX-II[m]	391.1 (153.1)	629.2 (404.3)	238.1	.25	0.76

[a]KOOS: Knee Injury and Osteoarthritis Outcome Score.

[b]ADL: activity of daily living.

[c]QOL: quality of life.

[d]NRS: Numerical Rating Scale.

[e]PASIPD: Physical Activity Scale for Persons With Physical Disability.

[f]PROMIS: Patient-Reported Outcomes Measurement Information System.

[g]PCS: Pain Catastrophizing Scale.

[h]ASES: Arthritis Self-Efficacy Scale.

[i]MOCS-A: Measures of Current Status–Part A.

[j]ActiGraph step count, which is the weekly average of the valid days (≥10 hours).

[k]IL-6: interleukin-6.

[l]TLR4: Toll-like receptor 4.

[m]CTX-II: Urine Cartilaps (Immunodiangostic Systems Inc).

Biomarker Analyses

Urine samples were successfully collected from all patients at both pre- and posttest time points, and CTX-II and creatinine values were above the lower limits of detection for all samples. CTX-II, expressed as nanogram per millimole creatinine, moderately increased. Whereas urine samples were successfully collected, only 60% (6/10) of the total possible blood draws were successful because of low vein patency, thereby prohibiting meaningful analysis of pre- to posttest changes. From the available samples, all TLR4 and IL-6 values were above the lower limits of detection; however, 67% (4/6) of the samples had IL-1β levels below the limits of detection.

Exit Interview Analysis

Participants shared positive overall impressions of the program, including the group setting, mind-body and activity skills, and home practice logs. Participants were more engaged with the program website than with the physical treatment manual. Almost all participants enjoyed the group setting. Several participants noted that the group normalized the challenges of living with KOA, unhealthy weight, and a low mood. The weekly meetings also increased motivation and accountability for their goals. Zoom was well liked, accessible, and feasible for everyone. Some emphasized the need to foster connections among group members (eg, exchange helpful information) to overcome the tendency for remote participation to be impersonal. There was some disagreement about program length; many reported that the 8 weeks and 90-minute sessions were too long, whereas a few were satisfied with these commitments. Other barriers to participation included previous commitments, life events, and health concerns. Reminders and individualized support from the study staff were helpful for staying engaged with the program.

Many reported improvements in their physical activity, pain-specific cognitions, and mood associated with the program components. Most notably, all participants highlighted mind-body skills as their favorite aspect of the program. Participants enjoyed the in-session mindfulness exercises and reported using mind-body skills outside of the session, with recordings on the program website. Participants described the mindfulness exercises as helpful when experiencing high levels of pain and for altering pain-specific cognitions (eg, use of deep breathing at night to dull throbbing sensations in the lower limbs, to manage pain, and to lessen rumination on pain experiences). Participants also reported positive impressions of the activity skills and that they increased their activity with pacing, individualized goal setting, and linking exercise to personally meaningful activities. A participant noticed that combining mind-body and activity skills, such as mindful walking, made gradual increases in activity safer. However, a few participants struggled to implement activity skills, citing lack of time and the ability to structure activity blocks into their daily routine.

Participants had mixed experiences of gratitude and self-compassion. Many participants acknowledged that these skills did not reduce self-criticism and self-doubt, which are both common in pain and depression. However, a participant noted that self-compassion resonated and helped them "break the spiral" of disability. Some participants believed that the healthy eating skills were helpful in changing dietary choices, whereas others believed that the information was redundant. Finally, adaptive thinking skills were generally not impactful on participants. Many did not recall these skills or implement them. However, a participant noted that adaptive thinking helped change their relationship with pain in a positive way.

Discussion

Principal Findings

Depression and obesity are highly comorbid with KOA, can accelerate knee degeneration, and share a common pathophysiology involving systemic inflammation and proinflammatory cytokines. Mind-body interventions targeting depressive symptoms, physical activity, and pain-related coping may promote healthy physical and emotional functioning and improve KOA biomarkers in these patients. We adapted a mind-body and activity program for live video delivery tailored to patients with this comorbidity (GetActive-OA). This study assessed the program's initial feasibility, credibility, and acceptability, as well as preliminary signals of improvement in pain, multimodal physical function, emotional function, coping, and KOA biomarker outcomes. Consistent with the early stages of the NIH model of intervention development, this study was not powered or intended to evaluate program efficacy. Rather, it aims to refine study procedures (eg, screening, recruitment, and assessment), identify participants' perceptions of the study or intervention (eg, acceptability, credibility, and barriers and facilitators to participation), and iteratively refine the program in preparation for a resource-intensive, fully powered RCT.

The phase 1 focus groups revealed the unique challenges, limitations of previous medical treatments, interest and expected benefits of a mind-body activity program for KOA, barriers and facilitators to participation, and minor concerns about data collection (eg, travel to clinics and blood draws). These findings provided important information about the unique needs of patients with KOA, depression, and obesity, which we used to tailor GetActive-OA and study procedures to reduce reported barriers to adherence (eg, group-based intervention for accountability, structured goal setting, teaching skills to tolerate increased walking or lifestyle changes, and regular reminders for walking or home practice) and increasing walking (eg, address misconceptions that walking is harmful for individuals with KOA). On the basis of these findings, clinicians and researchers working with this population should consider assessing functioning across physical, emotional, and social domains. Focus group participants openly described experiences of stigma and highlighted the importance of patient-provider relationships. To build trust and encourage participation in treatment and studies, clinicians and researchers should take the time to understand participants' underlying challenges and validate their efforts before introducing possible changes to weight, exercise, or depression.

The benchmarks for the phase 2 open pilot study indicated that the GetActive-OA program and study procedures met the criteria on nearly all a priori benchmarks for feasibility, acceptability, expectancy, and satisfaction. The exit interview findings complemented our feasibility marker results, as participants had favorable views of the live video delivery, group structure, and mind-body and activity skills. The group identified several external barriers to participation, which, coupled with concerns about the time commitment (100% of declined enrollments), suggest a need to shorten the program to optimize feasibility. The subsequent RCT will increase program reinforcements to further increase adherence, such as individualized support from study staff, recordings on the program website, and reminders for attendance and home practice. We plan to de-emphasize the skills that either participants did not use (adaptive thinking) or did not meaningfully reduce negative thoughts and emotions related to pain and depression. To improve the healthy eating component, we will streamline dietary education to bolster in-session meditation exercises (eg, mindful eating and urge surfing), with a focus on modifying their relationship with eating.

The phase 2 quantitative results offer preliminary evidence that GetActive-OA is sensitive to population-specific needs and that the measures are sensitive to changes in key outcomes [98,99]. We observed small to moderate improvements in KOA-related pain, KOA symptoms, and physical functioning and large improvements in general coping, arthritis self-efficacy, pain catastrophizing, depression, and anxiety on the quantitative outcomes. We observed minimal changes in quality of life, pain intensity, and disability, perhaps because of the high KOA severity endorsed by participants. During the exit interviews, some participants reported that their walking *increased* with the help of mind-body skills (eg, mindful walking) and linking walking to personally meaningful activities. This aligns with support from the literature that deep breathing and mindfulness can facilitate physical activity goals and decrease depression, obesity, and pain in individuals with OA [34-36]. Given this pattern of results, the lack of perceived improvement on the

MPGIC was surprising. Negative perceptions on the MPGIC may be due to several factors, such as unrealistically high initial expectations for improvement, realization of the effort required to develop healthier habits during the program, and regret about how much they engaged with the program. In the subsequent RCT, study staff and clinicians will help participants set more realistic goals for the program based on their ability levels and interests. It will also provide an opportunity to further explore the correlations between perceptions of improvement and KOA outcomes in a larger sample.

In addition to changes in self-reported knee function and psychosocial factors, pre- and posttest changes in biological markers were also observed, including large improvements in the inflammatory marker IL-6 and small improvements in TLR4. IL-1β values were often below the limits of detection, suggesting that this biomarker might not be viable for assessing systemic changes in the fully powered RCT. In contrast, we observed large increases in biomarkers of cartilage breakdown (CTX-II). Although increased CTX-II levels have predicted subsequent KOA progression [93], it remains unclear whether CTX-II acutely increases as a direct result of increased physical activity. Increasing physical activity may trigger a short-term increase in cartilage turnover; however, this may be offset by attendant cartilage synthesis. As such, the subsequent RCT will assess the relative ratio of cartilage catabolism and synthesis by measuring CTX-II as well as CS846, which is a biomarker of cartilage synthesis [104].

Limitations

Our study has several limitations. First, although we successfully recruited a complex medical population in underserved rural areas with limited access to quality care, our sample comprised exclusively women. This may have been due to several factors, including the risk of sampling bias in small samples, higher prevalence of both KOA and depression among women than among men in the United States, and stigma surrounding depression and other mental health problems [1,105]. Only patients who reported depressive symptoms and were willing to learn skills to better manage these symptoms in a group setting were included in this study. The data suggest that men and individuals from rural areas have higher levels of internalized mental health or depression stigma (ie, the tendency to agree with and internalize negative stereotypes that apply to oneself) [106,107] and thus may have been unwilling to participate. When screening and enrolling patients for the subsequent RCT, we will focus on normalizing stress and negative thoughts or emotions when living with KOA and obesity for men, specifically, while also avoiding terms such as *psychological disorder* or *major depression* to minimize stigma and increase acceptability for all patients.

Although GetActive-OA and study procedures met most of the a priori feasibility benchmarks, poor adherence to ActiGraph and blood collection at the postintervention time point hindered the interpretability of signals of improvement and should be addressed for the subsequent RCT. All participants wore the ActiGraph at baseline, but only 1 participant logged sufficient valid wear time at the postintervention time point to analyze pre- and posttest changes. Although we assessed familiarity with technology during the focus groups, we did not formally assess the technology profile of individual participants, which limits insight into specific factors that influenced adherence with either the live video aspects of the intervention delivery or activity monitoring performed at the pre- and posttest phases. Informal feedback collected by the study clinicians and research coordinators suggests low participant buy-in with ActiGraph. We will boost ActiGraph adherence for the subsequent RCT through improved incentive structures (eg, structuring compensation in proportion to the number of days and hours of wear time), explaining the purpose of the devices (eg, establishing a step count baseline for individualized quota-based pacing), and clarifying misconceptions raised during the focus groups (eg, no location tracking). We will also consider technological strategies to increase adherence, such as notification on wearable devices that they are not being worn and visualizing or gamifying step count data. In addition, owing to 4 unsuccessful blood draws, only 1 participant had both baseline and postintervention data. This was likely due to two factors: (1) a trained clinical research coordinator who completed a phlebotomy course collected blood specimens at baseline rather than expert phlebotomists and (2) consistent with the focus group results, blood draws can be more challenging in patients with obesity [108]. For the subsequent RCT, we will ensure that trained phlebotomists collect all blood samples to reduce participant burden and prevent missing data.

Conclusions

This study depicts the development and preliminary feasibility of the first mind-body and activity program (GetActive-OA) for patients with KOA, depression, and obesity—prevalent and challenging-to-treat comorbidities for which effective treatment is lacking. Participants' needs, preferences, and responses to the initial program yielded valuable suggestions for clinicians and researchers seeking to better support this patient population and integrate mind-body and activity interventions as complementary approaches for KOA, depression, and obesity. On the basis of our mixed methods results, we will refine the program to increase feasibility for participants (6 sessions, 45 minutes) and more comprehensively target all 3 comorbidities (renamed as *GetHealthy-OA*). The next phase will involve a live video pilot RCT (N=60 participants) of the GetHealthy-OA program with a time- and attention-matched health enhancement control (Health Enhancement Program) [68,109]. The study will yield critical information on how participants might engage differently with the intervention and control, as well as definitive information on feasibility, acceptability, and signal of improvement in the intervention before investment of resources in a fully powered efficacy trial.

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Disclaimer

The content is the sole responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group quotes that illustrate themes and subthemes.
[DOCX File , 20 KB - formative_v6i4e34654_app1.docx]

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Abbreviations

ASES: Arthritis Self-Efficacy Scale
IL-1β: interleukin 1-beta
IL-6: interleukin 6
KOA: knee osteoarthritis
KOOS: Knee Injury and Osteoarthritis Outcome Score
MCID: minimum clinically important difference
MGH: Massachusetts General Hospital
MOCS-A: Measure of Current Status–Part A
MPGIC: Modified Patient Global Impression of Change
NIH: National Institutes of Health
NRS: Numerical Rating Scale
OA: osteoarthritis
PASIPD: Physical Activity Scale for Individuals With Physical Disabilities
PCS: Pain Catastrophizing Scale
PHQ-9: 9-item Patient Health Questionnaire
PROMIS: Patient-Reported Outcomes Measurement Information System
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
TLR4: Toll-like receptor 4
UK: University of Kentucky

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Original Paper

Development and Evaluation of an Innovative Web-Based Training, Learning, and Sharing Platform for Social Workers (Hong Kong Jockey Club SMART Family-Link Project): Mixed Methods Evaluation Study

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Abstract

Background: Information and communication technology (ICT) use may enhance social work practice and continuous professional development. Under the Hong Kong Jockey Club SMART Family-Link Project, we developed an innovative web-based training, learning, and sharing platform (i-TLS) to support not only ICT and other learning needs of Hong Kong social workers but also their practice.

Objective: We developed i-TLS with 3 major components (i-Training, i-Learning, and i-Sharing) and assessed its acceptability and impact on facilitating ICT use in family services.

Methods: We described the i-TLS development based on a 4-phase model and evaluated i-TLS using the platform database, Google Analytics, a self-administered survey, and individual phone interviews 1 year after launching.

Results: i-TLS was launched in 12 nongovernmental organizations on July 1, 2019. The COVID-19 outbreak in December 2019 limited face-to-face services, which galvanized digital transformation in social work practice. By July 31, 2020, 313 social workers had registered with i-TLS. Approximately 79.6% (249/313) of users accessed i-TLS at least once in the past 28 days, averaging 3.2 (SD 1.35) platform visits per day and viewing 4.8 (SD 1.42) pages per visit. i-Training provided 41 mini-modules on applying ICT to family services, with 730 enrollments. Approximately 70% (511/730) of users completed the mini-modules and obtained digital mini-certificates. i-Learning provided 112 items of learning resources centered on ICT use in family services, with nearly 4000 page views. i-Sharing had 25 discussion threads with 59 posts. Approximately 53.7% (168/313) of users completed the 1-year evaluation survey, including 7.1% (12/168) who were phone interviewed. The mean i-TLS satisfaction score (out of 10) increased from light (4.99, SD 1.54) to occasional (6.15, SD 1.34) and frequent (6.31, SD 2.29) users. Frequent users showed higher scores (out of 10) than light users for an increase in knowledge (5.84, SD 1.34 vs 4.09, SD 1.74; $P<.001$), self-efficacy (5.23, SD 1.92 vs 3.96, SD 1.77; $P=.02$), and knowledge application (6.46, SD 1.33 vs 1.91, SD 1.40; $P<.001$). Interviewees reported increased ICT use in services and considered i-TLS an acceptable and supportive tool for learning and practice, especially during the pandemic.

Conclusions: i-TLS is acceptable to social workers and enhances their learning and use of ICT in family services. This was achieved through access to self-directed and collaborative learning and sharing of experiences within their practice. Further research on enhancing web-based platforms is needed to expand participation and capacity building among social workers and other health and social care professionals.

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KEYWORDS

web-based; learning platform; capacity building; social work practice; ICT; social work; professional development; information and communication technology; Google Analytics; family services; mobile phone

Introduction

Background

Widespread use of information and communication technology (ICT) has revolutionized human communications and the way social work practitioners and clients connect [1]. This has fueled the demand for ICT use in social work practice to improve service delivery and benefit society [2]. Social workers can choose from a wide range of ICT service delivery options, such as web-based counseling, self-help web-based interventions, social networking, email, and SMS text messaging [3], that have enhanced their availability and interaction with individual clients and specific groups and achieved better intervention outcomes [4,5].

Traditional face-to-face training with a fixed schedule and venue has restricted its reach and social workers' opportunities of learning. Skill and knowledge exchanges are limited and often confined to colleagues within the same center or organization. Before the COVID-19 pandemic, despite the potential benefits of ICT use, many social workers were hesitant to adopt ICT at work [6]. This may relate to the importance of in-person relationships in social work or the constraints on resources and knowledge in digital practice. Limited digital competence may hinder social workers from realizing the potential of ICT to support their practice. With limited exposure to a technology-rich environment, it will be more difficult for social workers to integrate technology into service effectively [4,7]. This in-person learning approach is essential but not sufficient as a method to meet the needs of the fast-growing digital practice.

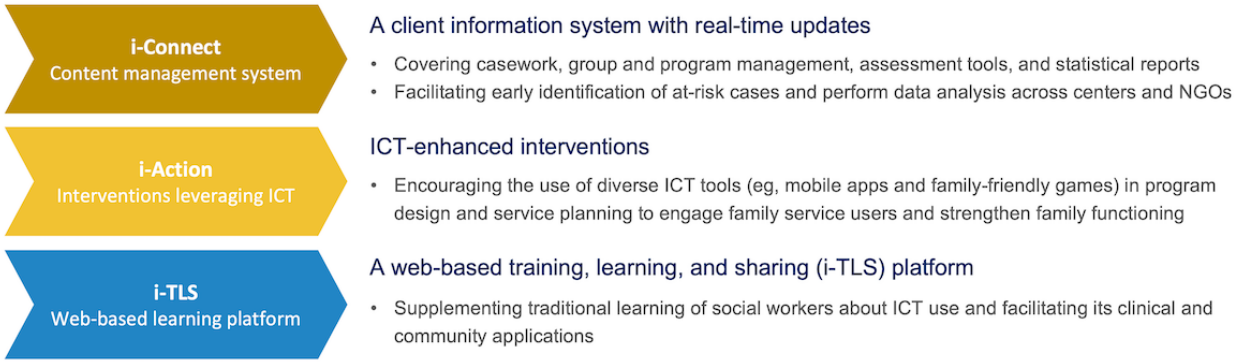
Conducting traditional teaching or on-site training can be challenging in certain situations, such as a pandemic [8,9]. The COVID-19 pandemic has significantly changed the context of ICT use in social work practice and learning. Owing to the unprecedented suspension of all nonessential in-person services, social workers are forced to rely on ICTs for most practice and communication with clients. Without preparation, an emerging and instant difficulty for social workers is how to transit and effectively use ICT to maintain service [10,11]. This urgent situation necessitates social workers to adopt more asynchronous and shared approaches to learning. They need a space where they can quickly access updated information and share a body of knowledge, tools, and ideas and learn from each other about how to improve web-based services and outcomes. During these challenging times, a web-based learning platform can offer timely support in providing essential learning resources at social workers' fingertips and leveraging technology to create a learning community that can benefit practice in the long term. Our search of PubMed and Social Care Online, using keywords such as *social work* and *online learning* or *digital learning* or *learning platform*, up to July 27, 2021, found only 1 study [12] on creating a platform for social work clinical practice in a health care setting; however, none were found on the development and evaluation of a web-based platform for social workers to learn about ICT use in family services.

The Hong Kong Jockey Club SMART Family-Link Project, funded by The Hong Kong Jockey Club Charities Trust since 2018, is a collaboration between the School of Public Health and the Technology-Enriched Learning Initiative of the University of Hong Kong (HKU) and 26 Integrated Family Service Centers and Integrated Services Centers operated by 12 nongovernmental organizations (NGOs) in Hong Kong. The goal of the project is to develop an advanced family service delivery system through the cost-effective use of ICT to support and enhance service delivery so as to promote family health, functioning, and well-being. Before this project, ICT use was minimal across the family service centers [13].

Apart from public education to promote family well-being by the HKU project team, the project includes design and development in close collaboration with all Integrated Family Service Centers or Integrated Services Centers of an i-Connect system and an i-Action component for promoting the use of ICT in preventive family service delivery. The i-Connect system includes a client information system, casework, group and program management, assessment tools, and statistical reports. It helps to reduce administrative work, facilitate the early identification of at-risk cases, and perform data analysis across centers and NGOs. i-Action promotes the use of ICT in program design and planning in services by cocreating a wide range of ICT tools with NGO partners. The tools include e-message portals, mobile apps, and family-friendly games to engage target families and further enhance service reach. As part of the project, an innovative web-based training, learning, and sharing platform (i-TLS) was developed, in parallel, to supplement the traditional learning of social workers regarding ICT use and facilitate its clinical and community applications. It is a multicomponent and web-based platform comprising social work and ICT-specific information covering tips and training in applying ICT to family services from counseling, program design, and implementation to evaluation.

The i-Connect system was launched in May 2020, and i-Action had its first ICT-enhanced program implemented in early July 2018. Throughout the implementation process, i-TLS provided additional training support and important information tied to i-Connect and i-Action. A summary of the project components—i-Connect, i-Action, and i-TLS—is presented in Figure 1, and the interface of the i-TLS components is presented in Multimedia Appendix 1.

Figure 1. Overview of the three project components (i-Connect, i-Action, and i-TLS). ICT: information and communication technology; NGO: nongovernmental organization.



Objectives

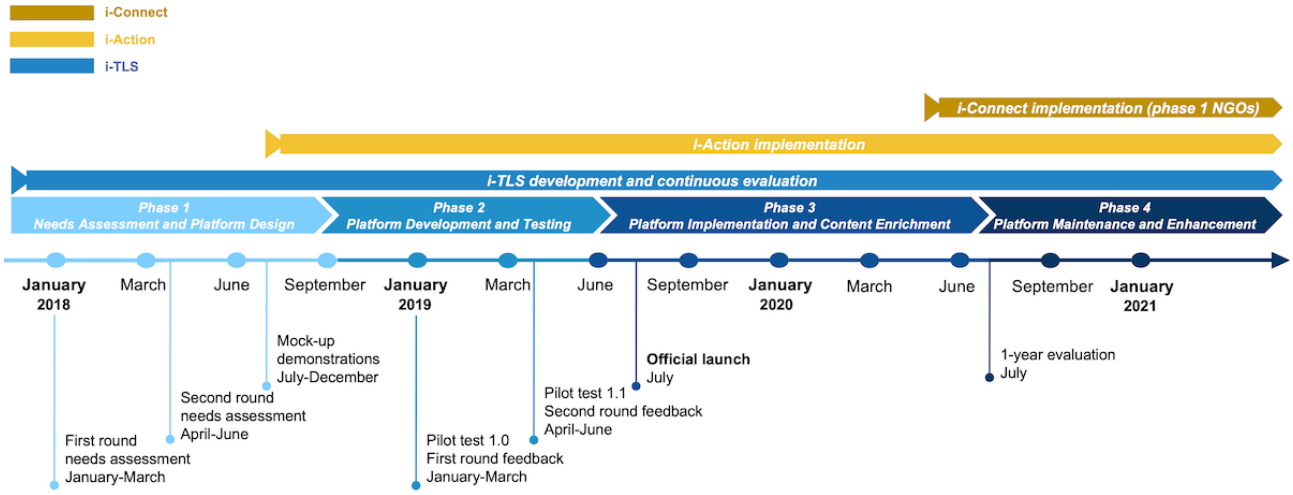
More than a website for information sharing, i-TLS encourages the collective wisdom of large groups of social workers to address the challenging conditions of the COVID-19 pandemic and facilitate ICT-enhanced services. Users are expected to improve their knowledge and skills in using digital tools in ways that benefit the values of the social work profession, enhancing service quality, efficiency, and experience. The aim of this paper is to provide an overview of the i-TLS design and development for social workers to learn about ICT use in family services and evaluate its acceptability and impact in its first year using both quantitative and qualitative methods.

Methods

i-TLS Design and Development

By integrating the principles of asynchronous and collaborative learning, i-TLS was developed based on a 4-phase model with a continuous evaluation that spanned the 4 phases. Figure 2 shows the development of i-TLS and the other 2 project components.

Figure 2. The development of the innovative web-based training, learning, and sharing platform (i-TLS) in 4 phases and the other 2 project components. NGO: nongovernmental organization.

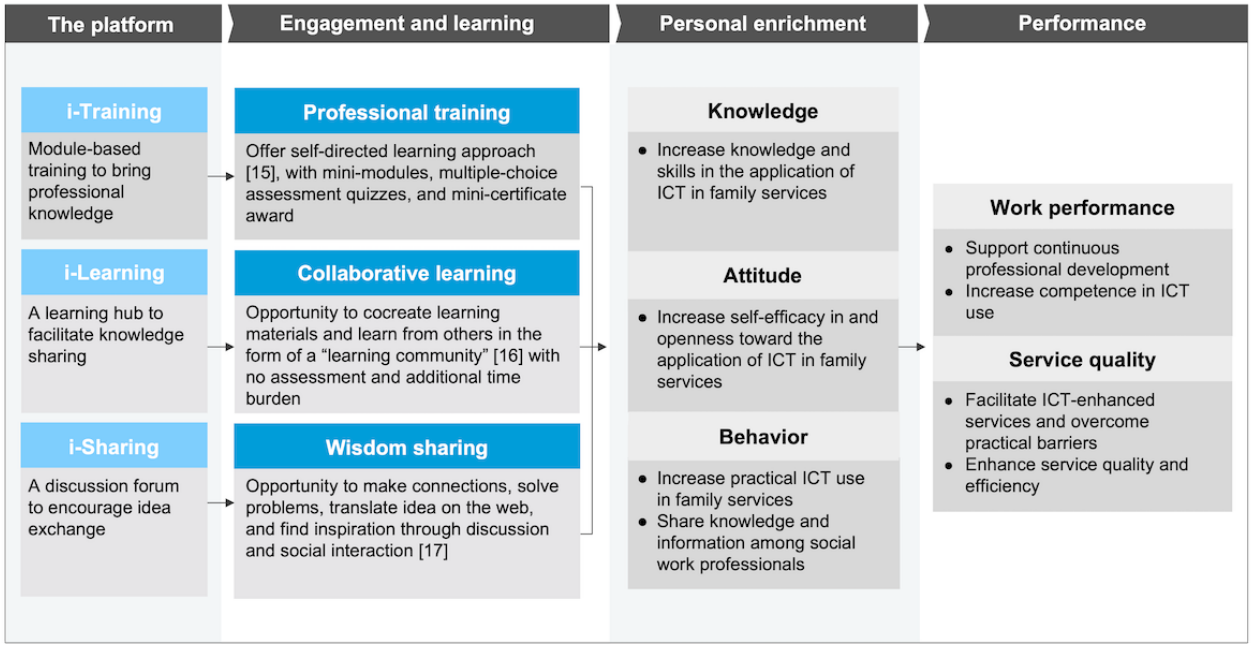


Phase 1: Needs Assessment and Platform Design

Overview

From January 2018 to June 2018, 16 face-to-face focus groups were conducted with 12 NGO partners to understand their learning needs, attitudes, and barriers to ICT use. Some of them participated twice as they have different centers across service boundaries. Overall, 108 social workers, including 28 (25.9%) supervisors and 80 (74.1%) frontline workers, participated. Approximately 61.1% (66/108) of them were women, and the median number of participants per group was 5 (range 3-21). Qualitative methodologies are optimal when the researcher wants to examine participants' views and experiences [14]. Semistructured interviews with open questions allow for flexibility and the discovery of more in-depth information that is important to participants and researchers. The information was analyzed to help design the i-TLS content and format. The design of the individual components (i-Training, i-Learning, and i-Sharing) and their theoretical backgrounds are shown in Figure 3 [15-17].

Figure 3. Overview of the innovative web-based training, learning, and sharing platform (i-TLS) components [15-17]. ICT: information and communication technology.



i-Training

i-Training adopts a self-directed learning approach [15], which includes self-monitoring and self-evaluation mini-modules designed by a multidisciplinary team of health, ICT, and social work professionals for materials that are considered to be most important, including 4 categories: data privacy and system security, ICT use in practice, program evaluation and ICT tools. On the basis of the concept of cognitive load theory [18-20], the contents were designed as mini-modules with multiple-choice assessment quizzes that can be completed in approximately 15 minutes to prevent information overload. It has been suggested that minimizing the extraneous load enables more working memory resources to be available that facilitate learning [20,21]. Social workers who completed a mini-module with a score of ≥50% in a quiz were awarded a digital mini-certificate. They could re-enroll or retake the module anytime.

i-Learning

i-Learning is a learning hub with no assessment. It adopts a flexible and collaborative approach that encourages social workers from different centers to join a colearning circle with less time burden than traditional methods. Social workers cocreated learning materials and tip packs, including sharing of successes and lessons learned in ICT-enhanced practice, with the HKU project team and shared any resources that are useful for social services. The contents are shareable, practical, and high-yield educational, benefiting social workers in the form of communities of practice through sharing their common concerns, learning from each other's experiences and growing in their practice [16]. We aim to support such communities of practices to enhance social workers' training and services that are frequently absent in the bustling clinical learning environment.

i-Sharing

i-Sharing is a sharing and discussion forum through which social workers can interact and exchange ideas on topics related to their professional interests or project information. They can also post questions, remarks, and comments on the training and learning resources to support ICT use in social services and professional development in social services and professional development. Through this process, users have the opportunity to make connections, solve problems, and find inspiration from others, which are crucial factors in learning [17]. Their feedback also guided us in platform improvements and planning.

Phase 2: Platform Development and Testing

We consolidated the learning content and multimedia tools. A series of digital learning resources with videos, graphics, and quizzes was created for a mock-up. Showing a video can provide easier understanding than a text description of complex ideas or procedures [22], whereas these diverse formats of web-based learning materials with quizzes may increase users' engagement in web-based learning use. Every feature of the platform was tested with all participating users in 2 pilot tests from January 2019 to June 2019 to ensure the usability of the platform and identify key challenges.

Phase 3: Platform Implementation and Content Enrichment

On the basis of the users' feedback, we conducted a thorough review of the platform and made the necessary adjustments before implementation. i-TLS was officially launched for all supervisors and frontline workers of 12 NGO partners on July 1, 2019. In parallel, we continued to enrich the learning content and facilitate cocreation with NGO partners. A series of training and learning resources, such as practical tips, prototypes, manuals, and video tutorials, was uploaded to i-Training and i-Learning on a regular basis.

Phase 4: Platform Maintenance and Enhancement

To enhance the users' experience, we worked with web developers to conduct platform maintenance. All information from the continuous evaluation was analyzed and incorporated into a new platform design to enhance navigation, display, layout, and user engagement.

Continuous Evaluation

As the HKU project team interacted with the NGO partners, their feedback and needs emerged through both formal inquiries and informal conversations. Collective platform use and activity data were reported to stakeholders each month to evaluate the development and progress of the platform. Approximately 1 year after launching i-TLS, we used the platform database, Google Analytics, a self-administered anonymous survey questionnaire, and individual phone interviews to assess its acceptability and impact in facilitating social workers' learning and ICT-enhanced family services.

Process Evaluation

Acceptability: Use

We assessed acceptability based on the number of registered and active users, platform use, and reactions to the platform. Registered users were those who were registered with i-TLS during the evaluation period (from July 1, 2019, to July 31, 2020). Active users were those who accessed i-TLS at least once in the past 28 days. Platform use included frequency of use and platform activity. Frequency of use was assessed using Google Analytics data on the duration and number of pages per visit and the following survey item: "In the past 3 months, to what extent did you use the platform?" Responses were given on an 11-point Likert scale ranging from *0=never* to *10=every day* and were analyzed as light users (score of 0-3), occasional users (score of 4-5), and frequent users (score of 6-10). Platform activity was directly assessed using the platform database on the number of mini-module completions and discussion posts, as well as Google Analytics data on the number of page views.

Acceptability: Reaction to Platform

The users' reactions to i-TLS were assessed using 2 survey items and phone interviews to cover their overall satisfaction with i-TLS and their likelihood of recommending it to others. Survey respondents were asked, "In general, how satisfied have you been with i-TLS?" and "How likely will you recommend the platform to other colleagues?" Responses were given from *0=very dissatisfied* to *10=very satisfied* using a dichotomous scale—*yes* and *no*—respectively.

Outcome Evaluation

Impact on Learning

We assessed the impact of i-TLS on learning and behavior. Learning was assessed using 2 survey items: "To what extent did you gain knowledge of applying ICT to family services?" and "To what extent did you feel confident in applying ICT to family services?" Responses ranged from *0=not at all* to *10=very highly increased*.

Impact on Behavior

We assessed the impact of i-TLS on learning using 2 items on the frequency of knowledge application and sharing: "In the past 3 months, how often did you apply the acquired knowledge to family services?" and "In the past 3 months, how often did you share the content of the platform to your colleagues in family services?" Responses ranged from *0=not at all* to *10=every day*.

We also conducted semistructured individual phone interviews with both supervisors and frontline workers to explore the usefulness of i-TLS for learning and practice and the practical barriers to ICT use in service.

Ethics Approval

Ethical approval was granted by the Institutional Review Board of HKU and Hospital Authority Hong Kong West Cluster (UW19-449) on July 11, 2019. This study was also registered at the National Institutes of Health (NCT04034420) on July 29, 2019. All participants provided web-based written informed consent at the beginning of the study.

Data Collection

From July 2020 to August 2020, we invited all 313 users (n=23, 7.3% supervisors and n=290, 92.7% frontline workers) to complete a self-administered anonymous survey questionnaire via email. A total of 168 users (n=18, 10.7% supervisors and n=150, 89.3% frontline workers) responded to our survey, and the 12 users (n=3, 25% supervisors and n=9, 75% frontline workers) who indicated willingness were randomly selected to participate in individual phone interviews from August 2020 to September 2020. The first author (MTMS) conducted and recorded all interviews, each lasting approximately 10 to 20 minutes with a mean of 15 minutes.

Data Analysis

Quantitative analyses were performed using SPSS Statistics (version 25.0; IBM Corp). One-way ANOVA followed by post hoc tests was used to compare the means between subgroups (light users, occasional users, and frequent users). All significance tests were 2-sided, with $P<.05$ indicating statistical significance. Effect size (Cohen *d*) was calculated with values of 0.2, 0.5, and 0.8 indicating small, medium, and large effects, respectively [23].

Phone interview data were analyzed using NVivo (version 12; QSR International) and thematic analysis [24]. Thematic analysis is a method of analyzing qualitative data that provides a rich account of the data collected [24]. In this study, it was used as a realist method to report the experiences of users. Transcripts were coded by the first author (MTMS) and a research assistant of the project, with guidance from an experienced researcher (AYKL). Themes were coded deductively based on the outcome assessment at the manifest level to provide personal insights and practical examples for social work professionals and researchers. Coding was conducted systematically, and the identified themes were reviewed and refined continually to ensure that they reflected the original meaning of the data set.

The consistency of an independent coder attributing themes is often used as a method of checking the reliability in qualitative methods [25]. Coding was conducted systematically, and the identified themes were reviewed by the experience researcher (AYKL) and refined continually to ensure that they reflected the original meaning of the data set. In total, 2 independent researchers were given the codebooks and interview excerpts and asked to code the excerpts using the themes to check the reliability of the themes.

Results

Survey Respondent Characteristics

Table 1 shows that 72% (121/168) of respondents were women, 49.4% (83/168) were aged 30 to 39 years, and 84.5% (142/168) had a degree or higher education. Approximately 89.3% (150/168) were frontline workers, and 52.4% (88/168) had at least 9 years of social work experience. Approximately 59.5% (100/168) had registered with the platform for <1 year.

Table 1. Characteristics of the survey respondents (N=168).

Characteristic	Survey respondents, n (%)
Sex	
Male	47 (28)
Female	121 (72)
Age group (years)	
18-29	43 (25.6)
30-39	83 (49.4)
40-49	31 (18.5)
≥50	11 (6.5)
Education level	
Diploma, subdegree, or below	26 (15.5)
Degree or above	142 (84.5)
Post	
Frontline worker	150 (89.3)
Supervisor	18 (10.7)
Social work experience (years)	
0-2	35 (20.8)
3-8	45 (26.8)
9-15	88 (52.4)
Registration duration (years)	
<1	100 (59.5)
≥1	68 (40.5)

Overview of Qualitative Themes

The phone interview data provided a deeper understanding of user views and experiences using i-TLS and ICT in social services. Textbox 1 shows the 5 key subthemes that emerged from our data analysis.

Textbox 1. Overview of qualitative themes.

Themes and subthemes

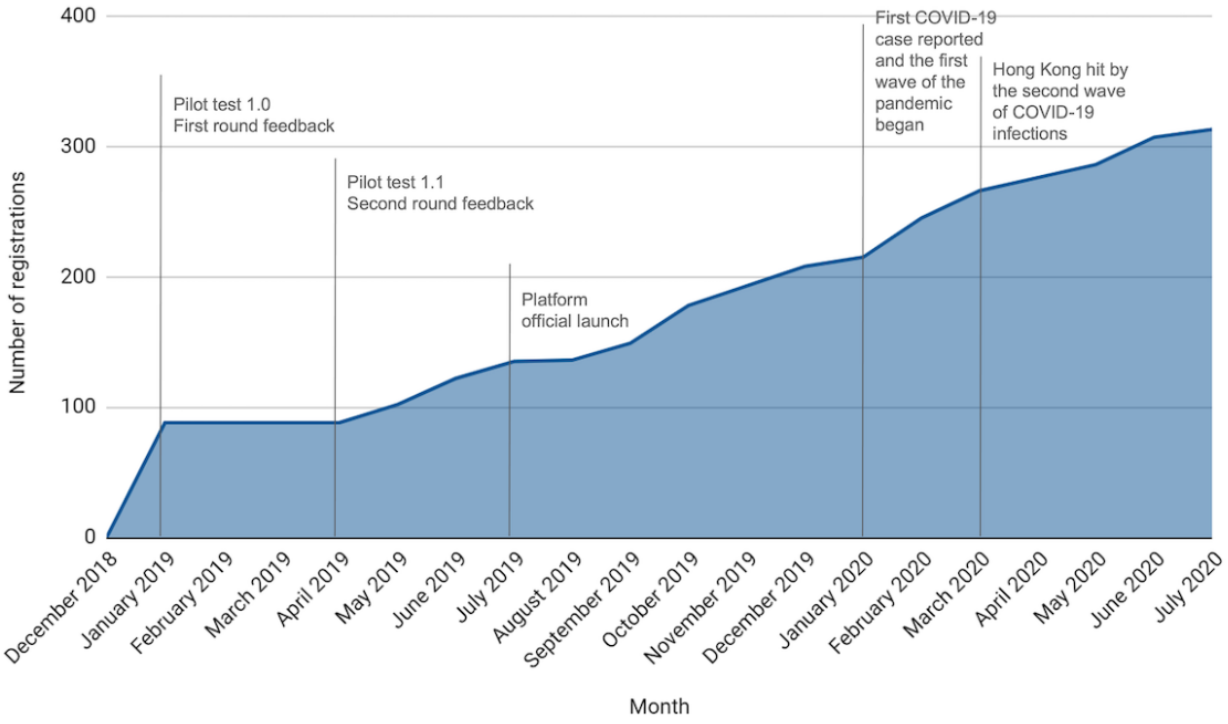
- Reactions to innovative web-based training, learning, and sharing platform
  - Enabled access to self-directed learning and resources
- Impact on learning
  - Enhanced memorization and application of information and communication technology (ICT) in services
  - Facilitated knowledge transfer through collaborative learning
- Impact on behavior
  - Increased openness and ICT use
  - Barriers to effective ICT-enhanced practice

Acceptability

Registered and Active Users

Figure 4 shows that i-TLS was launched to 135 initial users on July 1, 2019. The number of users has substantially grown thereafter. During the first wave of the COVID-19 pandemic, the number of users rose from 215 in January 2020 to 245 (14%) in February 2020. By July 31, 2020, 313 users (n=23, 7.3% supervisors and n=290, 92.7% frontline workers) from 12 NGO partners had registered. Six NGO partners reached a 100% registration rate the registration rates of the remaining 6 NGO partners ranged from 5.2% to 57.1% by July 31, 2020. Although the number of users doubled in a year, Google Analytics showed that 79.6% (249/313) of the users were active in the past 28 days during the evaluation period.

Figure 4. Registration trend since the platform pilot launch as of July 31, 2020.



Platform Use

Overview

The average duration of the visits was 4.3 minutes. The average number of visits per user per day was 3.2, and the average number of pages per visit was 4.8. Of the 168 survey respondents, 76 (45.2%) were light users, 79 (47%) were occasional users, and 13 (7.7%) were frequent users. On the basis of the platform database and Google Analytics data, the most commonly visited resources across i-Training, i-Learning, and i-Sharing were related to ICT use in practice.

i-Training

A total of 41 mini-modules in 4 categories were created and uploaded to i-Training from July 1, 2019, to July 31, 2020. Table 2 shows a total of 730 enrollments in the mini-modules, with 70% (511/730) awarded digital mini-certificates. Training on data privacy and system security had the highest average number of enrollments, with 71.5% (271/379) completion.

Within each of the 4 categories, mini-modules *Data Best Practice*, *The Application of E-messaging Intervention in Services*, *The BACK* Model, and *i-Connect System—Group/Program Enrolment* were the most popular, with 90.9% (50/55), 80% (28/35), 78% (18/23), and 75% (6/8) completed, respectively.

Table 2. Number of enrollments in and completions of the 41 mini-modules in i-Training.

Category	Minimodules (N=41), n (%)	Enrollments (N=730), n (%)	Enrollments per mini-module, mean (SD)	Completions[a] (N=511), n (%)	Completions[a], mean (SD)	Completion rate (%)
Data privacy and system security	13 (32.3)	379 (51.9)	29.2 (13.1)	271 (53)	20.8 (13)	71.5
ICT[b] use in practice	5 (12.2)	127 (17.4)	25.4 (18)	94 (18.4)	18.8 (16)	74
Program evaluation	3 (6.8)	72 (9.9)	24.0 (1)	54 (10.6)	18.0 (0.5)	75
ICT tools	20 (49.4)	152 (20.8)	7.6 (4.9)	92 (18)	4.6 (3)	60.5

[a]Including all who completed the post–mini-module quizzes with an overall score of ≥50% and were awarded mini-certificates.

[b]ICT: information and communication technology.

i-Learning

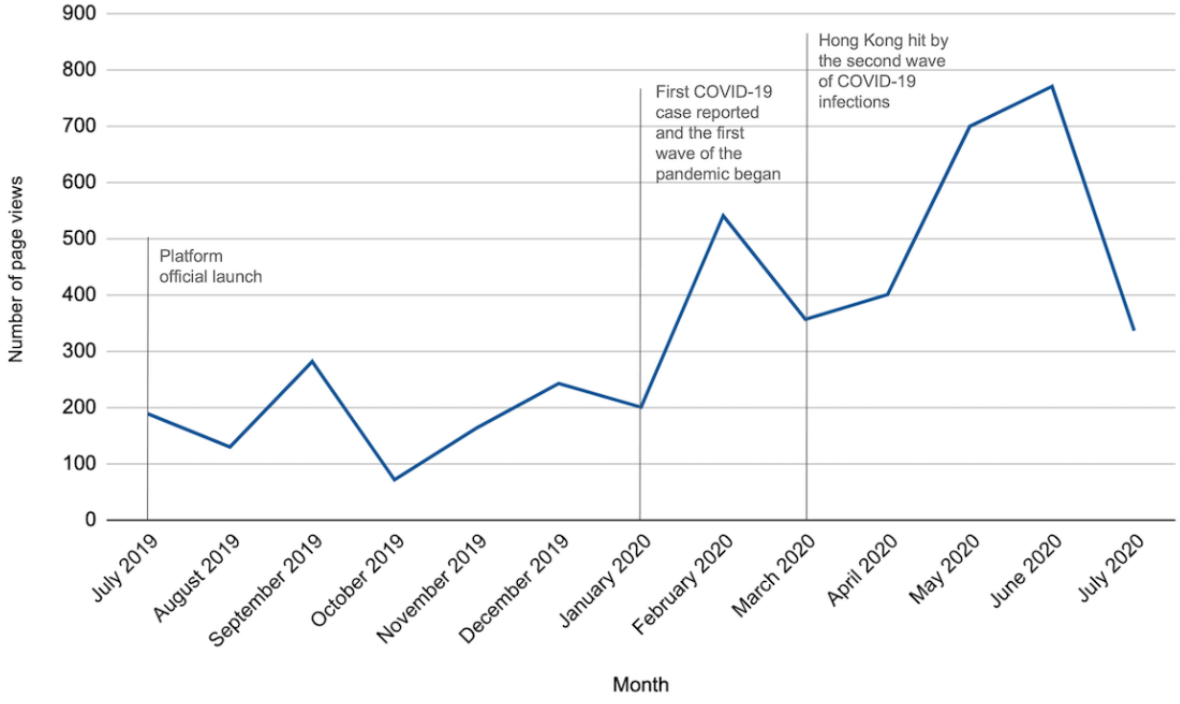
A total of 112 items of learning resources were created and uploaded to i-Learning from July 1, 2019, to July 31, 2020, with 4388 page views recorded from Google Analytics. Table 3 shows that the item with the highest average number of page views was experience sharing of ICT use in practice, followed by ICT tools and games. Figure 5 shows the number of page views by month for the period from July 1, 2019, to July 31, 2020. The number of page views maintained steadily between 100 and 300 in the first 6 months but increased sharply from 201 in January 2020 to 541 following the first COVID-19 case reported. The number of page views slightly dropped in March 2020 but rebounded and surged to 771 in June 2020 after the second wave of the COVID-19 pandemic hit in mid-March.

Table 3. Number of items and page views in i-Learning.

Category	Items (N=112), n (%)	Page views (N=4388), n (%)	Page views per item, mean (SD)
Experience sharing of ICT[a] use in practice	8 (7.13)	696 (15.86)	87.0 (27.7)
ICT tools and games	54 (48.18)	3116 (71.01)	57.7 (18.9)
Professional practice	50 (44.64)	576 (13.13)	11.5 (5.7)

[a]ICT: information and communication technology.

Figure 5. Number of page views in i-Learning by month from July 1, 2019, to July 31, 2020.



i-Sharing

A total of 25 discussion threads with 59 posts, including all the replies and follow-up comments, were posted in the i-Sharing forum from July 1, 2019, to July 31, 2020. Approximately 75% (9/12) of NGOs created at least one post, with a median of 2.5 posts. Table 4 shows which ICT tools and their uses had the highest average number of posts per thread, followed by project information.

Table 5 summarizes the number of activities in i-Training, i-Learning, and i-Sharing, as well as the number of project target deliverables. The number of activities of each platform component exceeded the targets by 190% to 3224%.

Table 4. Number of discussion threads and posts in the i-Sharing forum.

Category	Threads (N=25), n (%)	Posts (N=59), n (%)	Posts per thread in each category, mean (SD)
ICT[a] tools and use	8 (32)	41 (70)	5.1 (2.30)
Project information	8 (32)	9 (15)	1.1 (0.35)
Professional practice	9 (36)	9 (15)	1.0 (0)

[a]ICT: information and communication technology.

Table 5. Target deliverables and output activities for i-Training, i-Learning, and i-Sharing.

Component	Target deliverables, N	Output activities, N	Target (%)
i-Training (module completions)	141	511	362.4
i-Learning (page views)	132	4388	3324.2
i-Sharing (posts)	31	59	190.3

Reactions to i-TLS

Satisfaction with i-TLS on a scale of 0 to 10 showed a median of 5 (IQR 5-7). Table 6 shows a significant difference in satisfaction according to the frequency of use (P<.001). Frequent and occasional users showed significantly higher satisfaction than light users, with moderate to large effect sizes (Cohen d=0.68-0.80). However, we found no differences between frequent and occasional users. In addition, 74.4% (125/168) of respondents would recommend i-TLS to their colleagues.

In individual phone interviews, the respondents reported that the typical busy schedule of family services made it difficult for them to find resources and learn. i-TLS helped overcome barriers in traditional face-to-face settings, in particular during the COVID-19 pandemic when almost all communication with others shifted to the web. Social workers highlighted the benefits of web-based learning with increased access to resources and reach to colleagues, which provided a good way of continuing development and maintaining service:

> *I think it is good because it's accessible to us when we need the resources. It is much easier on a web-based platform, where I could learn anywhere at any time...As you know, we always have a busy schedule in service. With i-TLS, we can revisit the webinars or other resources at our convenience.* [Frontline worker, male, 7-8 years of experience]

> *Training and learning that are related to ICT are really rare in social work...except your project. So I think it is quite nice to have many different ICT resources available on a web-based platform. You know, the COVID-19 situation has forced us to adapt to online learning and service.* [Supervisor, male, 9-15 years of experience]

> *Family services are very busy...especially when the pandemic doesn't always allow us to meet face-to-face. It is hard for us to keep everyone updated and teach colleagues how to use ICT tools for program activities as we seldom meet each other. The platform allows us to learn and read through the training resources at our own pace.* [Frontline worker, female, 7-8 years of experience]

Table 6. Survey respondents' satisfaction with i-TLS and change in knowledge, self-efficacy, and behaviors in applying information and communication technology in family services (N=168).

Variable	Platform users[a], mean (SD)			Platform users[b], Cohen *d*			Platform users[c], *P* value		
	Light users (n=76)	Occasional users (n=79)	Frequent users (n=13)	Occasional vs light users	Frequent vs light users	Frequent vs occasional users	Occasional vs light users	Frequent vs light users	Frequent vs occasional users
Reactions to i-TLS[d,e]									
Satisfaction	4.99 (1.54)	6.15 (1.34)	6.31 (2.29)	0.80	0.68	0.09	<.001	.01	.94
Impact on learning[f]									
Change in knowledge	4.09 (1.74)	5.61 (1.30)	5.84 (1.34)	0.99	1.13	0.17	<.001	<.001	.86
Change in self-efficacy	3.96 (1.77)	5.48 (1.29)	5.23 (1.92)	0.98	0.69	0.15	<.001	.02	.86
Impact on behavior[g]									
Knowledge application	1.91 (1.40)	4.59 (1.06)	6.46 (1.33)	2.15	3.33	1.55	<.001	<.001	<.001
Knowledge sharing	1.80 (1.54)	4.65 (1.31)	5.46 (2.44)	1.99	1.79	0.41	<.001	.001	.18

[a]*P* value for differences between innovative web-based training, learning, and sharing platform users (3 groups) <.001 in all cases.

[b]Effect size (Cohen *d*): small=0.20, medium=0.50, and large=0.80.

[c]*P* value for the difference between innovative web-based training, learning, and sharing platform users (2 groups).

[d]i-TLS: innovative web-based training, learning, and sharing platform.

[e]11-point Likert scale ranging from 0 to 10 (0=very dissatisfied, 3=dissatisfied, 5=half, 7=satisfied, and 10=very satisfied).

[f]11-point Likert scale ranging from 0 to 10 (0=not at all, 3=slightly increased, 5=moderately increased, 7=highly increased, and 10=very highly increased).

[g]11-point Likert scale ranging from 0 to 10 (0=not at all, 3=seldom, 5=sometimes, 7=almost every day, and 10=every day).

Impact

Impact on Learning

Table 6 shows significant differences in the change in knowledge and self-efficacy in applying ICT to family services according to the frequency of use (*P*<.001). Frequent and occasional users showed a significantly greater increase in knowledge and self-efficacy than light users, with moderate to large effect sizes (Cohen *d*=0.69-1.13). However, we found no differences between frequent and occasional users.

In individual phone interviews, respondents appreciated that the learning resources were easy to understand, which facilitated memorization and application in their daily practice. The web-based shared resources were easy to retrieve and helped reinforce their ICT skills in program implementation:

> *Many of our services are changing from offline to online now. Those video tutorials on ICT tools really help us a lot, as our colleagues are not active ICT users and do not know how to use them. The videos teach us step-by-step and we know how to use Zoom and other tools to conduct online programs now.* [Frontline worker, female, 9-15 years of experience]

> *The recommended ICT tools and other resources on the platform are informative and easy to use. They help strengthen our ICT skills and stimulate ideas in online program implementation. They also help us maintain online services during the pandemic.* [Frontline worker, male, 3 years of experience]

> *The game demonstration videos helped remind me of things I had done and learned from other NGO partners during the project launch. Sometimes, I might have forgotten and am not sure how it [the game] works, so it is nice to have that documentation...I will follow the steps and do it again in my program.* [Frontline worker, male, 9-15 years of experience]

Respondents also believed that i-TLS facilitated knowledge transfer within their professional practice. They especially enjoyed learning from the experiences of workers from other centers. Sharing information in i-TLS boosted their confidence and was highly applicable to their service, which benefited everyone by filling the gaps between knowledge and practice. It also built an environment of colearning:

> *I guess it [i-TLS] is like a learning hub...we are learning together. We have more confidence in applying ICT after reading others' experience sharing. Their sharing provides us concrete ways of implementation, which also helps stimulate new ideas in practice. It is nice to learn from others.* [Frontline worker, male, 5-6 years of experience]

> *We like something practical...my colleagues and I like skimming through the examples of the program plans and designs from other workers. They are very good ideas for reference. It helps facilitate our*

> *learning through knowing how to do it in practice.* [Frontline worker, female, 7-8 years of experience]
>
> *Many social workers from other family centers shared their experiences in applying ICT to engage vulnerable families. I learned a lot of practical skills from their experiences and was able to apply them to my work.* [Frontline worker, male, 1 year of experience]

Impact on Behavior

Table 6 shows significant differences in applying and sharing knowledge according to the frequency of use (P<.001). Frequent and occasional users showed a significantly greater increase in applying and sharing the acquired knowledge in family services than light users, with large effect sizes (Cohen d=1.79-3.33). Frequent users also showed a significantly greater increase in applying the acquired knowledge to family services than occasional users, with a large effect size (Cohen d=1.55). However, we found no differences between frequent and occasional users in knowledge sharing.

In individual phone interviews, respondents had mixed views on whether ICT tools should be used or how they should be supported in family services. In general, respondents felt that ICT offered many benefits, and they saw the potential use of ICT in family services after knowing more about ICT and its related resources. They became more open to ICT and increased ICT use in family services:

> *It was challenging to my colleagues when it started, especially to those who were not active ICT users...But we see the advantages of them and more of our colleagues are using ICT in service now. The materials on the platform are good sources for us to start off.* [Supervisor, female, 9-15 years of experience]
>
> *I see my colleagues changing their attitude toward ICT use after using the platform. In the past, they were very reluctant to apply ICT tools. Most of them preferred face-to-face as their usual practice. However, they are more willing to incorporate ICT tools into their program now. They also take the initiative to explore the ICT tools on i-TLS and use more ICT in their program.* [Frontline worker, male, 2 years of experience]

However, a few respondents were not very positive. Some remained hesitant about adopting ICT in family services. They reported that barriers included the absence of human quality and emotional bonding during counseling. How to navigate the electronic environment to effectively apply learning to an in-person practice setting remains a challenge to some social workers:

> *Counseling is somewhat relational that involves human interactions and emotional bonding while ICT is more informative...I think counseling cannot be replaced by ICT completely. We need to think about how to flexibly incorporate ICT into this ever-changing environment and to facilitate current service.* [Supervisor, male, 9-15 years of experience]
>
> *ICT might be useful, but it does not play a large role in motivating service users and enhancing the counseling process. Face-to-face interaction is still a priority in our service, especially in casework.* [Frontline worker, female, 1 year of experience]

Service users' ability to use ICT could also affect social workers' attitudes and use of ICT tools during program activities. Indeed, as the respondents reported, not all service users were information technology–literate and had access to electronic devices, which was essential for ICT use. Therefore, social workers usually preferred adopting simple or usual ways in their practice to meet the needs of service users:

> *So...the way things work usually for our service users is very much sort of pen and paper. The outcomes can be very different from using a laptop or smartphone for many of our service users. We need to think carefully about what devices or ICT tools suit our service users...we usually go back to the basics or stick to the old practice.* [Frontline worker, male, 3 years of experience]

Discussion

Principal Findings

We have reported the development and evaluation of a web-based platform aimed at supporting social workers' learning during the early stage of digital transformation in social work family practice. The results provided insights into the acceptability and impact of an innovative learning platform with 3 different components and learning approaches. Overall, we enrolled 313 social workers, with around 80% (249/313) of active users at 13 months. The demographic characteristics of the respondents revealed similar trends to those in the statistics report from the Hong Kong Social Workers Registration Board [26]. Although the pandemic might have led to more ICT use and targets being exceeded, the continuous increase in the number of users and platform activity showed that the platform was acceptable and useful in its first year but with room for further improvements and increase in use. Users were satisfied with the platform, and more frequent users showed increased knowledge, self-efficacy, and use of ICT in services compared with light users. Through focus groups and individual phone interviews, we found nuances in motivation and behavior change, which gave us a better understanding of how this platform influenced the learning of social workers and their clinical practice.

Users in this study were positive about the potential use of i-TLS in supporting continuous learning. They felt that i-TLS could increase accessibility to learning in a way that might not be possible in traditional face-to-face settings. Some admitted that they felt unease in finding time for learning amid the busy professional duties and time pressures they faced in clinical settings. These findings support previous assertions by clinicians and researchers that the asynchronous and hybrid nature of web-based learning allows for more learning opportunities [12] and provides more access to a wide range of information independent of space and time [27]. These findings are also consistent with a British sample of social workers in a

web-based learning pilot study [28], who also felt that web-based platforms could increase flexibility and autonomy for learning.

Importantly, our data suggest that i-TLS could increase support by reaching more social workers across centers at the point of need, particularly during the outbreak of COVID-19. Given the primary face-to-face nature of social work practice, keeping social workers engaged in such a digital environment is challenging. However, the rapid transformation and need for digitalization in this specific situation necessitated the use of web-based learning and new communication modes to maintain the quality of professional development and service delivery. Training on data best practices and video tutorials on web-based communication tools and creative platforms such as Zoom videoconference, YouTube, and Prezi have become the most popular materials among social workers. Social workers across centers were more willing to use and share information over time as they learned more about the platform's capabilities. Before launching i-TLS, the exchange of information, ideas, and knowledge on ICT use across centers was limited, with little peer collaboration. Although books [29,30] and social work professional bodies such as the National Association of Social Workers and the Association of Social Work Boards [31] have recommended ways of ICT use and set new standards regarding social workers' ability to use ICT in practice earlier, factors such as limited access to ICT-related training and resources mean that many social workers and service users may not be able to receive timely access to the support they need during this difficult time. It is expected that the demand for and use of web-based learning will continue to increase.

We found that frequent users showed a higher score in knowledge and self-efficacy than light users. Users expressed that i-TLS encouraged collaborative learning through sharing of knowledge and experiences in the sense of a learning community. The adopted collaborative learning approach created a peer-to-peer environment that could benefit users' learning through learning from others [32]. As such, knowledge acquisition occurred not only via self-experiences but also indirectly through the experiences of others. Successful presentations with applause and appreciation by peers created a sense of success and positive feeling regarding their learning experiences, which boosted the self-efficacy of both presenters and attendees. According to the self-efficacy theory [33,34], one's self-efficacy increases not only through positive personal experiences but also by seeing others succeed. There has been an increasing awareness and understanding of learning from others within higher education [35,36] and various professions that require clinical practice [32,37,38]. However, this learning approach has not been well-described in the social work learning literature. The cocreating feature of our i-TLS, which fosters the sharing of knowledge and experiences, was identified as a strength by the users.

Despite concerns about human interaction and some practical barriers inherent in ICT tools, the attitude of the participating social workers toward the use of ICT in practice was largely positive and much more open after using i-TLS, especially under the challenges of social distancing measures amid the pandemic. We found that frequent users, who showed higher perceived knowledge and self-efficacy, used ICT in services more frequently. However, some social workers remained hesitant to fully embrace technology and expressed concerns about its practical use, especially in traditional in-person services such as counseling, although they were aware of the benefits of incorporating ICT into their practice. Considering the principles of social work ethics, which value the central importance of human relationships [39], social workers may see ICT as only a supplementary tool and less important. Therefore, those who emphasize the development of in-person relationships may remain struggling to incorporate ICT into practice to maintain emotional bonding with clients.

By contrast, this suggests that the perception of users toward ICT is also a key factor influencing the adoption of ICT. These findings are largely supported by the theory of planned behavior, with one's belief, perceived behavioral control, and intention predicting a behavior [40]. A review of ICT use in Norwegian social work practice [41] also suggested that the perception of new ICT solutions may affect how far and well they spread and evolve according to the diffusion of innovation theory by Roger [42]. Knowing the benefits and understanding alone does not ensure widespread adoption; rather, it requires changes in the values, beliefs, and needs of the adopter. The reluctance of some social workers to use ICT suggests that the information currently available does not adequately address their concerns. With the increasing demand for web-based services and the propensity to seek help on the web [43], it is essential for social workers to master ICT practices from scheduling appointments to program implementation, therapeutic discussions, and counseling. To enhance social workers' professional development, experienced practitioners in the field indeed play an important role in wisdom sharing and providing a clearer understanding of building effective web-based relationships. Their sharing may help lay the foundation for this new trend in using ICT to achieve the desired values of social work. Future educators and researchers should put more effort into ensuring that the ICT training content promotes both professional and technical improvement and enhancement of services.

Limitations

This was the first evaluation of i-TLS approximately 1 year after its official launch [13]. Our study had some limitations. The survey sample size and response rate were not great. This is similar to those reported in the literature [44], which showed a relatively lower participation rate of social workers on a learning and sharing platform than other service providers across care centers. Owing to the busy schedule in family services, especially challenges from the pandemic, many social workers were not able to set aside the time to use the platform or complete the survey questionnaire. In addition, the culture of some agencies relied on the coordinator to collate information, which further limited social workers' self-learning and individual access to the platform. Before the SMART Family-Link Project, most participating social workers were in the same form of training or work environment with very limited exposure to ICT in their centers. i-TLS was their first web-based learning platform, and some would be slow to join and adopt it. Moreover, we did not have objective data on knowledge and behaviors, and self-reported data might be subject to social

desirability bias. Objective assessments in future research are warranted. Consequently, our results might not be generalizable to all social workers and other social welfare services. Nevertheless, these limitations should not detract from our findings, which suggest that the participating social workers were eventually well-versed in the benefits of and barriers to ICT use in family services.

Recommendations

The feedback from i-TLS users revealed some important elements that researchers and technical developers need to consider when developing web-based learning platforms, whereas the results of this evaluation also underscored the need for further enhancement of the platform to help social workers learn. Additional promotion and engagement are required to further increase the use and ensure that social workers receive sufficient support to access web-based resources. Attempts are continuously being made to improve the i-TLS platform's layout and functionality. A revamped version of i-TLS was officially launched on June 28, 2021, and access to the site can be provided upon request. From the results of this study, literature reviews, and social work feedback, we propose several recommendations (Textbox 2).

Textbox 2. Recommendations for the development of web-based learning platforms.

Recommendations for the web-based learning format

- The accessibility, convenience, and simplicity that came from the platform and digital resources were valued.
- Videos, including animations, module recordings, and demonstration clips, were the preferred types of e-learning resources among participating social workers, which should be considered in future web-based learning design in social work curricula.
- Various formats of web-based learning and their combinations, including videos, animated clips, text documents, or links to external web-based resources, as opposed to a single delivery mode, may address a diversity of needs and increase the users' engagement. Further research on the effectiveness of using web-based learning and training by integrating various formats of learning is needed.
- More graphics, animated text documents, and illustrations should be provided to increase user engagement and adherence. As suggested by Keller and Suzuki [45] in a motivation model of instructional design, the learning process begins by providing knowledge and information using multimedia such as animation videos, text, and illustrations to gain and sustain attention.

Recommendations for professional development

- Training and resources that facilitated applicability in services bridged the gaps between knowledge and practice, which were perceived as important to social workers' professional development.
- Sharing of experiences supported social workers' learning process and created valuable content that maximized their experiential learning.
- Documentation of procedures helped memorization and reinforced social workers' skills in practice.
- The learning together environment provided a potential means by which social workers could be inspired and then generate more creative ideas that benefited their services. A cocreating nature was identified as a strength by users.
- A diverse collection of learning items should be included to fit the needs of social workers with various backgrounds and interests to increase learning engagement.
- Key leaders in social work and health-related fields sharing valuable resources and feedback may play an essential role in social workers' professional development. Leaders are expected to play active roles in initiating chat topics and sharing valuable insights, which could draw social workers' attention and facilitate more sharing and participation on the platform.

Conclusions

We have shown that the newly developed learning platform for family service social workers is acceptable and effective, as reflected in the substantial growth in platform use and increased knowledge, self-efficacy, and ICT use in family services. Social workers identified some key elements through which i-TLS was perceived to optimize their learning, including enabling access to promote self-directed and collaborative learning and encouraging sharing of experiences within their practice. i-TLS can foster unique collaborations across boundaries by allowing social workers from different service centers to interact and share equally in a colearning environment without time and space constraints. Our results should be a useful reference for researchers, health and social care professionals, and administrators considering developing a web-based learning platform for continuous professional development. Further research on the development and enhancement of web-based platforms to promote and expand the participation and capacity building of social workers and other related professionals is warranted.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the innovative web-based training, learning, and sharing platform (i-TLS) displaying the home page and the interface of the three individual components (training, learning, and sharing).
[DOCX File , 2113 KB - formative_v6i4e32894_app1.docx]

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Abbreviations

HKU: University of Hong Kong
ICT: information and communication technology
i-TLS: innovative web-based training, learning, and sharing platform
NGO: nongovernmental organization

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Original Paper

A Web-Based Communication Tool for Postoperative Follow-up and Pain Assessment at Home After Primary Knee Arthroplasty: Feasibility and Usability Study

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Abstract

Background: We report the use of an electronic tool, Eir (Eir Solutions AS, Norway), for symptom registration at home after knee arthroplasty. This electronic tool was used in a randomized controlled trial (RCT) comparing 3 different analgesic regimens with respect to postoperative pain and side effects.

Objective: The aim of this substudy was to investigate this electronic tool for symptom registrations at home with respect to usability (ie, how easy it was to use) and feasibility (ie, how well the tool served its purpose).

Methods: To assess the tool's usability, all participants were invited to fill out the 10-item System Usability Scale (SUS) after using the tool for 8 days. To assess feasibility, data regarding the participants' ability to use the tool with or without assistance or reminders were collected qualitatively on a daily basis during the study period.

Results: A total of 134 patients completed the RCT. Data concerning feasibility of the web-based tool were collected from all 134 patients. The SUS was completed by 119 of the 134 patients; 70.2% (94/134) of the patients managed to use the tool at home without any technical support. All technical challenges were related to the login procedure or internet access. The mean SUS score was 89.6 (median 92.5; range 22.5-100).

Conclusions: This study showed high feasibility and high usability of the Eir web tool. The received reports gave the necessary information needed for both research data and clinical follow-up.

Trial Registration: ClinicalTrials.gov NCT02604446; https://www.clinicaltrials.gov/ct2/show/NCT02604446

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KEYWORDS

feasibility studies; postoperative follow-up; primary knee arthroplasty, pain assessment; mobile application; pain treatment; follow-up at home

Introduction

Background

Length of hospital stay (LOS) after hip and knee arthroplasty is shorter with modern fast-track surgery [1]. Therefore, symptoms and complications previously observed and treated in the hospital will now occur at home. These include risks for respiratory depression caused by opioid analgesics and infectious complications. Tools for active communication with the patients after early discharge from the hospital will be important to avoid or address these problems.

Benefits of communication via the internet using tablets and smartphones for postoperative follow-up after surgery have been reported by previous research [2-5]. Modern technology can provide detailed postoperative surveillance data at home [2], guide patients in postoperative pain management [3], provide detailed data on postoperative pain development and opioid use [4], and measure recovery of activity level after total joint arthroplasties [5]. Several advantages of using electronic tools for patient-recorded outcomes have been identified, such as fast and direct communication between patient and health personnel, higher data quality and response rates, easier storage of data, easier access to data for both patients and health personnel, access to real-time patient data for health care personnel, and easier connection of different sources of data [6]. Challenges when using electronic tools can be software failure when used at home or user errors, or the tool can be inconvenient and tiresome to use for the patients over time. These factors can lead to missing data [2,3,5]. Electronic tools should be user-friendly and understandable for the patients, and they should be able to obtain the information needed for clinical follow-up. Evaluations of electronic tools related to specific patient populations must highlight these features and should be done before implementing a tool in routine use.

Objectives

We report the use of an electronic tool, Eir (Eir Solutions AS, Norway), for symptom registration at home after knee arthroplasty. This electronic tool was used in a randomized trial [7] comparing 3 different analgesic regimens with respect to postoperative pain and side effects. An electronic tool for symptom registration was initiated to closely monitor the patient's course at home over the succeeding postoperative week. The aim of this substudy was to investigate this electronic tool for symptom registration at home with respect to usability (ie, how easy it was to use) and feasibility (ie, how well the tool served its purpose).

Methods

Study Design

The study was conducted and is reported according to the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist (Multimedia Appendix 1). In a randomized, double-blinded, placebo-controlled study comparing 3 different postoperative analgesic regimens [7], we used a web-based tool, Eir, for registration of patient-reported outcomes and medication [8,9] to evaluate the effect of the pain management and to assess side effects. The web-based tool was used by all patients regardless of intervention arm. We present the results for the full sample regardless of which intervention arm they were allocated to in the randomized controlled trial (RCT), as we did not expect the different postoperative analgesic regimens to influence the patients' ability to use the tool. The patients registered pain levels, medication use, and side effects for the first 8 days after surgery. Two of the postoperative regimens included the use of opioids: oxycodone 10 mg twice daily or tapentadol 50 mg twice daily. All 3 groups had access to immediate-release oxycodone 5 mg as rescue medication for pain. Other sedative medications were not given as a part of the study interventions. Assessment of the tool's usability and feasibility was an integrated part of the trial. To assess the tool's usability, all participants were invited to fill out the 10-item System Usability Scale (SUS) after using the tool for 8 days. To assess feasibility, data regarding the participants' ability to use the tool with or without assistance or reminders were collected qualitatively on a daily basis during the study period.

Patients and Setting

The study was a single-center, prospective, randomized, double-blinded trial carried out in a university hospital setting from November 26, 2015, to November 7, 2018. Patients scheduled for surgery with total knee arthroplasty (TKA) between 18 years and 80 years of age were considered for inclusion in the study. Exclusion criteria were cognitive impairment, inability to read or speak Norwegian, lack of a cell phone or wireless Wi-Fi connection at home, or use of drugs or medical conditions that conflicted with one or more of the study drugs or any of the multimodal basal pain medications given in the study. The trial was completed by 134 patients [7].

The Web-Based Application

Eir is an electronic symptom assessment tool developed by the European Palliative Care Research Centre at the Norwegian University of Science and Technology and St. Olavs Hospital, Trondheim University Hospital for use in cancer care. A separate patient module was designed for patient-reported postoperative symptom assessment and medication registration after fast-track knee arthroplasty. It consisted of measurements of pain and side effects and detailed registration on use of analgesic drugs (Multimedia Appendix 2).

Procedures

Patient-reported data concerning effect and side effects of the pain treatment were registered daily for 8 days by use of Eir on a tablet and transferred wirelessly to the Eir database. The patients used Eir either on their personal tablet or on a tablet supplied by the study (Apple iPad Mini 2, 16 GB). The patients were introduced to the application and the tablet after surgery when awake and after mobilization. All patients were supervised for 2 electronic self-reports while hospitalized, to check that the system was working and that the patient was able to comply with the procedure. To be able to use Eir on tablets at home, the patient had to log on to a wireless Wi-Fi connection, use the correct password to log in, and answer 15 questions regarding use of study drug and other analgesics, pain intensity,

and side effects of analgesics (Multimedia Appendix 2). Pain intensity and side effects were all measured on an 11-point numeric rating scale, from 0 to 10 (Figure 1).

All patients were instructed to self-report on the tablet each day before noon. A reminder was sent by the main author as an SMS if no registrations were received within the agreed time. The patient received a second reminder as a phone call if there were no registrations after the SMS reminder. The patient`s closest relative was contacted if none of these communication methods succeeded. All patients received a paper version of the tablet questions for back-up in case of technical failure.

Figure 1. Picture of the application in use with English text (Norwegian text was used in the study).

Data Collection Instruments

For each patient, the completeness of data, use of reminders, potential user problems, solution to problems, and phone calls were registered for feasibility assessment. Usability was measured by use of the 10-item SUS, which is designed to measure the subjective usability of websites and software [10,11]. The SUS gives a score ranging from 0 to 100, with higher scores meaning better usability. A paper version of the SUS questionnaire was given to the participants on the day of discharge from the hospital, and the participants were instructed to complete the form 8 days after surgery. All patients received a reminder about the SUS form as an SMS and returned the questionnaire by mail.

Two weeks after the operation, all patients were interviewed by telephone as a follow-up, and a global satisfaction score on the pain treatment was registered. The patients were given the opportunity to comment on any part of the treatment and follow-up after the operation.

The participants were grouped into 5 levels of technical skills, or tech groups. The 5 different groups were made by the first author (TR), based on the level of intervention needed to retrieve data (Table 1). The patients' skill levels were compared with the registered data on side effects, drug consumption, age, and gender to assess if such factors could explain the difference in feasibility.

Table 1. Classification of the tech groups.

Tech group	Level of technical skills
1	No intervention was needed.
2	1-2 reminders were provided, but no technical support was needed.
3	Technical support was provided 1 time.
4	Technical support was provided several times.
5	Not able to use the application at all, all data were collected by paper forms.

Statistical Methods

Descriptive statistics were reported as mean (SD) or median and 25th and 75th percentiles, as appropriate, according to the distribution of variables. The distribution of feasibility categories was reported as multinomial probabilities with exact 95% CIs. Correlation between feasibility and SUS and between feasibility and other clinical characteristics (eg, age, gender, type, and amount of drug received) was calculated using the Kendall nonparametric correlation coefficient and plotted appropriately. Correlation between feasibility and use of a personal tablet as opposed to those who borrowed a tablet from the hospital was calculated using the Mann-Whitney *U* test.

Ethics

The study was approved by the Regional committee for Medical and Health Research Ethics (2015/209/Rek-Midt) and the Norwegian Medicines Agency (15/01581-13) and registered at clinicaltrials.gov (NCT02604446) on November 13, 2015. The study was conducted in compliance with the Declaration of Helsinki and Good Clinical Practice. Written informed consent was obtained from all participants before inclusion.

Results

Patients

A total of 134 patients (61 men and 73 women) between the ages of 32 years and 78 years completed the RCT. Data were collected from all 134 patients concerning feasibility of the web-based tool. The SUS was completed by 119 of the 134 patients.

Evaluation Outcomes

The mean SUS score was 89.6 (median 92.5; range 22.5-100). This score corresponds to an A+ in a scoring system given by Sauro [12].

Most of the patients (94/134, 70.2%) managed to use Eir without any technical support (Table 2). Patient-reported data were provided by 68 patients for the defined period of 8 days without any intervention (tech group 1); 26 patients received 1 to 2 reminders but did not need any technical support (tech group 2); 24 patients received simple technical support once, typically on their first attempt to answer after hospital discharge (tech group 3); 10 patients received technical support several times (tech group 4); and 6 patients did not use the application system at home at all (tech group 5). For this tech group, all data after hospitalization were collected from the paper version.

In tech group 5, 1 patient was transferred to ward home for blood transfusion and never managed to connect to the internet, 1 patient could not find the password for his home network, and 1 patient was sent home without a tablet. These 3 patients did not complete the SUS. The last 3 patients in tech group 5 did not use the tablet at home and gave a SUS score based on their use of the application while hospitalized, their scores being 50, 62.5, and 85.

Of the 134 patients, 49 (37%) used their own tablet with the application installed, while 85 of 134 (63%) patients borrowed a study tablet in the registration period at home.

Patient demographics, study drug, level of self-reported side effects, and mean SUS score for each tech group related to their technical skill level is displayed in Table 2.

Figure 2 shows the relationship between tech group and SUS. We observed a significant negative correlation between technical performance (feasibility) and the patient´s evaluation of the electronic tool’s usability (SUS score; correlation coefficient –0.18; P=.02). The 6 patients who were not able to use or not interested in using the tablet for self-registration (tech group 5) had a significantly higher age than the rest of the patients (P=.004). We found a correlation between feasibility and use of personal tablet (P=.04) as opposed to those who borrowed a tablet from the hospital. We observed no gender differences related to technical skills (P=.16). There were no significant associations between the patients' technical skills and the use of study drug (placebo versus the opioid groups: tapentadol and oxycodone).

The total amount of reports possible was 1072 both at hospital and home. At home, the maximal total number of reports was 642, of which 631 (98.3%) was delivered. The patients delivered 450 of 631 reports (71.3%) at home without technical support.

Table 2. Patient demographics, study drug, level of self-reported side effects, and mean System Usability Scale (SUS) score for each tech group.

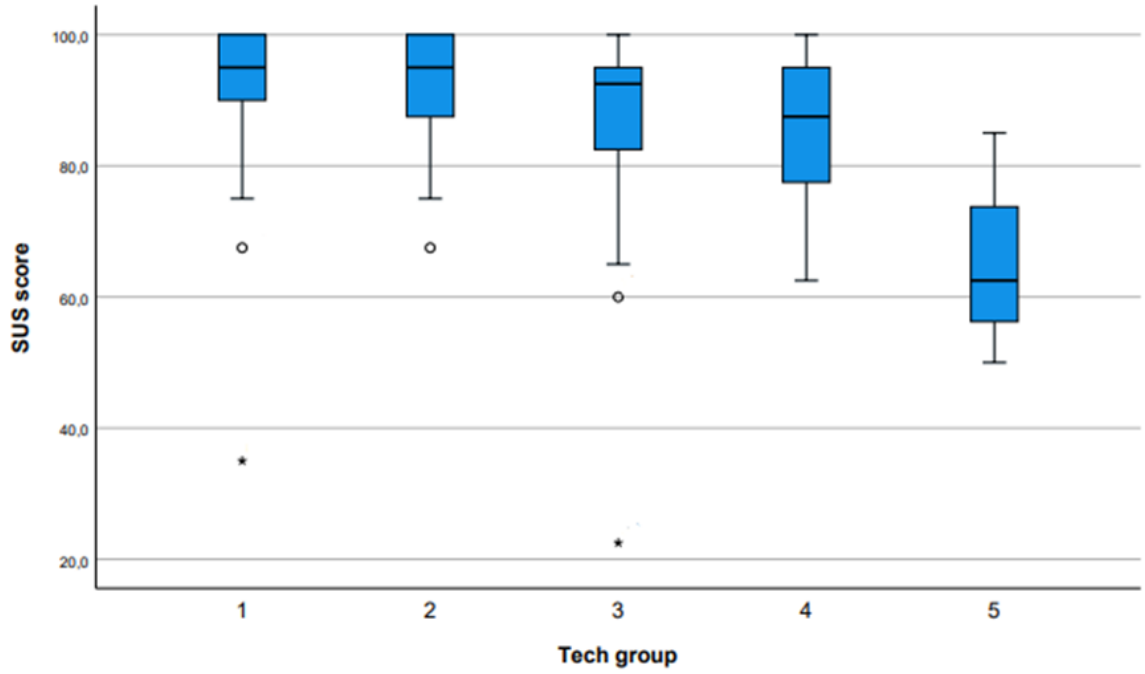
Characteristics	Tech group 1 (n=68): no intervention	Tech group 2 (n=26): 1-2 simple reminders	Tech group 3 (n=24): technical support once	Tech group 4 (n=10): support on multiple occasions	Tech group 5 (n=6): unable to use
Proportion of the total sample (95% CI)	0.51 (0.39-0.62)	0.19 (0.12-0.30)	0.18 (0.10-0.27)	0.07 (0.03-0.15)	0.05 (0.01-0.11)
Sex, n (%)					
Male	29 (43)	10 (38)	12 (50)	6 (60)	4 (67)
Female	39 (57)	16 (62)	12 (50)	4 (40)	2 (33)
Age (years), mean (SD)	61 (9.82)	58 (9.76)	64 (9.92)	62 (7.69)	71 (5.37)
LOS[a] (days), mean (SD)	2.1 (0.66)	2.5 (0.76)	2.1 (0.58)	2.3 (0.95)	2.5 (0.84)
Study drug in original trial, n (%)					
Oxycodone depot	23 (34)	12 (46)	6 (25)	3 (30)	2 (33)
Tapentadol depot	24 (35)	8 (31)	10 (42)	3 (30)	0 (0)
Placebo	21 (31)	6 (23)	8 (33)	4 (40)	4 (67)
SUS[b] form completed, n (%)	61 (90)	25 (96)	21 (88)	9 (90)	3 (50)
SUS score, mean	91.8	92.9	85.2	84.4	65.8
Pain (at rest), mean[c]	2.17	2.35	2.09	3.26	1.21
Constipation, mean[c]	0.66	0.47	0.42	0.59	0.93
Dizziness, mean[c]	0.95	1.13	0.88	2.29	0.57
Headache, mean[c]	0.42	0.76	0.59	0.90	0.14
Nausea, mean[c]	0.88	1.08	0.99	1.79	0.76
Sedation, mean[c]	2.03	2.21	2.16	3.26	1.21
Sleep quality, mean[c]	2.97	3.4	3.49	4.53	1.98
Amount of rescue drug (oxycodone 5 mg tablet), mean value per 24 hours	1.59	2.3	1.79	3.2	1.02
Used personal tablet, n	30 (44)	9 (35)	7 (29)	2 (20)	1 (17)
Used borrowed tablet, n (%)	38 (56)	17 (65)	17 (71)	8 (80)	5 (83)

[a]LOS: length of hospital stay.

[b]SUS: System Usability Scale.

[c]Measured on a 0-10 numeric rating scale (0=best, 10=worst).

Figure 2. The relationship between tech group and System Usability Scale (SUS) score.



Discussion

Principal Findings

This study showed high feasibility and high usability of the Eir web tool. A large majority (94/134, 70.2%) of the patients managed to use the tool at home without any technical support. All technical challenges were related to the login procedure or internet access. The received reports gave the necessary information needed for both research data and clinical follow-up.

Almost 90% (119/134, 88.8%) of the patients completed the SUS to evaluate the usability of the electronic tool. Missing reports were evenly distributed between all technical skill groups. We found a clear correlation between the SUS score and feasibility of the tool (ie, the level of technical support given). In the tech groups with higher need of technical support, there was also a higher fraction of patients not having their own tablet, and those not able to complete the reports were older. This implies that the differences in feasibility and usability score between the tech groups are more related to technical experience and skills, rather than effects of the original study intervention or factors explained by the tool itself. The total score for usability was high and more than 80 in groups 1 to 4.

Comparison With Prior Work

The electronic tool evaluated in this study has previously been tested among patient groups with cancer treated in hospital [8,9]. This is the first time the tool was evaluated for unassisted symptom registration at home. There are a few studies on electronic symptom assessment at home after surgery [2-5], indicating that electronic postoperative follow-up at home might be an emerging field. Previous studies for electronic follow-up have obtained different information. Chevallier et al [2] evaluated 29 patients using a home assessment tool after ambulatory surgery and measured pain, nausea, vomiting, comfort, oxygen saturation, heart rate, and blood pressure. Pombo et al [3] used an electronic tool for pain registration with 32 patients, which generated treatment recommendations for the patients after ambulatory surgery. Hajewski et al [4] used automated mobile messaging to gather detailed data on pain development and opioid utilization in 29 patients after periacetabular osteotomy. Lyman et al [5] used a smartphone application to measure step counts and patient-recorded outcome measures, including pain scores, with 267 patients after TKA and total hip arthroplasty (THA) surgery. These 4 studies had patients with mean ages of 47, 48, 22, and 61 years, respectively, while the mean age in our study was 61.5 years.

The technological tools and patient populations differ in these previous studies. The study by Chevallier et al [2] was a pilot study testing advanced monitoring equipment at home. The electronic tools provided 62% (2038/3248) of the expected data items compared with 82% (2656/3248) from a paper back-up. The major reason for missing data was software malfunction. The percentage of missing data in the study by Pombo et al [3] was 29.6%. They used an electronic pain diary based on periodic alarms to recommend pain treatment. The major reason for missing data was that the participant did not hear the alarm or it occurred at an inconvenient time. Hajewski et al [4] reported missing or incomplete data for 16% of the patients but stated no reason. In the study by Lyman et al [5], 6 months of follow-up was completed by 65% of THA patients and 68% of TKA patients. Reasons for noncompletion included time commitment, phone battery, app issues, and health complications. In our study, missing data were considerably less. We received 631 of 642 reports and hence, had only 1.7% (11/631) missing data. We used the tool to gather information in a drug study and had to assist 30% of the patients to avoid loss of data. The fraction of missing data is approximately the same in these studies, but with different causes. In our study, it was more important to gather all data regarding the effect of

the different drugs than to let the patients use the electronic tool without assistance.

Use in Research

The original trial [7] used this tool to obtain data for pain research. The pain data from the Eir database provide a detailed diary with daily pain scores with an exact time stamp and is a promising tool for pain research in the early postoperative period after early admission to home. Electronic assessment at home provides unbiased data from the patients and may be more reliable as the patients are not influenced by the investigators. As for other surgeries, the LOS after arthroplasty has been reduced in recent years, and in our study, the mean LOS was 2.1 days. This advocates for closer evaluation of symptoms at home.

Limitations

There is no consensus in previous studies evaluating electronic tools on how to measure feasibility. The need for technical assistance has been defined differently between studies. Our intention was to describe the variation, and we found that a division into 5 tech groups was informative, as it elaborates the variation between the tech groups with regard to need for support. This symptom assessment system requires a well-developed technological infrastructure, which is present in Norway and many developed countries but not in all countries. It also demands a population that is familiar with use of technology. The study population is not necessarily representative of all patients operated with TKA since patients with cognitive impairment, an age older than 80 years, and inability to read or speak Norwegian were excluded from this study. For a home electronic registration of symptoms to be of use for patients, it must also be connected to an organization that monitors the patients' responses and, if needed, intervenes.

Conclusions

In this study, we evaluated an electronic symptom assessment tool that most patients used without technical support. The tool's usability was scored as high, and it seems as if the differences in feasibility and usability scores were more related to technical experience and skill rather than the tool itself or the clinical intervention in this study. An electronic tool that is easy to use for patients and does not require technical support can provide adequate follow-up for patients in the early postoperative period at home.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 519 KB - formative_v6i4e34543_app1.pdf]

Multimedia Appendix 2
Questions on tablet.
[DOC File , 39 KB - formative_v6i4e34543_app2.doc]

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Abbreviations

LOS: length of hospital stay
RCT: randomized controlled trial
SUS: System Usability Scale
THA: total hip arthroplasty
TKA: total knee arthroplasty

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Original Paper

Promoting Health Behavior Change in the Preconception Period: Combined Approach to Intervention Planning

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Abstract

Background: Half of women begin pregnancy above the healthy weight range, increasing the risk of complications and adversely affecting the lifelong health of their babies. Maternal obesity remains the strongest risk factor for offspring obesity across childhood, adolescence, and adulthood. Previous research suggests that women should be encouraged to be within a healthy weight range before conception to improve health outcomes.

Objective: We outlined the intervention planning and design process to develop an evidence-informed eHealth intervention to promote weight management. The intervention, based on psychological theories and behavior change techniques, has been developed for women affected by overweight or obesity who intend to become pregnant. The *Begin Better* web application is part of an integrated program being evaluated in a clinical trial to assess if weight management *before* pregnancy can influence clinical outcomes for mothers and babies.

Methods: Our intervention development process was guided by intervention mapping and person-based methods. This study documents steps 2 to 4 of a 6-step iterative intervention mapping approach informed by the Information-Motivation-Behavioral Skills model and the findings of a previous interview study. We defined behavior change objectives for each of the Information-Motivation-Behavioral Skills behavioral determinants as well as theory-based behavior change techniques and practical strategies. We also used persuasive system design principles to assist in translating these strategies into a digital environment.

Results: The resultant intervention comprises nutritional and physical activity content along with psychological strategies, which are notably absent from mainstream weight management programs. Strategies to increase motivation, garner social support, and promote self-care are integral to maintaining engagement with the intervention, which aims to improve lifestyle behaviors and enhance well-being. Important elements include tracking mechanisms for percentage progress toward goals to enable feedback on behaviors and outcomes; in-application messages of praise on entry of goals or habits; and strategies to prompt habit formation and action planning via small, easily achievable steps toward positive change.

Conclusions: Design decisions and processes for idea generation about intervention content, format, and delivery are often not reported. In this study, we respond to this gap in the literature and outline a process that is potentially transferable to the development of other interventions.

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KEYWORDS

intervention mapping; preconception; behavior change; healthy lifestyle; maternal health; weight management

Introduction

Background

Women who begin pregnancy above the healthy weight range (BMI ≥25.0 kg/m^2) can experience a range of complications such as gestational diabetes mellitus, pre-eclampsia, premature birth, and stillbirth and have a higher risk of fetal malformations [1]. In addition, babies born to women above the healthy weight range are more likely to be born with high birth weight and experience a range of health conditions—including obesity—across childhood and into adulthood [2]. The resulting costs to the health system and society are considerable [3]. Previous research suggests that being within the healthy weight range should be encouraged before pregnancy to improve outcomes [1]. Although clinical weight management interventions can be rigorous, they are often time- and resource-intensive. Interactive communication technology in the form of an eHealth application offers a low-cost, high-reach, and potentially scalable solution. Such technologies also seek to engage the intended population group—women of childbearing age—with a product that is enjoyable to use and effective in promoting behavior change.

This paper outlines the intervention planning approach used to develop the *Begin Better* eHealth intervention. The web application is part of a multicomponent intervention that is being evaluated via a clinical trial to establish whether weight management *before* pregnancy can influence clinical outcomes for women and their babies. Although theories often describe what is required to prompt healthy behaviors, they rarely describe *how* intervention techniques induce these changes [4,5]. In addition, design decisions and idea generation about intervention content, format, and delivery are often not discussed within frameworks or reported widely [6]. Researchers also acknowledge that scientific knowledge is too often valued over the practical and social wisdom of experience-based contextual knowledge [6]. Furthermore, it is thought that a person-based approach is crucial in determining which intervention design features will be most acceptable and effective for a particular population and context [7,8].

Intervention mapping (IM) is a method used to devise health promotion programs that enable effective decision-making at each development step [9]. The planning process integrates theory and empirical findings with the collection and use of new data to develop interventions [9]. IM has been used successfully across programs for diabetes prevention and weight control, chronic disease self-management, and complex behavioral interventions for diet and physical activity [10].

It is widely recognized that selecting appropriate behavior change techniques (BCTs) can greatly enhance the effectiveness of interventions [11]. A recent meta-analysis of 46 postpartum weight management interventions found that the most successful behavioral strategies for decreased energy intake were *problem-solving*, *goal-setting*, *reviewing goals*, *feedback on behavior*, *self-monitoring of behavior*, *behavioral substitution*, and *credible source* [12]—all predominantly related to self-regulation. Some evidence exists that including a greater number of BCTs predicts greater behavior change in some contexts [13], whereas this association was not found elsewhere [12]. Meta-analyses have found greater effects when *self-monitoring* was combined with other self-regulation techniques such as explicit *goal-setting*, *feedback on goal progress*, and *action planning* [14-16]. A weight loss randomized controlled trial (RCT) found that *action planning* had the highest "usefulness" rating of all self-regulation intervention components, with daily action plans noted as being particularly effective [15]. However, much of the existing research is not specific to preconception women. Several studies related to maintenance of behavior change [17,18], including our previous work [19], have also emphasized the need for ongoing positive motivational support and encouragement—a common barrier to long-term adherence.

Interventions that provide a person-centered and autonomy-supportive communication style such as those based on self-determination theory and motivational interviewing are associated with long-term efficacy [20]. Despite this, motivational interviewing remains challenging to implement in a web-based environment [21]. Although behavior change interventions with a theoretical background are more effective than those that are not theory-informed, translation difficulties mean that theory does not underpin many developed interventions [22]. In addition, theory-based interventions are often poorly reported, making replication or adaptation difficult. It is often unclear how the BCTs have been implemented or which ones are most effective in promoting positive change [5] as techniques are rarely implemented in isolation.

Researchers have suggested that one of the most important ways to improve health care is through the use of persuasion [23]. Persuasive design uses interactive technology to change users' attitudes, behavior, or both [24]. A systematic review of 81 web-based interventions found that higher levels of interaction significantly predicted greater adherence [23]. In addition, a large-scale study of 568 participants investigated the perceived effectiveness of various individual strategies in motivating behavior change [25]. *Suggestion* was perceived as the most persuasive as it increases confidence for change, followed by *praise*, *self-monitoring*, and *reminder* [25].

Our Research Objective

Our primary objective is to plan, design, and develop a behavior change web application as part of a multicomponent intervention—the *Begin Better* trial for preconception weight management. Although the application also includes general preconception care information, nutrition and physical activity sections, and a recipe database, this study is primarily concerned with the *Mind* modules of the application. We outline the application of methods adapted from IM [9] and person-based approaches [7] to develop an evidence-informed eHealth intervention to promote weight management. The intervention, based on psychological theories and BCTs, has been developed for women affected by overweight or obesity who intend to become pregnant. Begin Better is part of an integrated program being evaluated in a clinical trial to assess whether weight management *before* pregnancy can influence clinical outcomes for mothers and babies. Participants will, at least initially, also have access to face-to-face sessions with a health coach to

complement the strategies used in the application and build on the personalized and collaborative approach to aid motivation.

Although intervention effects can often diminish over time or when support ends, the intent of the Begin Better program is a lifestyle change that women can sustain in the long term. Contrary to the *initiation* of change, theories of behavior change and weight loss *maintenance* focus on strategies such as sustained motivation, self-regulation, psychological and physical resources, habit formation, and environmental and social influences [17,26]. These reflect how health changes can be maintained over time and in different contexts. At least one sustained motivator, which may include enjoyment, satisfaction with outcomes, self-determination, or a sense of alignment with values or beliefs, is required to maintain the new behavior [17]. This aspect is especially salient as our previous interview study found that all participants had made previous attempts to lose weight but could not maintain the changes in the long term [19]. We intend to build motivation, skills, and self-efficacy so women can make sustainable lifestyle changes.

Methods

Overview

We aim to systematically describe the adapted IM and person-based process and the evidence-informed and practical strategies used to develop the *Begin Better* intervention. Begin Better targets cognitive restructuring around weight management, stress reduction, physical activity, and healthy eating behaviors. A person-based approach was used in initial interviews with 23 target women [19] to ground the design in an in-depth understanding of users' beliefs and psychosocial contexts. This process is particularly relevant in increasing engagement with digital interventions [7] and complements the theory- and evidence-based approaches to intervention development.

IM Approach

We used the 6-step IM protocol for behavior change interventions as a basis for our intervention planning [9]. Although it is an iterative process, this study reports on steps 2 to 4. Step 1 (needs assessment) occurred via the previous qualitative interview study with 23 women aged 23 to 48 years who were above the healthy weight range and wanted to make lifestyle changes [19]. Exploring the women's emotional and social contexts, knowledge, motivations, skills, and self-efficacy in changing health behavior, this qualitative study identified the personal determinants of change that drove the intervention development and enabled the production of a logic model.

Step 2 involved defining the intervention objectives for each of the behavioral determinants. Change objectives were drafted by the first author (JS) informed by the barriers, facilitators, and needs identified in the interview study, and a consensus was reached with other authors (DT and MO). In a person-based approach, these reflect the psychosocial characteristics and context of the intended users.

In step 3, BCTs and practical strategies were identified to address the objectives based on appropriate theory and evidence. The selection of BCTs was based on what has been deemed effective within each construct domain [27] and what is known to be effective in previous studies in similar contexts [12]. Change methods were operationalized to meet the parameters for effectiveness set out in the IM behavior change tables [9], where crossover occurs with BCTs [28] used in the intervention. Examples include *goal-setting*, whereby the women are prompted to set challenging but achievable goals. Similarly, *providing cues* enables the women to have the autonomy to select their own cues for healthier habits. Brainstorming and lateral thinking were used to consider practical strategies that were engaging and met the objectives of the intervention while still addressing the parameters. Where parameters were undefined, we used discretion to apply assumptions for effectiveness given the situation and context. Persuasive principles were also chosen to assist in translating design features for greater user engagement, enjoyment, and effectiveness [29].

Step 4 comprised refining the program structure and producing content. A multidisciplinary team comprising academic researchers, clinical and health psychologists, dietitians, designers, computer scientists, web developers, and women in the target population were consulted to develop the intervention. The first author (JS) completed the planned content outlines for the *Mind* modules and developed draft content along with annotated mock-ups of interactive components. A stepped approach of psychological skill building was adopted throughout the 5 modules, with plans integrated for effective delivery within the constraints of the medium.

Mind module content and interactive components were reviewed by an obstetrician (JD), clinical and health psychologists (DT and MO), a midwife, a dietitian, a nutritionist and health behavior researcher, academic researchers (AD), and clinical psychologists not associated with the project to ensure clinical accuracy and comprehension. Feedback was provided regarding simplifying some psychological concepts for our target audience and further use of metaphors to explain difficult or unfamiliar ideas. Minor grammatical edits were also made. The web programmer reviewed the overall structure and interactive elements to ensure that they were feasible to build into the application within the constraints of the medium. Drafts were reviewed and discussed with all authors, and agreement was reached on final content.

Videos and podcasts were recorded and edited by members of the research team with skills in this area. A PhD-qualified registered nutritionist and health behavior researcher—who is not an author of this paper—presented all videos and podcasts to eliminate bias in the evaluation process. The web programmer integrated the interactive tasks at key points within each video aligned with the appropriate session of the module.

Informal pilot testing of various components provided direction for the final interface. A total of 9 women in the target age group provided feedback on branding and design options for the look and feel of the application. General feedback was that the fun and relaxed designs depicting warmth and care were favored over the more clinical representations of health—in part because of the highly stigmatizing nature of being overweight in clinical settings.

Various sources of knowledge are often valued differently and can change across the development process [6]. Design decisions were driven primarily by the new interview data from the target group, with theory and empirical evidence, and informal pilot-testing providing secondary sources of guidance. Although all sources of knowledge were valuable, the stakeholder views allowed us to tailor the content to the personal determinants of our target population and to suit the context of their lives. These were women in a busy phase of life, time-poor, and often with competing work and child-rearing demands. Some belonged to lower socioeconomic groups, with limited access to information and resources. Many had also tried unsuccessfully to lose weight previously, so we knew that they required a less prescriptive approach to weight management with flexible options that could be maintained in the longer term. Some of the women struggled with comorbidities that could be improved with lifestyle changes. Many in this life phase also told us that their partners or children created barriers to healthier habits, so strategies that included partners for support were prioritized given that the intent was to conceive a child.

The intervention content and structure were also informed by published theories and evidence to enhance effectiveness. Learnings from previous complex intervention development projects also guided decision-making [6,30,31]. In addition, consideration was given to developing an eHealth solution that would be feasible to develop and deliver within time, resource, and funding constraints.

Finally, steps 5 and 6 involve planning the implementation, delivery, and evaluation. Although these stages are not reported in this paper, considerations for implementation begin with the initial needs assessment and continue throughout all steps. Change methods and practical strategies were carefully selected to support implementation. Forward planning included ensuring that all aspects of delivery satisfied the change objectives and implementation outcomes and could be easily tracked in evaluation studies. Planning also established that the intervention could be readily adapted following feedback or scaled up for future use if proven effective through RCT.

The iterative process means that steps are often not cycled through in a systematic linear manner; instead, it was necessary to readdress aspects of previous steps and refine the program to ensure that intervention strategies were feasible. An example is that we scaled back personalization aspects as developing a complex level of tailored content was not achievable within the resources available—therefore, BCT methods, persuasive system design (PSD), and practical strategies were revised accordingly.

Information-Motivation-Behavioral Skills Model

We used the Information-Motivation-Behavioral Skills model [32] for the interview study that informed the planning process. This allowed us to address any knowledge, motivation, and skill deficits of the target population. The model's simple structure allows for the easy translation of constructs into intervention components. It provides a framework for defining intervention objectives and candidate change techniques that may be key to the effectiveness of the final program [11]. The model has been well-tested in changing health behaviors and is highly applicable to weight management [33].

BCTs Used

The BCTs we used in the intervention were classified and described using the Behavior Change Technique Taxonomy [28], consisting of 93 techniques clustered across 16 categories (Multimedia Appendix 1 [28]).

PSD Model Principles

We used the PSD framework [34] to develop the eHealth intervention's technology elements, features, and interactivity to increase participant engagement and adherence. The framework proposes persuasive principles across 4 categories: primary task support (supporting users to perform the intended tasks), dialogue support (providing feedback that directs users toward healthier behaviors), system credibility support (supporting the development of trustworthy systems), and social support (motivating users through social influence; Multimedia Appendix 2 [34]). We chose this framework for the design principles' particular relevance to well-being, nutrition, and physical activity given their success in these areas [29].

Ethics Approval

The interview study that informed the planning process was approved by the Women's and Children's Health Network (HREC/19/WCHN/108) and the University of Adelaide Human Research Ethics Committee (33863).

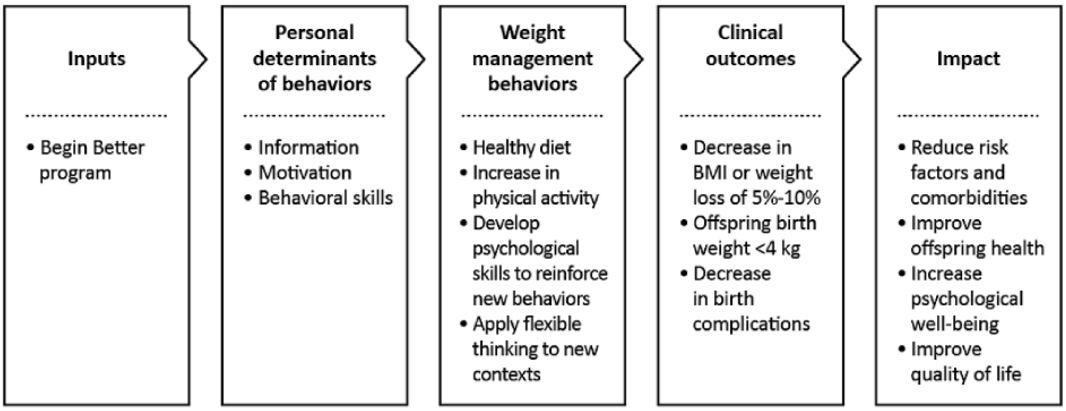
Results

Overview

Compared with the reductionist philosophy often used in weight management programs, the Begin Better intervention uses a holistic approach informed by the biopsychosocial model [35], which considers the biological, psychological, and socioenvironmental factors integral to health behavior change. A logic model of the intervention based on the personal determinants of the Information-Motivation-Behavioral Skills model; the desired weight management behaviors; clinical outcomes for the program; and the health, social, and emotional impact is shown in Figure 1. Multimedia Appendix 3 describes the change objectives, BCTs, PSD principles, and practical strategies used throughout the intervention aligned with each of the determinants.

Some of the more important techniques supported by strong evidence of effectiveness and with relevance to our context are described below, with the BCTs and PSD principles highlighted in italics.

Figure 1. Logic model of the Begin Better intervention.



BCTs Used

BCTs are used throughout the eHealth intervention. Techniques known to be the most effective, such as *goal-setting* and *self-monitoring*, are used early in the intervention. Women are guided to set goals that align with their values and encouraged to set a weight goal and several whole-person goals related to health, social, or mental well-being. Self-monitoring of weight and whole-person goals occurs within the application, with the ability to add, review, or update goals and habits as they are achieved or maintained to build self-efficacy for change. Bar charts that track percentage progress toward goals and a graph showing the overall trend line enable timely *feedback on behavior* and *outcomes* to increase motivation. Users are also encouraged to consider health benefits and measures of success beyond just the number on the scale.

One of the more effective BCTs is providing *information about health consequences*. Interviews with target women demonstrated that knowledge of the impacts of their weight status on themselves and their babies was alarmingly low. By highlighting the benefits of a healthy lifestyle before pregnancy in a nonjudgmental and supportive tone, we hope to provide women with added motivation. The language used was conversational rather than clinical, using terms such as *benefits of weight management* rather than noting the *risks*. Similarly, women are encouraged to consider the benefits of a healthy lifestyle beyond just weight management, with *information about emotional consequences* and *information about social and environmental consequences* provided. This was done via an animated sequence that highlighted the benefits not just for their babies but also for themselves—including psychosocial benefits such as more energy, positive mood changes, and being a role model for others.

The intervention also includes aspects of *nudge* theory, whereby small, simple *micronudges* are used to initiate healthy change rather than complex or restrictive regimes. For example, *restructuring the physical environment* prompts small changes in the women's choice architecture (eg, placing healthy food within easy eyeshot and reach, keeping sneakers by the front door as a reminder to take a walk, or preloading a meditation app that is visible each time the phone is used). These strategies make healthier choices easier to make.

Research also indicates that habits are important drivers of behavior [36], especially healthy eating and physical activity. *Habit formation* is promoted through ideas and inspiration to implement new healthy habits into women's daily routines. These techniques can influence behavioral flexibility and have been effective in clinical trials [37,38]. As noted previously, effective interventions need to focus on prompting action rather than merely providing motivation [4,5]. *Action planning* is an important aspect of the intervention; women will create and upload habit action plans to the application.

Social support and encouragement remain important motivators as many women in our previous interview study reported that interpersonal challenges had affected their motivation toward lifestyle change [19]. An opt-in *buddy system* is offered, whereby participants are paired with another woman in the program to reciprocate motivation and encouragement. Some women in the interview study noted the motivation and satisfaction they would garner from helping a peer along their journey to health [19]. Buddies may also function as accountability partners who check in and keep each other accountable to their goals and problem solve issues together. Women's attention is also drawn to *identification of self as role model* for those around them. Strategies are promoted to encourage healthy change across their entire family.

Other BCTs important for mental well-being and self-efficacy, such as *problem-solving* and relapse prevention, are also used as strategies to maintain motivation and increase psychological flexibility. *Repetition and substitution*, including *habit formation*, are considered integral to behavior change. Women are encouraged to integrate microhabits into their daily routine—small changes they can repeatedly implement until they become automatic. Substitution ideas are also offered for less healthy foods and behaviors.

PSD Model Principles

Our intervention incorporates the following PSD techniques. *Tunneling* guides users through the process of behavior change without overwhelming them. Key *Mind* modules, unlocked at fortnightly intervals, include various psychological techniques to create a healthier lifestyle. These are aligned with key *Nutrition* modules to deliver a cohesive program with a natural progression of skill building. Some nutrition and physical

activity content is also free-roam so that the application provides information and engaging content at all times. Topics include how to read food labels, portion control, practical tips for simple meals, and reducing sedentary time.

In-application alerts are provided to motivate and draw attention to modules as they are unlocked. For example, if women do not upload their weight for a week, *reminders* prompt a weigh-in for self-monitoring. *Praise* is offered when goals are uploaded and action plans are set with in-application messages such as "Great work with the values. Let's discuss them at our next catch-up" and "It feels great to have plans in place! Now for the benefits to flow!" Women are also prompted to reflect on their progress.

Reduction is a key technique used to simplify complex behaviors into manageable tasks that women can easily integrate into their lives. Women in our interview study cited complexity and lack of flexibility as reasons why previous weight management programs were unsustainable [19]. *Suggestion* is also used, with ideas and inspiration for small daily changes that can be made to promote healthier behaviors. A database of easy, fast, dietitian-approved recipes is also included to reduce the cognitive load associated with making daily food decisions.

Dialogue support strategies such as *Suggestion* are integrated, providing ideas and inspiration to help women reach their goals. In response to short, interactive questionnaires about areas that users find particularly challenging, feedback provides encouragement and tips for overcoming these barriers.

The intervention integrates aspects of acceptance and commitment therapy and cognitive behavioral therapy. These approaches are more often used in face-to-face therapy and have only recently been introduced in eHealth interventions for weight management. The psychology component of the intervention is delivered via video and podcast in 5 modules, with therapeutic techniques and interactive content outlined in detail in a subsequent study. Intervention features and strategies may continue to evolve as the Begin Better intervention uses an adaptive design approach [39] that allows for ongoing improvements to the application following user feedback.

Discussion

Principal Findings

In this paper, we systematically report the planning process for a complex, evidence-informed eHealth intervention for preconception health in women above the healthy weight range. We integrated research evidence with BCTs and persuasive technologies that map directly onto behavioral determinants, an approach that is underused and underreported [5]. Incorporating the views of women from a previous study [19] and those of research and professional stakeholders was a valuable addition, allowing for more targeted decision-making about intervention design.

Although traditional weight management programs promote dietary and physical activity changes, the Begin Better intervention also addresses the complex psychological processes that underlie health behaviors. It is widely acknowledged that many of our lifestyle behaviors are governed by automatic responses to contextual cues in our environment—both with food and socially [40]. As humans, we have inherent cognitive limitations in this area [40], often using emotional—rather than logical or rational—decision-making, which can lead to poorer choices. These factors can override individual motivation and intention and have been cited as a reason why many behavior change interventions show only modest effect sizes [41]. We hope that the techniques and engagement strategies used in the Begin Better intervention can address some of these factors.

Our intervention integrates therapeutic approaches that are not often used for health behavior change to assist users in creating the psychological flexibility required to sustain these changes in the long term [42] and within different contexts. Alongside behavior change, the intervention aims to induce cognitive change [43] that may predict the achievement of personal health goals and the maintenance of lifestyle changes.

Some key learning points from various knowledge sources were especially salient in translating theory into an environment for users that would be acceptable, enjoyable to use, and effective. One of the main priorities was the need for simplicity that permeated each step of the planning and development process. This need came through very strongly from interviews and was addressed by keeping behavior changes small, achievable, and flexible for the women to build self-efficacy and motivation for change. Similarly, the interface itself was simplified to 3 key areas that the women would access the most (Nutrition, Mind, and Body). Previous research has also found that users dislike applications that require too much user input [18]. Although greater levels of interactivity predict greater engagement and behavior change [5], these aspects needed to be kept as simple and user-friendly as possible. It was particularly challenging to adapt face-to-face therapy techniques or activities that are often *pen and paper* tasks to a web-based environment. Strategies needed to be chosen and implemented carefully to maintain clarity and ease.

Although not all aspects of step 5—planning, delivery, and implementation—have been explicitly detailed in this paper, an understanding of the factors that influence the wider implementation, scaling, and maintenance of an intervention is crucial for selecting intervention components [44]. The process is highly iterative and context-dependent. In addition, challenges exist in engaging women in preconception planning beyond the current RCT project. At a later stage, undertaking step 6 of the IM protocol—the evaluation plan—will confirm whether the processes undertaken through the development of the intervention have been effective [44].

The outcomes of the Begin Better program are currently being evaluated via an ongoing RCT of 870 women. To be eligible, women will be above the healthy weight range (BMI ≥25 kg/m^2), intending to become pregnant, and willing to postpone conception for the 6 months of the trial. Women in the intervention group consult with a midwife and dietitian at trial entry, gain access to the full intervention within the Begin Better application, and receive fortnightly individual health coaching sessions. Women in the control group consult with a midwife at trial entry and receive standard preconception care advice

within the Begin Better application. At the time of writing, recruitment has commenced with approximately 100 women randomized. Women will complete questionnaires assessing food intake, physical activity, emotional health, and well-being (Depression, Anxiety, and Stress Scale–21) [45] and health-related quality of life (Short Form–12) [46] along with a measure of readiness to change at trial entry and upon completion of the 6-month program. Future research is required to test acceptability and engagement and the relationships between module completion, weight goals, and psychosocial outcomes. Plans are underway to examine the impact of the emotional and affective components of the program, including the mechanistic processes of cognitive change, using scales of stages of change, cognitive flexibility, cognitive fusion, and committed action.

Strengths and Limitations

Many behavior change interventions are designed with a *one-size-fits-all* approach that fails to account for individual differences [41]. Although the Begin Better application allows for individual values, goals, and habit action plans, personalization may be further integrated in future design iterations. Additional personalization may include motivational SMS text messages tailored to the participants' individual goals, habits, and coaching sessions.

The need for a pragmatic approach guided our planning methods. The IM protocol involves a highly prescribed, time- and resource-intensive process that could not be implemented in its entirety for this project. Its application can be complicated, as noted by other researchers [10], and consideration of the resources available within the time frames of funding opportunities drove the decision to simplify the process and adapt it to our needs. It is also recommended by experts that intervention developers apply individual approaches in a flexible manner to fit their individual problem and context [31].

Although the intervention evaluation is ongoing, the content was reviewed by specialists in obstetrics, clinical and health psychology, nutrition and dietetics, exercise physiology, and computer science. In addition, potential users reviewed other aspects of the intervention, such as look and feel, and commented on the design decisions, providing insights into how participants may perceive the intervention. However, we did not extensively pilot-test the *live* application with target populations because of time and resource constraints, so new feedback was not collected or integrated.

Conclusions

The use of an adapted IM process and person-based methods provided us with a clear and tailored approach to developing the Begin Better intervention. In this study, we address a gap in the literature about detailing underlying program mechanisms and outline a process that is potentially transferable to developing other interventions.

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Authors' Contributions

JS made substantial contributions to study conceptualization and design, including methodology, and drafted the manuscript. MO and DT contributed to study conceptualization and design, methodology, supervision, and manuscript editing. JD, CS, and AD also contributed to study conceptualization. All authors reviewed and commented on the manuscript and approved its final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques.
[DOCX File , 40 KB - formative_v6i4e35108_app1.docx]

Multimedia Appendix 2
Persuasive system design principles.
[DOCX File , 37 KB - formative_v6i4e35108_app2.docx]

Multimedia Appendix 3
Begin Better behavior change objectives, techniques, and practical strategies.

[DOCX File , 28 KB - formative_v6i4e35108_app3.docx]

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Abbreviations

BCT: behavior change technique
IM: intervention mapping
PSD: persuasive system design
RCT: randomized controlled trial

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Original Paper

Adherence to a Multidisciplinary Lifestyle Program for Patients With Atrial Fibrillation and Obesity: Feasibility Study

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Abstract

Background: Atrial fibrillation is commonly associated with obesity. Observational studies have shown that weight loss is associated with improved prognosis and a decrease in atrial fibrillation frequency and severity. However, despite these benefits, nonadherence to lifestyle programs is common.

Objective: In this study, we evaluated adherence to and feasibility of a multidisciplinary lifestyle program focusing on behavior change in patients with atrial fibrillation and obesity.

Methods: Patients with atrial fibrillation and obesity participated in a 1-year goal-oriented cardiac rehabilitation program. After baseline assessment, the first 3 months included a cardiac rehabilitation intervention with 4 fixed modules: lifestyle counseling (with an advanced nurse practitioner), exercise training, dietary consultation, and psychosocial therapy; relaxation sessions were an additional optional treatment module. An advanced nurse practitioner monitored the personal lifestyle of each individual patient, with assessments and consultations at 3 months (ie, immediately after the intervention) and at the end of the year (ie, 9 months after the intervention). At each timepoint, level of physical activity, personal goals and progress, atrial fibrillation symptoms and frequency (Atrial Fibrillation Severity Scale), psychosocial stress (Generalized Anxiety Disorder–7), and depression (Patient Health Questionnaire–9) were assessed. The primary endpoints were adherence (defined as the number of visits attended as percentage of the number of planned visits) and completion rates of the cardiac rehabilitation intervention (defined as performing at least of 80% of the prescribed sessions). In addition, we performed an exploratory analysis of effects of the cardiac rehabilitation program on weight and atrial fibrillation symptom frequency and severity.

Results: Patients with atrial fibrillation and obesity (male: n=8; female: n=2; age: mean 57.2 years, SD 9.0; baseline weight: mean 107.2 kg, SD 11.8; baseline BMI: mean 32.4 kg/m2, SD 3.5) were recruited. Of the 10 participants, 8 participants completed the 3-month cardiac rehabilitation intervention, and 2 participants did not complete the cardiac rehabilitation intervention (both because of personal issues). Adherence to the fixed treatment modules was 95% (mean 3.8 sessions attended out of mean 4 planned) for lifestyle counseling, 86% (mean 15.2 sessions attended out of mean 17.6 planned) for physiotherapy sessions, 88% (mean 3.7 sessions attended out of mean 4.1 planned) for dietician consultations, and 60% (mean 0.6 sessions attended out of mean 1.0 planned) for psychosocial therapy; 70% of participants (7/10) were referred to the optional relaxation sessions, for which adherence was 86% (mean 2 sessions attended out of mean 2.4 planned). The frequency of atrial fibrillation symptoms was reduced immediately after the intervention (before: mean 35.6, SD 3.8; after: mean 31.2, SD 3.3), and this was sustained at 12 months (mean 24.8, SD 3.2). The severity of atrial fibrillation complaints immediately after the intervention (mean 20.0, SD 3.7) and at 12 months (mean 9.3, SD 3.6) were comparable to that at baseline (mean 16.6, SD 3.3).

Conclusions: A 1-year multidisciplinary lifestyle program for obese patients with atrial fibrillation was found to be feasible, with high adherence and completion rates. Exploratory analysis revealed a sustained reduction in atrial fibrillation symptoms; however, these results remain to be confirmed in large-scale studies.

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KEYWORDS

cardiac rehabilitation; atrial fibrillation; obesity; participation; completion; adherence; lifestyle

Introduction

Worldwide, atrial fibrillation is the most common sustained cardiac arrhythmia in adults [1]. It has been estimated that 17.9 million people will suffer this condition in Europe by 2060 [2]. The prevalence of atrial fibrillation also increases with the presence of traditional cardiovascular disease risk factors including diabetes, obesity, and hypertension [3]. Importantly, several longitudinal studies [4,5] have demonstrated the association between obesity and cardiac dysrhythmias with increased risk of atrial fibrillation. Moreover, patients with obesity often have a higher burden and faster progression of atrial fibrillation symptoms compared with patients having a normal weight. Not surprisingly, sustainable weight loss is, therefore, associated with a decrease in atrial fibrillation symptoms [6]. Lifestyle modification, including education, psychosocial support, dietary counseling, and physical training, are effective strategies to achieve weight loss in order to reduce atrial fibrillation symptoms and improve quality of life [7]. European Society of Cardiology guidelines [8] for the management of atrial fibrillation recommend lifestyle modification to achieve weight reduction for obese patients with atrial fibrillation; however, in practice, the effects of traditional lifestyle modification programs are often not maintained in the long-term because regular cardiac rehabilitation programs, which focus on restoring the physical condition, improving lifestyle, and providing psychological support throughout, do not sufficiently focus on behavior change [9]. In addition, only a small proportion of patients with atrial fibrillation are included in cardiac rehabilitation programs, despite proven clinical benefits [10,11]. Low participation rates are caused by suboptimal referral by medical professionals. In addition, participation in cardiac rehabilitation programs for patients with atrial fibrillation is not reimbursed by health insurance in the Netherlands. Although at the start of cardiac rehabilitation, more than 80% of patients are overweight and more than 50% have metabolic syndrome [12], most cardiac rehabilitation programs do not contain a program specifically aimed at weight loss [12,13]. In addition, most efforts to change health behaviors have had limited success due to dropout and declines in adherence [14]. Therefore, addressing barriers that influence adherence, such as a lack of personalization or tailoring of the program to a specific disease is key for improving the effectiveness of lifestyle modification programs [15,16].

In this study, we aimed to investigate the adherence and feasibility of a lifestyle program for overweight atrial fibrillation patients specifically designed to improve long-term adherence by focusing on improving self-management and sustainable behavior change.

Methods

Study Design

We conducted a feasibility study; the results of this study will be used to optimize the intervention, specifically targeted to long-term behavior change, in an associated parallel multicenter open-label randomized controlled trial (Optimal Cardiac Rehabilitation XL; Netherlands Trial Register NL5589) that will evaluate the cost-effectiveness of a multidisciplinary cardiac rehabilitation program in obese patients with atrial fibrillation and coronary artery disease.

Ethics

The study protocol was reviewed and approved by the medical research ethics committee of Máxima Medical Center. All participants were informed about the goals of the study, and all participants provided written informed consent.

Participants

Patients with atrial fibrillation who presented at the cardiac rehabilitation unit (Centre Flow, Máxima Medical Center in Veldhoven/Eindhoven) in 2016 and 2017 were eligible for participation. Patients with atrial fibrillation and obesity were referred by the cardiologist, and subsequently, invited for an intake assessment with an advanced nurse practitioner. All participants were screened for trainability and practical possibilities. To personalize the lifestyle intervention, participants were counseled to formulate personal lifestyle goals based on SMART (Specific, Measurable, Achievable, Realistic and relevant, and Timed [17]), for a 1-year lifestyle program consisting of physical training, nutrition guidance, lifestyle counseling, and psychosocial therapy, with relaxation therapy as optional additional treatment module.

For this study, we chose a sample of 10 participants, rather than using a calculation-based sample size because the goal of this study was not to evaluate clinical effectiveness but to evaluate the feasibility of the intervention in this specific patient population.

Inclusion and Exclusion Criteria

Patients with symptomatic atrial fibrillation and a BMI higher or equal to 29 kg/m^2 were asked to participate in the study. Exclusion criteria were progressive symptoms of heart failure, myocardial ischemia during exercise testing (ST depression ≥2 mm), sinus tachycardia at rest with a frequency greater than 110 bpm or atrial fibrillation greater than 100 bpm at rest, and severe cognitive impairment (memory, attention, concentration and psychiatric disorders).

Intervention

An individual program was created with the patient, based on their exercise capacity and personal goals. To improve exercise capacity, aerobic training was included, as well as strength training. Training frequency, training duration, training intensity, length of the work and rest intervals, and dosage training were used as variables to determine prescribed aerobic and strength training. The first 6 weeks of the intervention consisted of 2 training sessions per week, and the 6 weeks thereafter consisted of training sessions once per week. Blood pressure and heart rate were checked before, during, and after sessions. Training sessions (total duration: 60 minutes) consisted of aerobic training (treadmill or bicycle ergometer; a build-up time of 2 weeks at 40% to 50% of maximum rate of oxygen consumption was recommended) and strength training. For each strength training exercise (seated leg press, chest press, biceps curls, triceps curls, core muscle exercises, low-dose hip abductor-adductor exercise, and low row back exercise), 2 sets were performed with 1 to 2 minute breaks in-between, and each set consisted of 12 repetitions. In addition to the exercise program, all participants received an individual intake assessment with a dietician and a psychologist. If indicated (ie, depending on care need), treatments were planned with the dietician or psychologist. Finally, participants were offered an optional relaxation module, which consisted of breathing exercise and body awareness relaxation techniques aimed at teaching participants to create more moments for rest and to cope better with stress.

At the end of the 3-month intervention and at the end of the year, participant progress was evaluated with the advanced nurse practitioner, and personal goals were adjusted (participants were coached on active lifestyle and personal goals). Participants were instructed to continue to pursue these goals in their home environment. We used behavior change techniques such as goal setting, action planning, motivational interviewing, information about healthy lifestyle and reviewing outcome goals.

Main Outcomes and Measures

The primary endpoints of the study were percentage of participants who completed the intervention and adherence to the treatment modules (percentage of visits attended out of those planned). Secondary endpoints included body weight, atrial fibrillation frequency and severity, exercise capacity, anxiety, and depression. The frequency and symptom severity of atrial fibrillation were assessed with the Atrial Fibrillation Severity Scale, which is a validated questionnaire [18] that combines measures of frequency and patient-perceived severity. Exercise capacity was measured using the 6-minute walking test. The 6-minute walking test was performed in a 25-meter-long corridor at a speed of the participants' preference with the instruction to cover the greatest possible distance during 6 minutes without running. The 1-repetition maximum, a measure of muscle strength, was defined as the maximum weight that could be pushed or lifted once. Anxiety and depression complaints were assessed using validated questionnaires (Patient Health Questionnaire–9 [19] and Generalized Anxiety Disorder–7 [20]). Weight and height were measured at all follow-up visits, and BMI was calculated. Secondary outcome measures were assessed at baseline, at 3 months (ie, immediately after the intervention), and at 12 months.

Statistical Analysis

Program completion and adherence to the treatment modules and changes in secondary endpoints (body weight and Atrial Fibrillation Severity Scale score) were analyzed by calculating descriptive statistics.

Results

A total of 10 participants participated in the feasibility study. The majority of participants were male (male: n=8; female: n=2; age: mean 57.2 years, SD 9.0; baseline weight: mean 107.2 kg, SD 11.8; baseline BMI: mean 32.4 kg/m^2, SD 3.5). Two participants did not complete their cardiac rehabilitation programs due to personal problems.

Of the 10 participants, 8 participants completed all 4 appointments with the advanced nurse practitioner to monitor their lifestyle (mean 3.8, SD 0.42 appointments attended per participant); 2 participants canceled their last appointment, resulting in an adherence of 95% (mean 3.8 sessions attended out of mean 4 planned). All participants were referred to the exercise training program sessions, for which adherence was 86% (mean 15.2 sessions attended out of mean 17.6 planned); 9 participants were referred to a dietician (1 patient had already received dietetic treatment in a referring hospital), for which adherence was 88% (mean 3.7 sessions attended out of mean 4.1 planned); and all participants were referred to a medical psychologist, for which adherence was 60% (mean 0.6 sessions attended out of mean 1.0 planned). Of the 10 participants, 9 participants were referred to, of whom 7 participants participated in, relaxation sessions for which adherence to the relaxation sessions was 86% (mean 2 sessions attended out of mean 2.4 planned).

After the initial 3-month cardiac rehabilitation period, weight decreased from mean 107.2 kg (SD 11.8) to mean 102.5 kg (SD 13.7), and there was weight loss at 12 months compared with baseline (Table 1). The frequency of atrial fibrillation symptoms was reduced immediately after the intervention (before: mean 35.6, SD 3.8; after: mean 31.2, SD 3.3), and this was sustained at 12 months (mean 24.8, SD 3.2). Severity of atrial fibrillation complaints immediately after the intervention (mean 20.0, SD 3.7) and at 12 months (mean 9.3, SD 3.6) were comparable with that at baseline (mean 16.6, SD 3.3). Depression and anxiety scores immediately after the intervention were comparable with those at baseline. The distance walked on the 6-minute walking test was higher after the intervention (before: mean 538.9, SD 70.6 meters; after: mean 595.3, SD 72.8 meters) and at 12 months (mean 600.8, SD 94.0). Quadriceps strength (1-repetition maximum) showed an increase immediately after rehabilitation (before: mean 179.5, SD 49.3 kg; after: mean 245.3, SD 63.7 kg) and at 12 months (mean 259.7, SD 52.7 kg). The 1-repetition maximums for biceps (before: mean 22.1, SD 8.9 kg; after: mean 25.6, SD 6.0 kg) and triceps (before: mean 27.1, SD 9.7 kg; after: mean 35.6, SD 6.8 kg) also showed increases in strength immediately after cardiac rehabilitation, and at 1 year,

remained higher (biceps: mean 29.8, SD 3.4, triceps: mean 39.6, SD 2.5) than those at baseline.

Table 1. Outcome measures at baseline, at 3 months (immediately after the cardiac rehabilitation intervention), and at 12 months (follow-up).

	Baseline, mean (SD)	Postintervention (at 3 months), mean (SD)	Follow-up (at 12 months), mean (SD)
Weight (kg)	107.2 (11.8)	102.5 (13.7)	105.1 (16.1)
Atrial Fibrillation Severity Scale			
Atrial fibrillation frequency	35.6 (3.8)	31.2 (3.3)	24.8 (3.2)
Atrial fibrillation severity	20.0 (3.7)	16.6 (3.3)	9.3 (3.6)
6-Minute walking test (m)	538.9 (70.6)	595.3 (72.8)	600.8 (94.0)
Patient Health Questionnaire–9	6.8 (4.3)	4.6 (4.3)	—[a]
Generalized Anxiety Disorder–7	4.4 (5.3)	2.7 (2.9)	—
1-Repetition maximum			
Quadriceps (kg)	179.5 (49.3)	245.3 (63.7)	259.7 (52.7)
Biceps (kg)	22.1 (8.9)	25.6 (6.0)	29.8 (3.4)
Triceps (kg)	27.1 (9.7)	35.6 (6.8)	39.6 (2.5)

[a]No data.

Discussion

General

This study shows that a multidisciplinary lifestyle program focused on sustainable behavior change in individuals who are overweight with atrial fibrillation is feasible with high completion rates (8/10 participants, 80%) and high adherence to the treatment modules (60% to 95%). Although exploratory analysis revealed sustained improvements in both the frequency and the severity of the atrial fibrillation symptoms and modest weight reduction, these results need to be confirmed in large-scale randomized controlled trials.

To the best of our knowledge, this is the first study to evaluate cardiac rehabilitation adherence specifically in obese patients with symptomatic atrial fibrillation. One study [21] showed that 81.3% of general patients referred for cardiac rehabilitation attended at least one-half of the sessions; however, nearly half of the patients did not follow any dietary recommendations or did not increase their physical activity levels, and in another, the dropout rate (24% [22]) was comparable to that in our study (20%). However, whereas participation in exercise training was high (90% [22]), participation in other modules (25% for dietary counseling, 9% for relaxation therapy, 9% for psychological therapy [22]) was substantially lower than those in our study. Data on adherence to the planned sessions were lacking [22].

The relatively high completion and adherence rates in our study may be explained by the design of the intervention. First, the intervention was designed to be a nurse-coordinated multidisciplinary intervention, rather than one that focused on exercise training or dietary counseling only, which is in line with the notion that holistic care models targeting are most effective for behavior change [23]. Second, counseling on expectations and individualized goal setting constituted an important part of the intervention. In fact, a previous study [24] showed that unrealistic expectations form an important barrier to lifestyle behavior change [24]. Also, it is well recognized that goal setting is an effective way of achieving behavior change [24,17]. Third, the high adherence rates may be explained by the fact that we used motivational interviewing, which is a communication skill set to help facilitate change and adherence to health behaviors. In fact, Pack et al [25] showed that continual, purposeful, and planned quality improvement efforts significantly increased patient participation in cardiac rehabilitation—motivational interviewing was an important strategy in achieving this.

Our exploratory analysis revealed that cardiac rehabilitation resulted in sustained reductions in the frequency and severity of atrial fibrillation symptoms. However, in contrast with other studies [6,26,27] that have shown that weight loss has beneficial effects on atrial fibrillation symptoms, the reduction in symptoms in our study was not associated with weight loss, suggesting that other physiological mechanisms, such as improvement of traditional cardiovascular risk factors and an increase in physical fitness, play a role. In line with this assumption, Pathak et al [6] observed a significant dose-response relationship between improvements in physical fitness and reduction in the risk of atrial fibrillation recurrence. Other studies [26,28] have shown positive effects of comprehensive management of concomitant cardiovascular risk factors on atrial fibrillation recurrence. Although these studies [26,28,29] underline that targeting modifiable risk factors, obesity and physical fitness should be an essential pillar of atrial fibrillation care, the optimal approach to achieve sustained long-term effects in obese patients with atrial fibrillation remains to be established.

Limitations

An important limitation of this study was the small number of study participants. We, therefore, described conclusions only about feasibility and not about the outcomes. Furthermore, a control group was not included because the primary goal of this study was to evaluate feasibility and adherence; therefore, the

reported effects of the intervention on weight and atrial fibrillation symptoms should be regarded as exploratory. The results of this feasibility study will applied to an ongoing study.

Conclusions

This study showed that a nurse-coordinated multidisciplinary lifestyle program for obese patients with atrial fibrillation is feasible, with a high level of completion and adherence. Effects on atrial fibrillation symptoms and weight reduction remain to be determined in a randomized controlled trial.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

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Original Paper

Effects of Using a Text Message Intervention on Psychological Constructs and the Association Between Changes to Psychological Constructs and Medication Adherence in People With Type 2 Diabetes: Results From a Randomized Controlled Feasibility Study

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Abstract

Background: Poor adherence to oral medications is common in people with type 2 diabetes and can lead to an increased chance of health complications. Text messages may provide an effective delivery method for an intervention; however, thus far, the majority of these interventions do not specify either a theoretical basis or propose specific mechanisms of action. This makes it hard to determine how and whether an intervention is having an effect. The text messages included in the current intervention have been developed to deliver specific behavior change techniques. These techniques are the “active ingredients” of the intervention and were selected to target psychological constructs identified as predictors of medication adherence.

Objective: There are 2 aims of this study: (1) to assess whether a text message intervention with specified behavior change techniques can change the constructs that predict medication adherence behaviors in people with type 2 diabetes and (2) to assess whether changes to psychological constructs are associated with changes in self-reported medication adherence.

Methods: We conducted a randomized controlled, 6-month feasibility trial. Adults prescribed oral medication for type 2 diabetes (N=209) were recruited from general practice and randomized to either receive a text message–based intervention or care as usual. Data were analyzed with repeated measures analysis of covariance and Spearman rho correlation coefficients.

Results: For 8 of the 14 constructs that were measured, a significant time-by-condition interaction was found: necessity beliefs, intention, maintenance self-efficacy, recovery self-efficacy, action control, prompts and cues, social support, and satisfaction with experienced consequences all increased in the intervention group compared to the control group. Changes in action self-efficacy, intention, automaticity, maintenance self-efficacy, and satisfaction with experienced consequences were positively associated with changes in self-reported medication adherence.

Conclusions: A relatively low-cost, scalable, text message–only intervention targeting medication adherence using behavior change techniques can influence psychological constructs that predict adherence. Not only do these constructs predict self-reported medication adherence, but changes in these constructs are correlated with changes in self-reported medication adherence. These findings support the promise of text message–based interventions for medication adherence in this population and suggest likely mechanisms of action.

Trial Registration: ISRCTN Registry ISRCTN13404264; https://www.isrctn.com/ISRCTN13404264

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KEYWORDS

medication adherence; type 2 diabetes mellitus; behavior change techniques; text messaging; feasibility studies; diabetes; medication; digital health

Introduction

Poor adherence to oral treatments is common in people with type 2 diabetes [1,2]. When such medication is taken suboptimally, blood glucose control can be poorer, leading to greater risk of developing complications [3], which can affect the heart, eyes, blood vessels, nerves, and other organs [4]. This has implications for people with diabetes and those supporting them, and is also associated with increased costs for health services [5].

An updated Cochrane review of 182 interventions to improve medication adherence concluded that "current methods of improving medication adherence for chronic health problems are mostly complex and not very effective," [6] and therefore, new approaches are needed to address this problem. Technology-based interventions may have the potential to improve medication adherence at scale at low unit cost. Thus far, no single approach has been identified as being the most effective or ineffective [7]. However, providing brief messages such as text messages is particularly promising, as text messages have the advantage of already being widely adopted and low-cost [8]. In a recent systematic review and meta-analysis of interventions based on multiple behavior targets, such as diet, exercise, and medication adherence, text messages were found to be effective in reducing levels of blood glucose for people with type 2 diabetes [9]. However, only 1 intervention included in this review exclusively targeted medication adherence, and this consisted only of medication reminder texts. This approach is unlikely to be sufficient unless the only barrier to adherence is forgetting, which excludes intentional nonadherence and the person with diabetes taking an active role in making adjustments to their medication regimen around their daily life, both of which have been observed in this population [10]. In a review specifically looking at medication adherence, it was concluded that although brief messages show promise, more high-quality evidence is needed [11]. Specifically, very few of the included studies stated an explicit theoretical basis, and of those that did, none discussed the results in relation to this theory.

Having an explicit theoretical basis provides clarity in terms of the proposed mechanism of action of an intervention; that is, what the intervention is intended to do and how. This helps with both the development and evaluation of digital health interventions. In development, having a logic model that describes how an intervention is intended to work can help designers choose what elements to include. By defining the constructs the intervention is targeting, components such as behavior change techniques (BCTs) that are hypothesized to affect these constructs can be chosen.

BCTs have been described as the "active ingredients" of an intervention and include techniques such as problem solving. There is currently a taxonomy of 93 BCTs with descriptions that can be used by intervention designers [12]. Using standardized BCTs as intervention components allows for easier comparison across interventions, greater transparency in what the intervention consists of, and the potential to use systematic reviewing and statistical analyses to identify effective BCTs across trials. For example, a meta-regression of randomized controlled trials that used either short messages and/or interactive voice recognition software to support medication adherence for cardio-metabolic conditions identified that the BCT, information about health consequences, was positively associated with effect size [13].

In terms of evaluation, an explicit logic model helps with understanding why a change in behavior either has or has not happened [14]. As an example, intention to take medication has been identified as a psychological construct that is important in changing medication adherence behavior [15]; therefore, an intervention designer might include BCTs thought to have an effect on intention, such as information about health consequences. Once the intervention has been delivered, evaluating the mechanism of action (ie, whether intention was changed as hypothesized) would help to explain the presence or absence of change in medication adherence behavior. This in turn would affect the further development of the intervention. Different adjustments would be made to the intervention if the proposed change in intention did not occur or if intention changed but this did not result in changes to medication adherence. Although links have been proposed between BCTs and psychological constructs, they are not often tested empirically [16]. Testing each link in the chain from BCT, to construct, to change in behavior would provide the strongest explanation of how an intervention functions and add to the understanding of medication adherence behavior. Furthermore, defining and evaluating components within an intervention and how they are proposed to work is considered key to facilitating the accumulation of evidence related to digital health interventions [17].

Prior to this study, a rapid systematic review was conducted that identified psychological constructs related to medication adherence from systematic reviews and meta-analyses as well as BCTs that target these constructs [15]. Although many of these psychological constructs have been found to predict medication adherence, there is not yet evidence that changing these constructs produces change in medication adherence. This evidence of causation is urgently needed. According to the evidence in this rapid systematic review, a conceptual model of the intervention was developed based on the Health Action Process Approach [18], with additions to reflect the evidence synthesized. This model conceptualizes medication adherence as a process, from forming an intention, acting on that intention, and then monitoring and adjusting these actions until adherence becomes habitual (see Figure 1). The approach taken follows the recommendations of the updated Medical Research Council

(MRC) framework for development and evaluation of complex interventions to develop such logic models to facilitate process analyses [19,20].

A library of text messages was developed to deliver specified BCTs that target multiple constructs relevant to this model (see Table 1). The included constructs relate to both intentional and nonintentional nonadherence.

Our previous research has confirmed that the messages in the library are good examples of the BCTs they were written to represent and are acceptable to the target population [21]. We are therefore confident that the messages can deliver the intended BCTs; however, at present we do not know if these BCTs will have the proposed effects on psychological constructs or if changes to these psychological constructs will be related to changes in medication adherence. Hence, there was a need for this formative study to indicate if changes are required to the intervention before causal links are further explored in an efficacy trial powered to conduct this analysis. To thereby test the mechanism of action of the intervention, relevant psychological constructs were measured as part of a randomized controlled feasibility trial [22] in order to answer the following 2 research questions: (1) Does a BCT-based brief message intervention produce changes in psychological constructs relative to control group?; (2) Are changes in psychological constructs correlated with changes in medication adherence?

Figure 1. Proposed theoretical model based on the Health Action Process Approach [17]. Underlined constructs indicate those that were significantly increased in the intervention group vs. the control group.

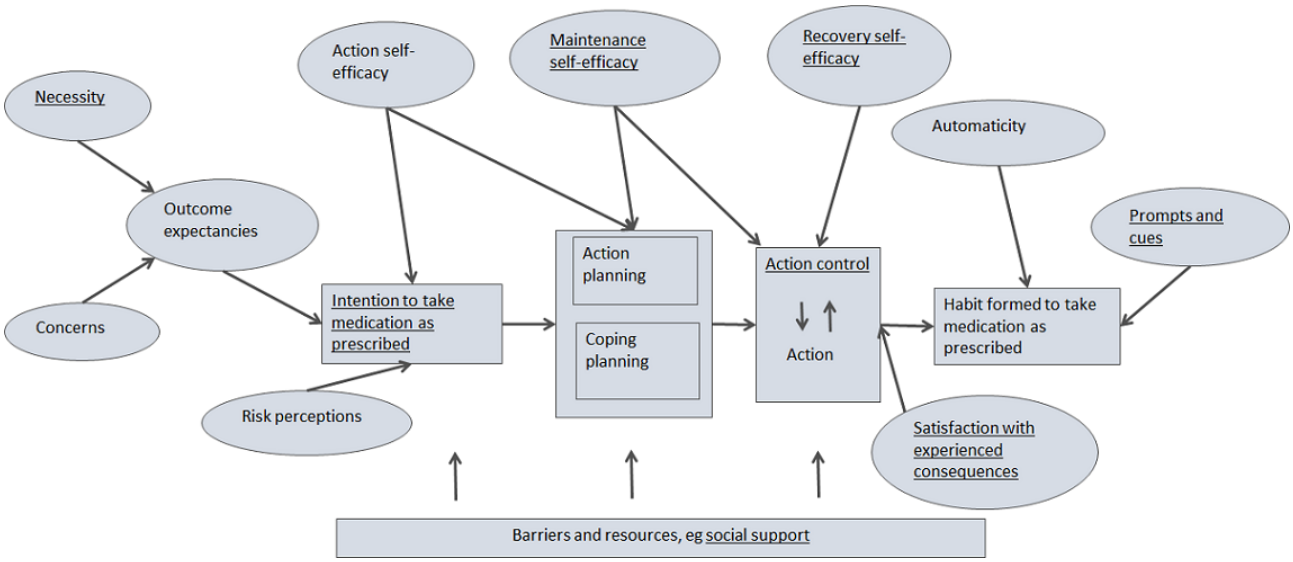


Table 1. Example messages with associated BCTs (replicated from Bartlett et al [21]).

Target and category of message	BCT[a]/belief or concern	Example messages
Medication adherence, BCT	1.4[b] Action planning	"Plan when, where and how you are going to take your medication."
Medication adherence, BCT	15.1[b] Verbal persuasion about capability	"If you are struggling with your diabetes tablets then don't worry, you will be able to master it in time. You will get on top of it."
Medication adherence, BCT	7.1[b] Prompts/cues	"It can be difficult to remember to take your tablets. Why not set an alarm to remind you to take them?"
Medication adherence, beliefs, and concerns	Health care system–related concerns	"Lots of questions? Check who the best person to see might be."
Diet management	Signposting	"Stuck for new ideas? You can search recipes for mains, desserts and snacks online at Diabetes.org.uk."

[a]BCT: behavior change technique.

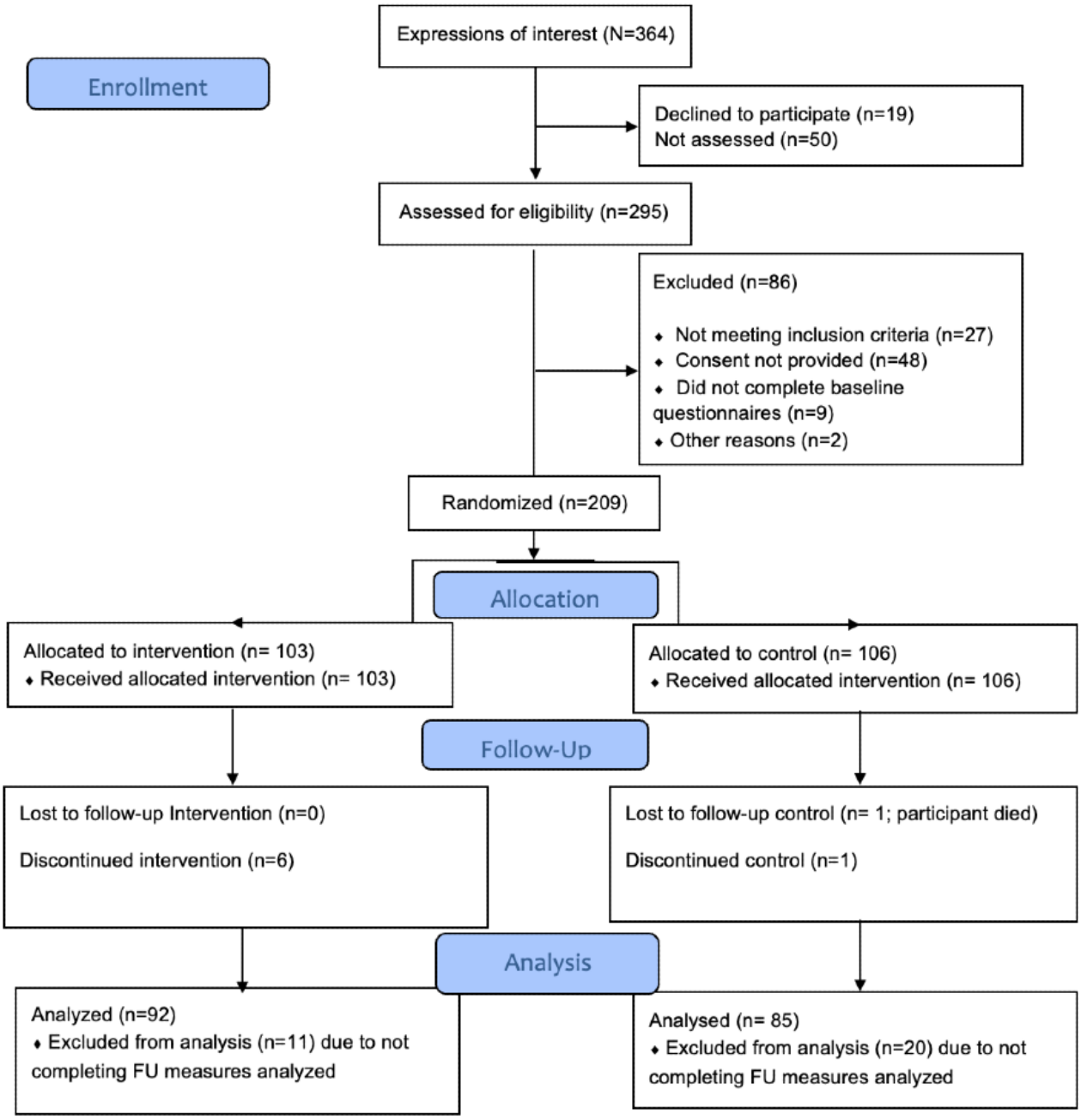
[b]Numerical identifiers from the taxonomy [12].

Methods

Recruitment

Participants were recruited from 16 general practices in England between January 2019 and June 2019. Potentially eligible patients were contacted about the study by the practice and invited to send a text message to express interest. On receipt of the text message, further information about the study was given either online or by post, and eligibility was assessed by the researchers by phone. Eligible patients were those who were ≥35 years of age, able to use a mobile phone to send and receive text messages, and taking oral medication for type 2 diabetes (including lipid and blood pressure–lowering medications for diabetes). Patients taking oral medication either with or without concomitant insulin were eligible. Patients who had been admitted to hospital in the previous 3 months with hypo- or hyperglycemia, were pregnant, were within 3 months postpartum, were planning a pregnancy within the trial, or had a serious medical condition that, in the opinion of the investigator, made them unable to take part were ineligible. Informed consent was given either online or by post. See Figure 2 for the CONSORT (Consolidated Standards of Reporting Trials) flowchart.

Figure 2. Support Through Mobile Messaging and Digital Health Technology for Diabetes (SuMMiT-D) feasibility CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Design

Data were collected for a 6-month, parallel-group, randomized controlled feasibility trial as part of the Support Through Mobile Messaging and Digital Health Technology for Diabetes (SuMMiT-D) program of work. Participants were randomized in a 1:1 ratio to the intervention or control arm. Randomization was completed through a validated secure web-based program (Sortition) using a nondeterministic minimization algorithm to ensure groups were balanced for age, study site, gender, duration of diabetes, and number of medications. The allocated intervention was then delivered directly through an online platform. Aside from those conducting qualitative interviews and the engineering team, all other research team members and health care staff were blinded. For further details of the design and development, see the protocol paper [22].

Ethical Approval

Ethical approval for the study was granted by National Health Service (NHS) West of Scotland Research Ethics Committee 05 (reference number 18/WS/0173). The trial is registered in the ISRCTN registry (ISRCTN13404264).

Intervention

Participants in the intervention group were sent up to 4 text messages per week for 6 months. There were 2 categories of messages: (1) those targeting medication adherence based on BCTs identified as relevant for this population [15] that have previously been confirmed as representing the intended BCT and being acceptable to the target population [21] and (2) those targeting diet and physical activity, introduced as a response to feedback during the development process, indicating that a broader view of diabetes self-management may benefit engagement. Messages in category 2 provided information from and links to credible sources such as the Diabetes UK or NHS Choices website. All messages were sent at a preferred time (AM or PM), and participants were able to text back “like” or “dislike” after any message received. For messages targeting medication adherence, texting “like” doubled the chance a future message would come from the same BCT as the message that had been liked, while texting “dislike” halved the chance of a future message coming from the same BCT as the disliked message. Texting “like” or “dislike” following messages targeting diet or physical activity did not result in any change.

Control

Participants in the control group received 1 message per month for 6 months thanking them for their participation in the study; this was in addition to their usual care.

Assessments

Assessments were completed online or on paper. At baseline, participants completed a demographic questionnaire and provided their postcode, and at baseline and 6 months, participants completed the 5-item Medication Adherence Report Scale (MARS) [23,24] and a health psychology questionnaire. The 5 items on the MARS are nonadherent behaviors, and thus participants respond by indicating how true each statement is for them on a 5-point scale from “always true” to “never true.” One item referred to nonintentional nonadherence, “I forget to take my diabetes medicines,” while the other 4 items measured intentional nonadherence.

The hypothesized mechanisms of action questionnaire was developed for this study and measured key constructs targeted by the messages (see Table 2). Two items were used to measure each of the following fourteen constructs: action self-efficacy, necessity, concerns, intention, automaticity, maintenance self-efficacy, recovery self-efficacy, action planning, coping planning, action control, prompts and cues, social support, satisfaction with the experienced consequences of behavior, and risk perception. The 28 items were sourced or adapted from previously developed questionnaires where possible and were phrased to specifically relate to taking diabetes tablets as prescribed (see Table 2). All questions were answered using a 5-point Likert scale with the anchors strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree. For further details on additional measures taken but not reported here, see Farmer et al [22].

Table 2. Properties of the psychological construct scales.

Construct	Example item	Interitem correlation at baseline			Paper adapted from
		Correlation coefficient (R_s)	*n*	*P* value	
Action self-efficacy	"I am confident that I can take my diabetes tablets as prescribed"	0.82	203	<.001	Schwarzer et al [25]
Necessity	"My health in the future will depend on my diabetes tablets"	0.53	203	<.001	Horne et al [26]
Concerns	"I sometimes worry about the long-term effects of my diabetes tablets"	0.19	203	.007	Horne et al [26]
Intention	"I will take my diabetes tablets as prescribed every day over the next 3 months"	0.81	204	<.001	Presseau et al [27]
Automaticity	"Taking my diabetes tablets as prescribed is something I do without thinking"	0.50	199	<.001	Gardner et al [28]
Maintenance self-efficacy	"I am confident that I am able to take my diabetes tablets as prescribed even when something disrupts my routine"	0.54	200	<.001	Greer et al [29]
Recovery self-efficacy	"If I don't take my diabetes tablets for any reason, I am confident that I am able to start taking them again even if I feel no different to when I was not taking them"	0.63	201	<.001	Greer et al [29]
Action planning	"I have made a detailed plan about exactly where to take my diabetes tablets"	0.72	200	<.001	Greer et al [29]
Coping planning	"I have made a detailed plan for how to deal with unpleasant side effects of taking my diabetes tablets as prescribed"	0.46	200	<.001	Greer et al [29]
Action control	"During the last 4 weeks I consistently monitored when, where, and how I took my diabetes tablets"	0.23	201	.001	Sniehotta et al [30]
Prompts and cues	"I use things around me to help me to take my diabetes tablets as prescribed (e.g. notes, phone reminders)"	0.63	202	<.001	N/A[a]
Social support	"I have felt supported in taking my diabetes tablets as prescribed"	0.29	202	<.001	Presseau et al [27]
Satisfaction with experienced consequences	"I am content with what I have experienced as a result of taking my diabetes tablets"	0.75	203	<.001	Baldwin et al [31]
Risk perception	"I feel very at risk of developing complications, or experiencing worsening of existing complications from my diabetes if I do not take my tablets"	0.64	201	<.001	N/A

[a]N/A: not applicable.

Analysis

The index of multiple deprivation (IMD) is a measure of relative deprivation used by the English government. Areas (32,844 across England) are ranked according to a variety of domains, including income, employment, health, and crime, and then the ranked list is divided into deciles [32]. Participants' postcodes were used to identify their IMD decile (1 missing, postcode invalid). Descriptive statistics were used to describe age, gender, and IMD, while a *t* test or chi-squared test was used to assess differences in these variables between those who did and did not complete follow-up assessments. Responses were coded in the following fashion according to the MARS: never true=5, rarely true=4, sometimes true=3, often true =2, and always true=1. Thus, higher scores would be associated with better self-reported adherence. The hypothesized mechanisms of action questionnaire was scored as follows: strongly agree=5, agree=4, neither agree nor disagree=3, disagree=2, and strongly disagree=1. Thus, higher scores would be associated with higher levels of the construct (eg, greater action control, higher self-efficacy, or higher concerns). Construct scores were calculated by summing the scores for both items. Interitem correlations were calculated (see Table 2).

Research Question 1: Does a BCT-Based Brief Message Intervention Produce Changes in Psychological Constructs Relative to a Control Group?

Repeated-measures analysis of covariance (ANCOVA) was conducted for each construct, with time as a within-subject factor at 2 levels (baseline and 6-month follow-up); group (intervention or control) as a between-subject factor; and age, gender, and IMD included as covariates. As a sensitivity analysis, univariate ANCOVA for each construct were conducted, with construct at follow-up as the dependent variable; gender and experimental group as fixed factors; and construct at baseline, age, and IMD as covariates.

Research Question 2: Are Changes in Psychological Constructs Correlated With Changes in Medication Adherence?

Standardized residual change scores were calculated using linear regression for each construct (baseline to follow-up) and MARS (baseline to follow-up). Spearman rho correlation coefficients were then calculated to assess the relationship between change in standardized residuals for each construct and change in self-reported adherence.

Results

Participants

Participants (N=209) had a mean age of 63.4 years (SD 10.16), were 41.1% (86/209) female, and were recruited from all 10 of the IMD deciles with a mean of 6.38 (SD 2.73). Thirty-one participants were excluded from this analysis, as they did not complete the follow-up assessments analyzed here, and one participant died prior to follow-up. There were no significant differences between groups in age, gender, or IMD at baseline or between those who completed and did not complete the questionnaire measures at follow-up (see Table 3).

Table 3. Demographics.

Variable	Overall, mean (SD) (N=209)	Intervention, mean (SD) (N=103)	Control, mean (SD), (N=106)	Between-group differences at baseline[a]	Differences between completers (n=177) and noncompleters (n=31)—hypothesized mechanisms of action questionnaire assessing constructs[a]	Differences between completers (n=168) and noncompleters (n=40) in MARS[ab]
Age, (years)	63.44 (10.16)	63.47 (10.64)	63.42 (9.72)	.98	.96	.91
Female	86 (41.1)[c]	42 (40.8)[c]	44 (41.5)[c]	.51	.36	.22
IMD[d] deciles[e]	6.38 (2.73)	6.10 (2.71)	6.65 (2.73)	.15	.55	.98

[a]Values in this column are *P* values.

[b]MARS: 5-item Medication Adherence Report Scale.

[c]Values in this cell are number and percentage.

[d]IMD: index of multiple deprivation.

[e]n=208: 1 postcode was incorrect and could not by mapped onto the IMD.

Research Question 1: Does a BCT-Based Brief Message Intervention Produce Changes in Psychological Constructs Relative to a Control Group?

A significant interaction between time and experimental group was seen in necessity (*P*=.009), intention (*P*<.001), maintenance self-efficacy (*P*=.03), recovery self-efficacy (*P*=.02), action control (*P*=.001), prompts and cues (*P*=.002), social support (*P*<.001), and satisfaction with experienced consequences (*P*=.002; see Table 4). All effects were such that the constructs increased between baseline and follow-up in the intervention group compared to the control group. Of the covariates (age, gender, IMD), only age had a significant effect on any constructs. Age had a significant effect on the model for necessity, action planning, social support, and satisfaction with experienced consequences. Sensitivity analysis treating baseline variables as covariates rather than as within-subject factors showed aligned significant or nonsignificant effects for 12 of the 14 constructs measured. Previously significant effects on recovery self-efficacy (*P*=.12) and maintenance self-efficacy (*P*=.30) were not replicated.

Table 4. Repeated-measures analysis of covariance effect of the text message intervention on psychological constructs.

Item	Control, mean (SD)		Intervention, mean (SD)		Main effect time, *F* test (*df*), *P* value[a]	Interaction time×group, *F* test (*df*), *P* value[a]	Significant covariates, Covariate: *F* (*df*), *P* value[a]
	BL[b]	FU[c]	BL	FU			
Action self-efficacy	8.87 (1.37)	8.65 (2.05)	8.55 (1.82)	8.80 (1.49)	.88	.10	N/A[d]
Necessity	7.67 (1.71)	7.73 (1.83)	7.44 (1.63)	8.15 (1.53)	.72	$F_{1,165}$=7.03, .009	Age: $F_{1,165}$=7.12, .008
Concerns	5.73 (1.67)	5.73 (1.84)	5.85 (1.65)	5.56 (1.64)	$F_{1,163}$=4.17, .043	.18	Age: $F_{1,163}$=7.58, .007
Intention	9.10 (1.06)	8.77 (1.62)	8.61 (1.51)	9.14 (1.24)	.11	$F_{1,164}$=14.31, <.001	N/A
Automaticity	7.51 (1.71)	7.51 (1.95)	7.12 (1.85)	7.59 (1.77)	.65	.06	N/A
Maintenance self-efficacy	8.48 (1.34)	8.29 (1.44)	7.91 (1.59)	8.19 (1.44)	.58	$F_{1,159}$=4.68, .032	N/A
Recovery self-efficacy[e]	8.55 (1.27)	8.56 (1.56)	8.10 (1.56)	8.67 (1.33)	.65	$F_{1,161}$=5.50, .02	N/A
Action planning	6.94 (2.21)	7.24 (2.10)	6.88 (2.01)	7.49 (1.96)	.72	.32	Age: $F_{1,161}$=4.51, .04
Coping planning	5.88 (1.83)	6.32 (1.66)	6.05 (1.63)	6.70 (1.77)	.11	.42	N/A
Action control	7.10 (1.79)	7.05 (1.81)	6.99 (1.74)	7.88 (1.59)	.12	$F_{1,160}$=10.80, .001	N/A
Prompts and cues	5.38 (2.07)	5.59 (2.09)	4.91 (1.75)	6.26 (1.99)	.22	$F_{1,160}$=10.31, .002	N/A
Social support	4.71 (1.55)	4.74 (1.71)	4.95 (1.75)	6.11 (1.65)	.24	$F_{1, 160}$=16.40, <.001	Age: $F_{1,160}$=4.80, .03
Satisfaction with experienced consequences	7.78 (1.91)	7.60 (1.68)	7.47 (1.81)	8.16 (1.62)	.45	$F_{1, 162}$=9.77, .002	Age: $F_{1,160}$=4.73, .03
Risk perception	8.08 (1.53)	8.78 (1.76)	8.07 (1.44)	8.22 (1.61)	.70	.53	N/A

[a]Test statistic and degrees of freedom are only reported for *P* values <.05 in this column.

[b]BL: baseline.

[c]FU: follow-up.

[d]N/A: not applicable (no significant covariates were found).

[e]Potentially there is less confidence in this result as recovery self-efficacy was significantly different between groups at baseline such that intervention (mean 8.07, SD 1.54) was higher than the control (mean 7.98, SD 1.52; t_{199}=2.59; *P*=.01).

Research Question 2: Are Changes in Psychological Constructs Correlated With Changes in Medication Adherence?

Standardized residual change scores in 5 of the 14 psychological constructs were significantly positively correlated with those in self-reported medication adherence, such that increases in the construct represented improvements in medication adherence action self-efficacy (r_s=0.28; n=149; *P*=.001), intention (r_s=0.20; n=149; *P*=.02), automaticity (r_s=.33; n=143; *P*<.001), maintenance self-efficacy (r_s=0.30; n=147; *P*<.001), and satisfaction with experienced consequences (r_s=0.16; n=148; *P*=.05).

Discussion

Principal Results

In this analysis we have shown that first, provision of a text message–based intervention using behavior change techniques results in improvements to multiple psychological constructs compared to usual care. Second, we have identified that changes in psychological constructs are correlated with changes in self-reported medication adherence. These findings support the hypothesized mechanisms of action that are amenable to change through a low-cost, scalable intervention, and that when changed, may have an effect on medication adherence in people with type 2 diabetes. These findings, although tentative, provide a strong base on which to progress to a full efficacy trial.

Strengths and Weaknesses

The intervention messages use a wide variety of BCTs that are thought to target different points in the process of adherence. The incorporation of a wide variety of techniques, including some BCTs that have not been applied in this context previously, constitutes one of the strengths of this intervention, as this represents a new way to approach medication adherence. However, a corresponding weakness is that this could make looking at each individual link between BCTs and constructs more difficult, as several BCTs might have affected the same construct.

These findings have shown that this intervention can have an effect on multiple constructs that may influence people at different points in the process of improving medication adherence from forming an intention, acting on that intention, to monitoring and adjusting these actions until adherence becomes habitual (see Figure 1). In addition, the intervention targets sources of both intentional and nonintentional nonadherence. The potential to affect change in people wherever they are in the process of improving medication adherence is a definite strength, from which a wide range of people with type 2 diabetes can benefit. In this feasibility study, we were not powered to conduct a formal mediation analysis, however this is planned for the definitive trial which is now underway (ISRCTN 15952379).

Medication adherence has been self-reported here using the MARS. In the future, we plan to take additional measures of adherence (eg, from medical records) so that the relationships between these constructs, self-reported adherence, and adherence measured through more direct means can be explored. Future work could also explore the use of objective measures of medication adherence, such as urine samples [33]. Overall, this study provides a more detailed picture of the potential mechanism of action for this intervention, which can be used to support development of further interventions for this target behavior.

The eventual aim is that the brief text message intervention can be delivered at scale, through general practice. In terms of future scalability, basing the intervention solely on text messages is highly cost-effective. Recent research has indicated combining text messages with interactive voice recognition can be an effective intervention for medication adherence in this population [34]; there is further evidence that incorporating tailoring can make interventions more effective [13]. Any additional components and technology required above and beyond text messages, and any additional complexity may limit the eventual scalability of the intervention. Understanding the unique effects of nontailored text messages alone in the first instance is useful, as this is the lowest-cost approach. Additional elements could then be added to the intervention where they would provide the most benefit and when the evidence is clearer on which conditions tailoring can be optimally applied to.

The measures of psychological constructs used in this study were by necessity brief to minimize participant burden. There is increasing recognition that high questionnaire burden in trials has undesirable consequences, such as reducing recruitment, increasing dropout in low socioeconomic status or minority ethnic groups, and producing unintended reactions to this measurement [35]. It was therefore necessary to use a questionnaire developed for this study. Items from pre-existing scales were used when possible, and the correlations for the majority of items were considered moderately or strongly correlated [36]. However, there were 3 constructs with weak correlations between items (concerns, action control, and social support), and we aim to improve these items for our future research. An alternative approach could be to use this preliminary work to identify specific constructs of interest and measure a smaller number of constructs with validated scales.

Future Development

Future research could use these findings for the following purposes: to investigate those constructs that did not change in this instance, and whether there are more effective BCTs to target these constructs than those used here; to explore those constructs where changes did not correlate with changes in medication adherence; and to improve the measurement of constructs where correlations between the 2 items were weak. This work would help to gather additional information that could be used to optimize interventions for this population.

The findings reported indicate that certain constructs are both amenable to change by text message and, when changed, are associated with changes in self-reported medication adherence (eg, intention, maintenance self-efficacy, and satisfaction with experienced consequences). These constructs could indicate the importance of continued feedback and adjustment within medication adherence interventions; following initial changes to intention, it may be necessary to support people to maintain and highlight the positive effects of changes made to support satisfaction with continued adherence. BCTs that target these constructs may be useful for focusing on future research into medication adherence.

This feasibility trial was not powered to look at direct effects of the intervention on the outcome. The findings do provide a clear indication of the potential value of an intervention such as this, but in the planned trial of this intervention participant numbers will be sufficiently high to ascertain efficacy of the intervention and allow for mediation analysis to further explore the potential mechanisms of action suggested here. By identifying likely mechanisms of action of the intervention beforehand, efficacy results will be more easily interpreted. In addition, with a larger sample, it may be possible to conduct subanalysis to explore whether changes in constructs are associated with particular participant characteristics, and this could provide evidence to inform future tailoring strategies. Incorporating tailoring increases the complexity of an intervention and potentially reduces the scalability. However, if future tailored interventions were compared with this nontailored intervention, an evidence base could be built on how to tailor in the most effective way, which would only introduce additional complexity where there is likely to be maximum benefit.

Conclusions

A text message intervention based on behavior change techniques can affect psychological constructs that are correlated with medication adherence. The use of a logic model enabled clear proposed mechanisms of action to be defined and tested. Future research can explore these potential mechanisms further to improve the understanding of adherence behavior and intervention design.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1370 KB - formative_v6i4e30058_app1.pdf]

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Abbreviations

ANCOVA: analysis of covariance
BCT: behavior change technique
CONSORT: Consolidated Standards of Reporting Trials
IMD: index of multiple deprivation
MARS: Medication Adherence Report Scale
MRC: Medical Research Council
NHIR: National Institute for Health Research
NHS: National Health Service
SuMMiT-D: Support Through Mobile Messaging and Digital Health Technology for Diabetes

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Original Paper

A 3-Item Measure of Digital Health Care Literacy: Development and Validation Study

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Abstract

Background: With increased reliance on digital health care, including telehealth, efficient and effective ways are needed to assess patients' comfort and confidence with using these services.

Objective: The goal of this study was to develop and validate a brief scale that assesses digital health care literacy.

Methods: We first developed an item pool using existing literature and expert review. We then administered the items to participants as part of a larger study. Participants were caregivers of children receiving care at a pediatric clinic who completed a survey either on the web or over the telephone. We randomized participants into development and confirmatory samples, stratifying by language so that exploratory factor analysis and confirmatory factor analysis could be performed with separate samples of participants. We assessed the scale's validity by examining its associations with participants' demographics, digital access, and prior digital health care use.

Results: Participants (N=508) were, on average, aged 34.7 (SD 7.7) years, and 89.4% (454/508) were women. Of the 508 participants, 280 (55.1%) preferred English as their primary language, 157 (30.9%) preferred Spanish, and 71 (14%) preferred Arabic; 228 (45%) had a high school degree or less; and 230 (45.3%) had an annual household income of <US $35,000. Using exploratory factor analysis, 3 items were retained in a reduced scale with excellent reliability (Cronbach α=.90) and a high variance explained (78%). The reduced scale had excellent fit, with factor loadings between 0.82 and 0.94. All fit statistics exceeded the criteria for good fit between the proposed factor structure and the data. We refer to this scale as the Digital Health Care Literacy Scale. The scale was positively associated with education (ρ=0.139; *P*=.005) and income (ρ=0.379; *P*<.001). Arabic speakers had lower scores than English (*P*<.001) and Spanish speakers (*P*=.02), and Spanish speakers had lower scores than English speakers (*P*<.001). Participants who did not own a smartphone (*P*=.13) or laptop computer (*P*<.001) had lower scores than those who owned these devices. Finally, participants who had not used digital tools, including health apps (*P*<.001) and video telehealth (*P*<.001), had lower scores than those who had used these tools.

Conclusions: Despite the potential for digital health care to improve quality of life and clinical outcomes, many individuals may not have the skills to engage with and benefit from it. Moreover, these individuals may be those who already experience worse outcomes. A screening tool such as the Digital Health Care Literacy Scale could be a useful resource to identify patients who require additional assistance to use digital health services and help ensure health equity.

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KEYWORDS

digital literacy; digital health care; telehealth; health equity; scale development; mobile phone

Introduction

Background

Digital technologies for managing health have proliferated in recent years, in large part as a response to the COVID-19 pandemic [1-3]. These technologies include telehealth, patient portals, and mobile health, such as app-based programs. Telehealth or the delivery of health care services at a distance using information and communication technology has been particularly helpful for allowing individuals to still receive treatment when in-person interaction is not possible. Given its convenience and now integration with many clinic workflows, it is likely that telehealth will continue to be offered as a delivery modality [4]. From a clinical trial standpoint, evidence supports the efficacy of telehealth to improve clinical outcomes across a variety of conditions [5]. Moreover, it may be more cost-effective than other approaches and patients who use it are generally satisfied with the experience [6,7]. However, to promote the continued utility of telehealth, consideration must be given to the types of individuals who have both access to, and confidence in using, it.

Despite increased access to technology over the past decade, disparities in access persist among those with lower income, with less education, or who are racial or ethnic minorities [8,9]. With respect to telehealth access, specifically, numerous studies have demonstrated stark racial and socioeconomic disparities during the COVID-19 pandemic [10-13]. This concept, known as the digital divide or the gap between people who do and do not have access to technology, affects health equity. Namely, there is concern that with the advancement in digital technologies, we may leave behind those individuals who tend to have worse health outcomes and need help the most, thereby widening the gap [14,15]. Recent efforts to expand broadband and telehealth access have begun at the federal and state levels and will require long-term, widespread investment [16,17]. An additional component of addressing the digital divide includes determining whether individuals who have access to the internet and digital devices also have the skills to use technology for accessing health care.

A certain level of digital literacy is necessary to effectively engage with, and benefit from, digital health tools. For example, individuals must feel somewhat confident in their skills using technology to install and engage with a health app or start up a telehealth visit with their provider. The telehealth modality of today's world requires that patients initiate the visit compared with prior telehealth approaches where clinics provided all required digital health care connection. Digital literacy is considered unique and separate from technology access. In a recent study of patients admitted to the hospital, most of the participants with low health literacy had access to digital devices and had used the internet previously but were unable to perform web-based tasks without assistance [18]. Digital literacy may in fact present as a larger barrier to using digital tools than access, which underscores the need to appropriately measure and understand it.

There have been attempts in the past to measure digital literacy, although many are based on using computers generally or using the internet to find health information [19-22]. For example, the Computer Literacy Scale focuses only on computers and recognizing computer symbols and terms [22]. Likewise, the eHealth Literacy Assessment Toolkit is a compilation of scales for assessing both health literacy and digital literacy; however, the digital literacy scales primarily focus on familiarity with computer terms and confidence using computers [21]. The eHealth Literacy Scale is a popular scale for assessing electronic health literacy, but all items are anchored on using the internet to find health information [20,23]. Another scale for assessing digital literacy, the Digital Health Literacy Instrument, assesses competencies for both gathering health information and using the internet; however, the skills it assesses are very specific (ie, protecting privacy and adding self-generated content, such as writing health-related messages to a physician) [19]. It was also developed among a highly educated sample, limiting its generalizability, and the full scale consists of 21 items, limiting its efficiency [19]. To our knowledge, there are no scales that assess one's comfort and confidence with the foundational digital skills necessary to use digital health care services such as telehealth. We refer to this as digital health care literacy. Such a scale has critical implications for clinical care and understanding the types of patients who are strong candidates for telehealth versus those who may need additional assistance.

Objectives

To address these gaps, we sought to develop a brief measure that assesses digital health care literacy called the Digital Health Care Literacy Scale (DHLS). The item pool was developed using existing literature and expert review, and the survey was then administered to participants as part of a larger study on telehealth equity. Participants in the larger study were randomly split into development and confirmatory samples to identify a reduced version of the survey. We assessed the scale's validity in a variety of ways, including examining its associations with digital access; prior digital health care use; and demographics, including education, income, language, race, and ethnicity.

Methods

Data Collection and Sample

This research was conducted as part of a larger study that sought to examine telehealth use among caregivers of young children from diverse populations. Participants were recruited from the Vanderbilt Pediatric Primary Care Clinic at Vanderbilt University Medical Center (VUMC) in Nashville, Tennessee. This clinic predominantly cares for underserved populations with higher medical and social needs. Eligible participants were aged ≥18 years; spoke a primary language of English, Spanish, or Arabic; and were a parent or guardian of a child aged <13 years who received care at the clinic between March 1, 2020,

and September 30, 2020. We used the electronic medical record to query for caregivers of children who met the inclusion criteria and received permission from their providers to recruit them through telephone calls.

Interested and eligible caregivers completed informed consent and a baseline survey. All data were collected using REDCap (Research Electronic Data Capture; Vanderbilt University), a secure web-based application designed exclusively to support data capture for research studies. Surveys were administered either on the web or over the telephone and in the participant's primary language (English, Spanish, or Arabic). Because of technical specifications in REDCap at the time of this study (ie, content was formatted to only read from left to right), all Arabic speakers (except for a single participant) completed the survey over the telephone. All key study personnel (KSP) were trained and certified before data collection and survey administration. KSP who collected survey data in a non-English language were either native speakers or fluent in the language concerned.

KSP started making telephone calls to caregivers on December 14, 2020. Rolling recruitment occurred for approximately 6 months until 500 eligible families of pediatric patients completed the survey. The final participant completed the survey on June 6, 2021. Participants were compensated with a US $15 Walmart gift card for completing the survey.

Ethics Approval

The Vanderbilt University institutional review board approved all study procedures (approval number: 201990).

Item Pool Development

Relevant literature and gaps in the literature were reviewed by 2 research team members (ECS and FP) to develop an initial potential item pool, covering a range of digital literacy domains and related digital skills and abilities. Input from experts from within and outside VUMC was then used to narrow down and finalize the set of items that was ultimately administered. Experts could also suggest modifications to existing items or propose new items to represent any aspects of digital literacy that may have been missing. Experts within VUMC included clinicians from the Vanderbilt Pediatric Primary Care Clinic and directors from Patient Care Operations, Interpreter Services, the Telemedicine Department, and the Department of Biomedical Informatics. We also elicited input from the manager of Nashville Public Library's Digital Inclusion Initiatives Program. The initial item pool consisted of 81 items; after synthesizing feedback, the refined item pool for administration consisted of 6 items that were focused on confidence in the ability to use technological programs or services and the ability to independently troubleshoot technical issues (Table 1).

Table 1. Finalized item pool for administration and factor analysis.

Item number	Refined item pool
1	I can install applications/programs (like Zoom) on my cell phone, computer, or another electronic device on my own (without asking for help from someone else).[a]
2	I can use applications/programs (like Zoom) on my cell phone, computer, or another electronic device on my own (without asking for help from someone else).[a]
3	I can set up a video chat using my cell phone, computer, or another electronic device on my own (without asking for help from someone else).[a]
4	I can solve or figure out how to solve basic technical issues on my own (without asking for help from someone else).[a]
5	If you encounter a technical issue while using your cell phone, computer, or another electronic device, what do you do first?[b]
6	How often do you need someone (like your child/children) to help you with using your digital devices?[c]

[a]Response options range from 0 (strongly disagree) to 4 (strongly agree).

[b]Response options include 0 (ask someone for help) and 1 (try and solve the technical issue on my own—without help from someone else).

[c]Response options include 0 (always), 1 (almost always), 2 (about half the time), 3 (not very often), and 4 (never).

Translation Process

The items were translated into Spanish by a native Spanish speaker from the VUMC Division of Academic General Pediatrics. The items were translated into Arabic by a formally trained medical translator and native Arabic speaker from the VUMC Interpreter Services Department. Both translators are fluent in, and understand, both English and their native language (Spanish or Arabic). Other than their role as translators, the Spanish and Arabic translators had no other involvement in the study. Both the Spanish and Arabic translations were checked by KSP from the research team to ensure that the translations were accurate. KSP who were involved in this process were either native speakers of, or fluent in, the language concerned. The original documents (in English), translated documents (in Spanish and Arabic), and translator declaration forms (for the Spanish and Arabic translators) were submitted to, and approved by, the Vanderbilt University institutional review board before participant recruitment and data collection.

Measures

The survey included (1) the 6 digital health care literacy items (Table 1), (2) demographic questions, (3) questions about digital access, and (4) questions about digital health care use.

To score the digital health care literacy items (Table 1), we used a sum score of all the items such that higher scores indicated higher digital health care literacy. For item 5, we recoded the response values—0=1 and 1=3—to better align with the

response values of the other items within the scale. The possible sum score for the 6 items ranged from 0 to 23.

Demographic data included age, gender, race, ethnicity, language, education, and income. Regarding digital access, participants were asked whether they owned a smartphone, a laptop computer, and/or a desktop computer. Participants were also asked about the stability of their network connection to use Internet at home and a cell phone data plan. Response options ranged from 1 (no internet or cell phone data plan) to 4 (very good). Finally, several questions assessed participants' prior experience using digital health care. Specifically, among participants who said that they owned a smartphone, we asked whether they had ever accessed a health app. We also asked participants whether they were currently signed up for the patient portal at VUMC. The portal is a secure, web-based tool that provides patients with 24-hour access to personal health information, visit summaries, test results, and secure messaging. Finally, we asked participants whether they had used video telehealth to get care for their child in the past year. Those who had used telehealth in the past year were asked how easy it was to schedule the visit, and those who had not used telehealth in the past year were asked how difficult they thought it would be to schedule a visit. For both these items, response options ranged from 1 (very difficult) to 5 (very easy).

Analyses

Data cleaning included evaluation of missing data, checking implausible values, and evaluating variable distributions. To evaluate the proposed scale, the participants were first divided into development and confirmatory samples so that exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) could be conducted with separate samples of participants. To ensure a balanced number of surveys in each language, participants were randomized into the development and confirmatory samples stratified by language. Demographic characteristics were reported for the overall sample as well as divided by sample. Chi-square tests of independence and independent samples 2-tailed *t* tests were computed to check for balance in demographic characteristics by sample. SPSS software (version 28.0; IBM Corp) was used for data cleaning, EFA, and validation analysis. The lavaan package in R (version 3.6.2; The R Foundation for Statistical Computing) was used for CFA analysis [24], and α was set at .05 for statistical significance.

EFA of Development Sample

EFA was performed on the development sample using principal axis factoring, and varimax rotation was allowed in the case of a solution with more than one factor. EFA was used to evaluate the factor structure of the 6 items proposed for inclusion in the scale as well as to reduce the 6 items to a smaller set of items that could potentially be used to measure digital health care literacy more parsimoniously. Eigenvalues >1, factor loadings >0.4, Cronbach α>.75, and variance explained >0.40 were used as the criteria to evaluate the items retained in the full factors and to attempt to create a reduced factor [25-27]. Once the full and reduced factors were finalized, CFA was performed on the confirmatory sample using the items suggested by the EFA.

CFA of Confirmatory Sample

The CFA was conducted using robust maximum likelihood estimation to test the goodness of fit between the theorized factor structure suggested by the EFA and the confirmatory sample data set. The robust estimation was used because of the Likert-type ordinal responses of the items and does not assume multivariate normality of the items. A constraint value of 1 was placed on 1 item in the factor as is common in modeling analyses with a defined scale. Goodness of fit for the CFA was assessed evaluating the absolute fit, incremental fit, and parsimonious fit of the full and reduced factors [28]. The absolute fit criteria to conclude good fit between the proposed factor structure and the data included nonsignificant chi-square values, root mean square error of approximation, and standardized root mean square residual <0.08 [29]. Incremental fit criteria included the comparative fit index and nonnormed fit index >0.95. Parsimonious fit was indicated by adjusted chi-square (c2/*df*)<3.0 [30]. To assess the reliability of the full and reduced factors, Cronbach α was computed for the EFA and CFA. Composite reliabilities, calculated according to the weighted Ω formula from McDonald [31], were also calculated for the CFA because of concerns that Cronbach α may be inappropriate for use in structural equation modeling [32]. The variance explained was also reported for the EFA, and the average variance explained (AVE) values were calculated for the CFA with the recommended critical value >0.50 indicating that the factors explained enough of the variance in the construct [33].

Validation

We assessed the scale's validity by examining its associations with participants' demographics (ie, gender, race, ethnicity, language, education, and income), digital access, and prior digital health care use. We used the Spearman ρ for continuous variables and the Kruskal-Wallis test for categorical variables.

Results

Sample Characteristics

Participants were, on average, aged 34.7 (SD 7.7) years. Of the 508 participants, 454 (89.4%) were women; 173 (34.1%) were Hispanic, 129 (25.4%) Black, 95 (18.7%) White, and 78 (15.4%) Middle Eastern; 280 (55.1%) preferred English as their primary language, 157 (30.9%) preferred Spanish, and 71 (14%) preferred Arabic; 228 (45%) had an educational attainment of high school degree or less; 230 (45.4%) had an annual household income of <US $35,000; and 351 (69.1%) had children with Medicaid insurance (Table 2). Chi-square and independent samples 2-tailed *t* tests revealed no significant differences between the development and confirmatory samples for any demographic characteristics.

Table 2. Demographic characteristics of the sample overall and by development and confirmatory samples (N=508).

Characteristic	Overall	Development sample (n=254)	Confirmatory sample (n=254)
Participant age (years), mean (SD)	34.7 (7.7)	34.3 (7.9)	35.0 (7.6)
Gender, female,[a] n (%)	454 (89.4)	223 (87.8)	231 (90.9)
Race and ethnicity,[b] n (%)			
White	95 (18.7)	46 (18.1)	49 (19.3)
Black	129 (25.4)	64 (25.2)	65 (25.6)
Hispanic	173 (34.1)	88 (34.6)	85 (33.5)
Asian	13 (2.6)	5 (2)	8 (3.1)
Middle Eastern	78 (15.4)	39 (15.4)	39 (15.4)
Multiple	13 (2.6)	7 (2.8)	6 (2.4)
Prefer not to answer	7 (1.4)	5 (2)	2 (0.8)
Preferred language, n (%)			
English	280 (55.1)	139 (54.7)	141 (55.5)
Spanish	157 (30.9)	79 (31.1)	78 (30.7)
Arabic	71 (14)	36 (14.2)	35 (13.8)
Education level, n (%)			
Less than a high school graduate or GED[c]	97 (19.1)	51 (20.2)	46 (18.1)
High school graduate or GED	131 (25.8)	67 (26.4)	64 (25.2)
Some college or technical or vocational school	125 (24.6)	62 (24.4)	63 (24.8)
College degree (associate's or bachelor's)	105 (20.7)	47 (18.5)	58 (22.8)
Postgraduate or professional degree	49 (9.6)	26 (10.2)	23 (9.1)
Missing	1 (0.2)	1 (0.4)	0 (0)
Annual household income (US $), n (%)			
<10,000	56 (11)	33 (13)	23 (9.1)
10,000-19,999	45 (8.9)	26 (10.2)	19 (7.5)
20,000-34,999	129 (25.4)	63 (24.8)	66 (26)
35,000-49,999	75 (14.8)	36 (14.2)	39 (15.4)
≥50,000	93 (18.3)	43 (16.9)	50 (19.7)
Don't know or not sure	110 (21.7)	53 (20.9)	57 (22.4)
Child's or children's insurance, n (%)			
None	7 (1.4)	3 (1.2)	4 (1.6)
Medicaid	351 (69.1)	184 (72.4)	167 (65.7)
Private insurance	75 (14.8)	33 (13)	42 (16.5)
Other type of insurance	74 (14.6)	34 (13.4)	40 (15.7)
Missing	1 (0.2)	0 (0)	1 (0.4)
Digital Health Care Literacy Scale reduced score, mean (SD)	8.6 (3.1)	8.7 (3.0)	8.5 (3.3)

[a]Gender was assessed with the following response options: male, female, and other. No participant identified as other.

[b]Separate databases were used for English-, Spanish-, and Arabic-speaking participants, and the data were combined for analysis. Race and ethnicity were collected with a single item; the response options included White, Black, Asian, Middle Eastern, Hispanic, Native American, Native Hawaiian, other race or ethnicity, and prefer not to answer. In the English and Arabic database, participants could select all options that applied. Participants were coded as multiple if they selected more than one race and/or ethnicity, except for Middle Eastern+White, which was coded as Middle Eastern. Because of incorrect configuration, the race and ethnicity item was not enabled as a check-all item in the Spanish-speaking database (ie, these participants could only check 1 race or ethnicity). Of the 151 participants who completed the Spanish survey, 144 (95.4%) selected Hispanic, 6 (4%) selected White, and 1 (0.6%) selected Black.

[c]GED: General Educational Development.

EFA of Development Sample

To evaluate the full digital health care literacy score, all 6 items were initially entered into the EFA, and 1 factor was extracted with an eigenvalue >1 and factor loadings between 0.45 and 0.96. Cronbach α was excellent at .89, and the variance explained was high at 62% (Table 3). Next, a reduced factor was created by eliminating items from the full factor one at a time and evaluating the resulting factor loadings and variance explained. Items were eliminated based on correlations with other items >0.90 with conceptual overlap (1 item; *I can install applications/programs...* overlapped with *I can use applications/programs...*) and the lowest factor loadings (2 items). On the basis of these criteria, 3 items were retained in the reduced scale (Table 3), with a resulting excellent reliability (Cronbach α=.90) and a high variance explained (78%).

Table 3. Summary of factor loadings and fit statistics for the full and reduced models.

	Full		Reduced	
	EFA[a]	CFA[b]	EFA	CFA
I can use applications/programs (such as Zoom) on my cell phone, computer, or another electronic device on my own (without asking for help from someone else)	0.96	0.95	0.96	0.94
I can set up a video chat using my cell phone, computer, or another electronic device on my own (without asking for help from someone else)	0.89	0.81	0.89	0.82
I can solve or figure out how to solve basic technical issues on my own (without asking for help from someone else)	0.81	0.84	0.80	0.85
I can install applications/programs (such as Zoom) on my cellphone, computer, or another electronic device on my own (without asking for help from someone else)	0.93	0.93	N/A[c]	N/A
If you encounter a technical issue while using your cell phone, computer, or another electronic device, what do you do first?	0.52	0.42	N/A	N/A
How often do you need someone (like your child/children) to help you with using your digital devices?	0.45	0.38	N/A	N/A
Absolute fit				
Chi-square	N/A	15.99	N/A	<0.01
RMSEA[d]	N/A	0.07	N/A	<0.01
SRMR[e]	N/A	0.41	N/A	<0.01
Incremental fit				
CFI[f]	N/A	0.99	N/A	>0.99
NNFI[g]	N/A	0.98	N/A	>0.99
Parsimonious fit, adjusted chi-square	N/A	1.78	N/A	0.00
Reliability				
Cronbach α	.89	.88	.91	.90
Composite reliability (coefficient Ω)	N/A	0.88	N/A	0.90
Variance explained (EFA); average variance explained (CFA)	0.62	0.62	0.78	0.75

[a]EFA: exploratory factor analysis.

[b]CFA: confirmatory factor analysis.

[c]N/A: not applicable.

[d]RMSEA: root mean square error of approximation.

[e]SRMR: standardized root mean square residual.

[f]CFI: comparative fit index.

[g]NNFI: nonnormed fit index.

CFA of Confirmatory Sample

Both the full and reduced factors were evaluated with CFA (Table 3). The factor loadings for the full factor ranged from 0.38 to 0.95, with model statistics of χ^2_9=16.0; *P*=.07. All the fit statistics exceeded the criteria for good fit between the proposed factor structure and the data. The reliability was excellent, with coefficient Ω=0.88, and the AVE was high at 0.62. The reduced scale also had excellent CFA fit, with factor loadings between 0.82 and 0.94. The chi-square value was 0, meaning the model was saturated (equal number of parameters and df). This also means that the factor was perfectly parsimonious (adjusted chi-square value of 0). All the fit statistics well exceeded the criteria for good fit between the proposed factor structure and the data. The reliability was

excellent, with coefficient Ω=0.90, and the AVE was high at 0.75.

DHLS Validation

Overview

Because of the excellent fit of the reduced factor, we focus on this version of the scale and its validity in the following sections.

Figure 1 shows the final version of the scale with response options and scoring instructions. The associations between the DHLS and measured categorical variables are shown in box plots in Figure 2. Associations with continuous variables are described only in the text.

Figure 1. Digital Health Care Literacy Scale (DHLS).

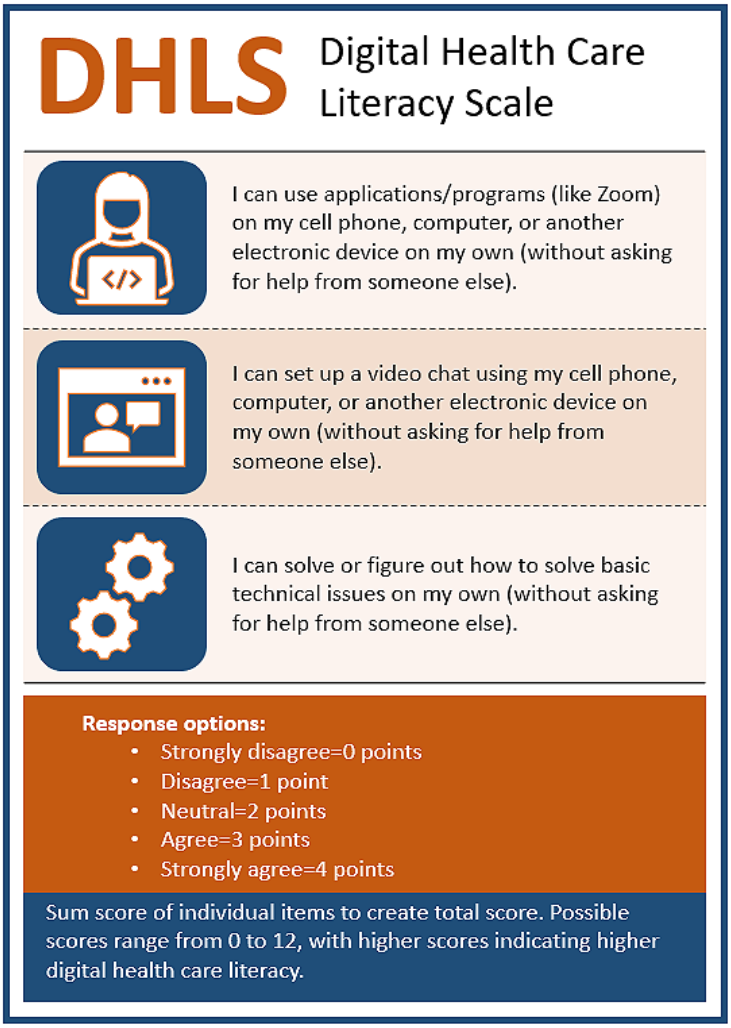
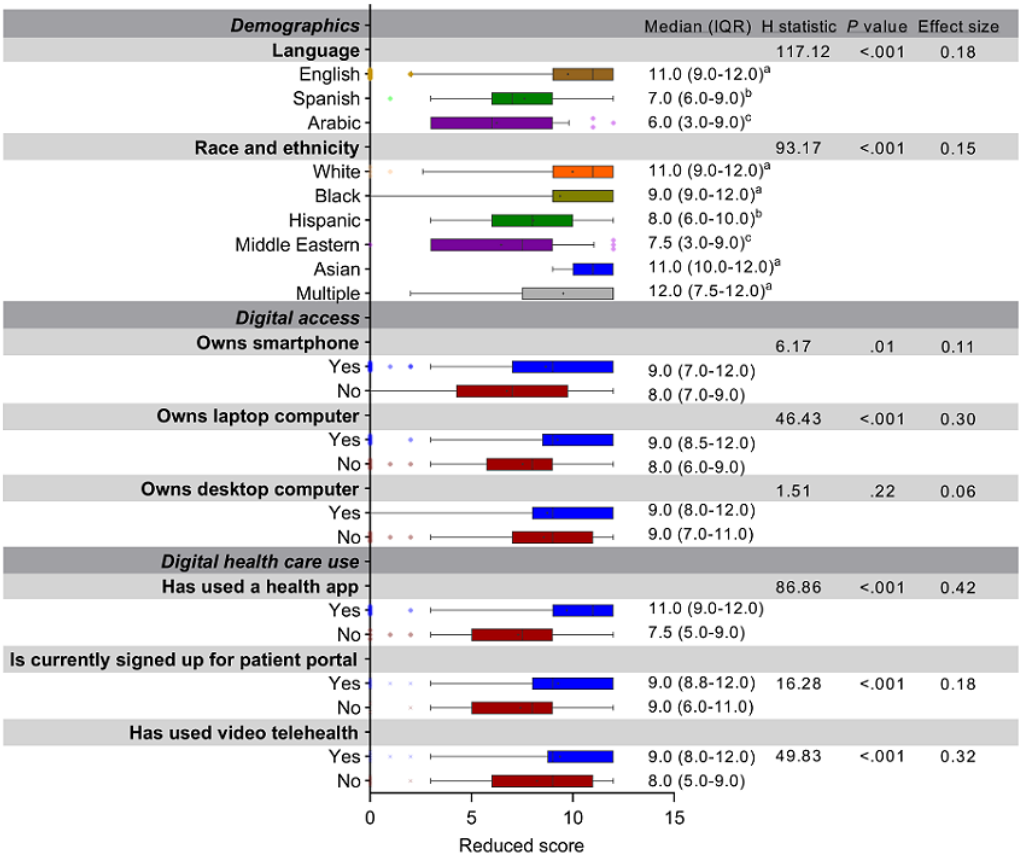


Figure 2. Associations between scores on the Digital Health Care Literacy Scale and participants' demographic variables, digital access, and digital health care use. For all variables with the same superscripted designator, the difference between the medians is not statistically different. If 2 variables have different superscripted designators, they are significantly different from each other.



Demographics

The DHLS score was negatively associated with age (ρ=–0.164; *P*<.001), and positively associated with both education (ρ=0.139; *P*=.005) and income (ρ=0.379; *P*<.001). There was not a significant association with gender, H_1=1.267; *P*=.26. The overall model for language was significant, H_2=117.115; *P*<.001. Arabic speakers had lower scores than English and Spanish speakers, and Spanish speakers had lower scores than English speakers (Figure 2). The model for race was also significant, H_5=93.167; *P*<001. Middle Eastern participants had lower scores than all other racial groups, and Hispanic participants had lower scores than all groups, except Middle Eastern (Figure 2).

Digital Access

Among the 508 participants in the study, 25 (4.9%) did not own a smartphone, 191 (37.6%) did not own a laptop computer, and 401 (78.9%) did not own a desktop computer; in addition, 30 (5.9%) did not have internet access at home and 43 (8.5%) said that their internet connection was not good. We found significant associations between most of our digital access items and the DHLS score such that participants who did not have digital tool access had lower scores than those who did. Specifically, participants who did not own a smartphone or a laptop computer had lower digital literacy scores (Figure 2). However, there was not an association between desktop computer ownership and scores (Figure 2). Having a more stable network connection to use the internet at home (ρ=0.343; *P*<.001) and to use a cell phone data plan (ρ=0.312; *P*<.001) were both associated with higher scores.

Digital Health Care Use

Nearly half of the participants (211/508, 41.5%) had never accessed a health app, and 35.8% (182/508) were not signed up for the patient portal. Most (341/508, 67.1%) had not used video telehealth to obtain care for their children. Participants who had never used a health app had lower digital health care literacy scores than those who had (Figure 2). In addition, participants who were not signed up for the patient portal had lower scores than those who were signed up. Participants who had not used video telehealth to obtain care for their children had lower literacy scores than those who had (Figure 2). Among those who had, there was a positive association between the ease of scheduling the visit and their DHLS score (ρ=0.279; *P*=.001). Among those who had not used video telehealth, perceived difficulty of scheduling a visit was associated with lower scores (ρ=0.459; *P*<.001).

Discussion

Principal Findings

Given the increased reliance on digital technologies during the COVID-19 pandemic, it is critical that we understand which

patients are and are not equipped for this shift in health care delivery. Without gauging patients' confidence in skills for using telehealth and similar health care technologies, we risk exacerbating health disparities [14,17]. We developed the DHLS, a scale designed to measure an individual's digital health care literacy, and validated it among a diverse sample of caregivers of young children. Overall, the scale had strong psychometric properties, and the reduced version of the scale performed just as well as the full version, supporting its continued and more efficient use. Participants with lower digital health care literacy had less experience with digital health care and were less likely to own digital tools. In addition, those with less education, with lower income, and people of color had lower digital health care literacy.

To our knowledge, this is one of the first tools intended to measure confidence with the skills necessary for using digital health care services, including telehealth. The Digital Health Literacy Instrument is another scale designed to measure digital health literacy; however, the items are complex and highly specific (eg, *When typing a message [e.g., to your doctor, on a forum, or on social media such as Facebook or Twitter] how easy or difficult is it for you to clearly formulate your question or health-related worry*); furthermore, the scale is long (21 items), which could lead to attrition among users with less education or literacy. The DHLS is a brief, 3-item assessment developed among a racially and socioeconomically diverse sample, and it measures the basic skills necessary for using digital health services. Of note, we focused our application of the scale in this paper on telehealth; however, it may have application to other types of digital tools. This is supported by our study, which validated the scale against the use of similar technologies (eg, whether patients had used a health app and whether they were signed up for a patient portal). Although the reduced 3-item scale is easier to administer, we encourage other researchers to use either the reduced or full scale (the latter includes additional items about digital skills, more broadly, beyond video chat) to explore other applications.

Overall, we found similar associations between participants' characteristics and DHLS scores as other studies reporting on similar digital literacy tools. For example, having less education and lower income has previously been associated with lower eHealth Literacy Scale scores [34]. Although lower telehealth literacy was associated with older age, aligning with other studies examining digital literacy [35,36], the effect was very small. This is likely due to the limited variation in age among our sample: all participants were caregivers of children aged <13 years, with the average caregiver age being only 34.7 (SD 7.7) years. In our study, we found that Hispanic and Middle Eastern participants had lower digital health care literacy than White and Black participants, and Middle Eastern participants had significantly lower scores than Hispanic participants. A similar pattern emerged when looking at language such that Arabic speakers had the lowest digital health care literacy, followed by Spanish speakers, and then English speakers. The findings highlight the importance of examining differences in race and language by unique groups rather than collapsing groups into non-White or non-English.

Our scale could be applied as a brief assessment in clinical settings when assessing individuals' ability to use telehealth. If a participant identifies as more digitally fluent, they may be a strong candidate for telehealth and can receive subsequent instructions for setting up a visit. However, if they identify as being less digitally fluent, resources can be provided to help that individual be better equipped for a visit. Several organizations are exploring solutions to help those with lower technology literacy prepare for telehealth appointments. For example, at VUMC, a medical student–led volunteer initiative was started to help patients set up and test devices for their telehealth appointments [37]. Students used a standardized telephone script to guide patients with downloading the proper software and understanding what to expect for the visit [37]. Another approach in Harris County, Texas, included a nonphysician staff member reaching out to ensure that patients had the proper technology and had resolved issues before the appointment [38]. Primary care practices at University of California San Francisco started an outreach program to all patients aged >65 years with scheduled visits to walk them through setting up and using the video platform app [39]. Although such initiatives have had success with preparing patients for telehealth, they are extremely time and resource intensive; a screening tool such as the DHLS could help identify only those who are most in need of assistance, thereby increasing efficiency and effectiveness. Another approach could be to simply ask patients whether they need extra help setting up a telehealth visit; however, this may have the opposite effect and lead to missing patients who do require help. That is, it is possible that some individuals may not know they need the help, especially if they have never had a telehealth visit. By using items that target the basic skills necessary to use digital tools, the scale could help to accurately identify patients who are unaware that they need assistance. Moreover, some patients may feel uncomfortable communicating that they need help. We hope that this tool provides a respectful approach for identifying those patients who require assistance.

With respect to research, the DHLS could be used as a way to help describe the digital literacy of the sample and determine whether there was representation from low digital literacy communities. It could also be useful to assess whether the use rates or efficacy of a digital technology or program were related to digital literacy. In general, we hope that the scale is included in other studies, whether for descriptive purposes, as a predictor, or as a covariate, to broaden our understanding of its applications and how it functions.

This study includes several limitations. First, these data were collected cross-sectionally; therefore, we cannot draw conclusions regarding causality. It is possible that having lower digital health care literacy leads to a lower likelihood of accessing digital health care services or vice versa. Similarly, as part of a cross-sectional study, we are limited in our ability to propose a cutoff score for determining who requires additional assistance with digital health care; however, certain study designs can effectively answer this question. For example, a future study might administer the DHLS and then attempt to conduct a telehealth visit with all participants. By examining the difference in scores between those who were and were not

successful with completing the visit, we could determine a cutoff score that helps identify the likelihood of being able to successfully carry out a telehealth visit in typical circumstances. In this study, one of our goals was to explore associations between the scale and a variety of barriers to telehealth, of which scheduling a visit was one; however, scheduling a visit is likely reflecting both clinic-level and patient-level characteristics and therefore we recommend interpreting this association with some degree of caution. All participants were caregivers of children and recruited from a clinic in Middle Tennessee, which limits generalizability to other populations and other regions; however, we enrolled a racially, ethnically, and socioeconomically diverse sample of participants. We developed the items such that they can theoretically be used widely with different types of individuals, and we encourage researchers to use and validate the scale in other populations. Although the DHLS was negatively correlated with age, the sample was, on average, of younger age (mean age 34.7, SD 7.7 years), and it will be especially important to see how the scale functions with older populations who tend to experience more barriers to digital health [40-42]. In addition, although we included participants who spoke English, Spanish, and Arabic, there were likely confounding differences among the groups, and we did not use a sample-matching approach to ensure comparability of participant characteristics among languages. To consider the scale validated for all languages, a future study would need to include large numbers of individuals who spoke each language with sufficient heterogeneity and representation of participant characteristics. Relatedly, because our scale items were originally written and derived by English speakers, it is possible that the lower mean scores observed within the Spanish and Arabic groups could have been at least partially caused by intrinsic bias. Full validation within each language would help to confirm whether intrinsic bias was present. Finally, patients were not included in the development of the scale; it is possible that the inclusion of patient input could have strengthened it.

Conclusions

Widespread adoption of telehealth by clinicians and patients alike has the potential to revolutionize health care delivery, improving both quality of life and clinical outcomes. However, as part of this quest, we must consider those patients who may not have the digital access or skills to use telehealth—in many cases, these are the same patients who tend to have worse outcomes. A screening tool such as the DHLS can be a useful resource to identify patients who require additional assistance to effectively engage with telehealth. Validating the scale among other patient populations and in other settings will support the scale's ultimate utility to reduce health care inequities.

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Conflicts of Interest

None declared.

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Abbreviations

AVE: average variance explained
CFA: confirmatory factor analysis
DHLS: Digital Health Care Literacy Scale
EFA: exploratory factor analysis
KSP: key study personnel
REDCap: Research Electronic Data Capture
VUMC: Vanderbilt University Medical Center

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Original Paper

Adapting Child Health Knowledge Translation Tools for Somali Parents: Qualitative Study Exploring Process Considerations and Stakeholder Engagement

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Abstract

Background: We have developed a series of knowledge translation (KT) tools that integrate parental experiences to communicate evidence-based information about acute childhood health conditions to parents and caregivers. While we created these tools with parent input, it is unclear if they are useful for diverse parent groups, including specific immigrant and refugee groups in Canada.

Objective: This study aims to explore the usefulness of our preexisting KT tools within our local Somali community, and understand what cultural and linguistic adaptations could improve their usability.

Methods: After viewing 4 KT tools (differing in design and format) about various acute child health conditions, health care providers (HCPs) and knowledge brokers (KBs) who work with Somali families were interviewed about the usability of these tools and discussed considerations for adapting KT tools for use within the Somali community.

Results: A total of 13 HCPs and KBs participated and indicated that the Somali community values accessibility, representation, and the role of trusted others in delivering effective KT products. Understanding accessibility barriers, the power of adequate representation, and engaging meaningfully with prominent community leaders were key suggestions for ensuring relevance of KT products and uptake by community members.

Conclusions: This study represents an essential piece of understanding processes for adapting or developing KT products for culturally and linguistically diverse communities.

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KEYWORDS

knowledge translation; cultural adaptation; trust; linguistics; parents; child health

Introduction

Knowledge translation (KT) efforts in health promotion, education, and communication are the avenues through which end users obtain and implement evidence-based information with relevance and meaning for their lives [1]. Over the past decade there have been considerable advances to involve end users in this process, spurred by the notion that collaborating with end users creates more applicable, accessible, and meaningful products [2].

Recognizing this, our research program is focused on improving health outcomes for children with acute health conditions through the application of the best available evidence. Situating our work within the Knowledge-to-Action Framework [3], we

involve end users throughout the process to identify priority topics [4], learn of their experiences and needs [5-16], develop prototypes, and evaluate final products through usability testing [17-23], to ensure they are tailored to their needs. To date, we have developed over 24 evidence-based KT tools for parents of children with acute health conditions [24].

Although integrating end user feedback is a valued component in KT product development [25], majority cultures often comprise the accessible pool of engaged end users [26,27]. Consequently, KT products to improve patient knowledge and inform health care decisions within Canada frequently entail English or French communication, and mainstream cultural images. Additionally, the majority of resources assume end users possess a certain level of health literacy, which may not represent the knowledge base of those unfamiliar with Canadian health care systems. It is currently unknown how preexisting KT tools are received by those less familiar with Canadian health care systems.

In situations where new comers or immigrants may face challenges in adjusting to new social environments and health systems, health-related KT is particularly important to address their needs [28]. Unfortunately, there are only few sources offering guidance to researchers interested in pursuing cultural and linguistic adaptation of health information resources. Ideally, researchers would create KT products through collaboration with the end users for effective and relevant health messaging [29], but this may not be feasible for those with finite resources and time.

As diversity and immigration increase in Canada, there will be a greater need for understanding the cultural and linguistic considerations for developing and adapting KT products. Acknowledging this need, we engaged with stakeholders at multicultural organizations who voiced the lack of health resources for the Somali community. In an effort to address this gap, we sought to understand if our KT tools (in their current form) could be useful for the Somali community, and what specific cultural and linguistic adaptations could improve their usability. Additionally, we explored what sociocultural contexts should be considered to increase KT tool usability in general.

Minority cultural groups in Canada, like the Somali community, are not always readily accessible to engage in research processes [30]. Often knowledge brokers (KBs) who can help bridge the gap between research processes and community partnerships support diverse community groups. Through working with researchers and community members they help build and maintain relationships, speak on behalf of community interests, and are able to prioritize community perspectives and values [31]. In the context of health care, moving evidence into action is a key role KBs play [32]. Therefore, as a means of *initially* exploring the usability of our existing KT tools and understanding cultural and linguistic considerations for adapting our products, we first approached stakeholders (health care providers [HCPs] and KBs) who work closely with the Somali community.

Methods

Overview

We conducted 1-on-1 semistructured interviews with HCPs and KBs who have previously worked, or currently work, with the local Somali community. Four different KT tools (differing in design, format, and topic) were sent to participants to review in advance. Participants were then asked to comment on the usefulness and appropriateness of each tool's content and format for use with Somali parents and families.

Recruitment

Following institutional ethics approval, HCPs and KBs serving Somali families were recruited through known multicultural community connections and snowball sampling [33]. Two research team members (MM and AF) are part of the Somali community and helped guide our recruitment efforts, and provided linkages to community associations. All participants provided informed consent prior to data collection.

Survey and Interview

Participants were asked to complete a brief online demographic survey to collect information on their age, sex, cultural identity, job title, work setting, and years of practice. Data were collected and managed using REDCap electronic data capture tools hosted at the University of Alberta [34,35].

Participants then attended a one-on-one interview over Zoom with a research team member (MM or KSW). Prior to each interview, the participants received emailed links to 4 of our existing KT tools: (1) a whiteboard animation video on croup, (2) an interactive infographic on fever, (3) an animated video on what to expect at the emergency department, and (4) an eBook on bronchiolitis, and asked to view each of the tools ahead of the meeting (Multimedia Appendix 1). Participants also had the opportunity to view the KT tools at the start of the interview and while they were providing their feedback.

Members of the research team conducted the interviews by following a semistructured interview guide (Multimedia Appendix 2). For each tool, participants were asked to comment on (1) how useful the tool would be in helping Somali parents, families, and/or caregivers make decisions when their child is sick, (2) if the tool met the needs of Somali parents and families, (3) what adaptations would be needed to make the tool more suitable for Somali parents, families, and/or caregivers. Participants were also asked about what current child health resources they use, and what general considerations were needed when developing tools for diverse community groups.

The semistructured nature of the interviews allowed for exploration of the most meaningful components of participants' testimonies. During and after each interview, the involved researcher wrote detailed field notes to capture nonverbal communication and reflect on their biases [36]. The interviews were conducted in English, recorded, and transcribed verbatim.

Data Analysis

Qualitative data management and analysis were facilitated using NVivo version 12 (QSR International PTY Ltd.). Each interview

transcript was analyzed through thematic analysis [37] where they were read multiple times, and coded with verbatim terms [38]. These codes were then grouped into preliminary categories, which were organized into themes once all transcripts were compared. The common themes were reviewed by several members of the research team to promote analytic rigor and trustworthiness [39]. Rigor was enhanced through continual communication within the research team and detailed field notes [40], where researcher bias was acknowledged and challenged [41]. Descriptive statistics were computed in a Microsoft Office Excel workbook (version 2016; Microsoft Corporation) and were used to describe the study sample.

Ethics Approval

Ethics approval was granted by the University of Alberta Health Research Ethics Board (approval number Pro00102950).

Results

Participants

A total of 13 HCPs and KBs who work with Somali parents in Alberta, Canada, participated in interviews, and 11 completed the demographic questionnaire.

Demographics

Participant demographics are shown in Table 1. Among the 11 participants, 8 (73%) identified as Somali, with 4 of these preferentially speaking Somali within the home. The most common occupation of participants was community KB (6/11, 55%), while others were nurse (1/11, 9%), social workers (2/11, 18%), and pediatricians (2/11, 18%), all serving Somali families within the community.

Table 1. Demographic characteristics of participants (n=11).

Variable	Value, n (%)
Sex	
Male	3 (27)
Female	8 (73)
Language spoken at home	
English	7 (64)
Somali	4 (36)
Marital status	
Married/partnered	11 (100)
Single	0 (0)
Immigrant or refugee identity	
Yes	10 (91)
No	1 (9)
Community position	
Doctor/pediatrician	2 (18)
Health knowledge broker	6 (55)
Nurse	1 (9)
Social worker	2 (18)
Years serving the community	
<5	2 (18)
5-9	3 (27)
10-15	2 (18)
16-20	3 (27)
>20	1 (9)

Qualitative Interview Findings

Interviews with participants revealed 3 key themes relevant for developing or adapting KT tools for Somali parents: accessibility, representation, and the role of trusted others.

Theme 1: Accessibility

Overview

The HCPs and KBs who participated in this study described several barriers that would limit the access of information for members of the Somali community. Primarily, accessibility barriers were related to language and dissemination considerations.

Language

One of the most prevalent themes across the interviews was the necessity for oral translations of health information. Participants emphasized the importance of translating health information into the Somali language when communicating evidence with the community. Beyond literal translations, participants emphasized the need for a deeper understanding of Somali language and culture to provide high-quality translations. One participant described this need in saying,

> *Many terminologies actually don't exist in Somali that exist in English. So it's not just interpreting things directly, it's actually having a solid understanding of the Somali language in order to assist someone.* [Participant_002]

Additionally, many of the interviewed HCPs mentioned that even those whose only spoken language is Somali may not have knowledge of the written language, making oral communication essential. One participant described the importance of oral communication in saying,

> *The illiteracy rate is very high. So when resources are being created for the Somali community, I think if it's a written material often likely won't reach its audience widely.* [Participant_001]

Those interviewed suggested videos would be more effective than any text-based KT tool, which could lend itself to online dissemination.

Dissemination

HCPs and KBs interviewed suggested that producing videos would be more accessible than text-based KT tools, but often community members (families) are unaware of culturally more "accessible" tools. To enhance the reach of dissemination, HCPs and KBs suggested using applications such as WhatsApp. When asked where to connect with Somali parents, one participant said,

> *A WhatsApp group. On a scale from 1 to 10, I think it has been an 11 when connecting with Somali individuals.* [Participant_003]

One participant mentioned that online dissemination should be used with caution, as some members of the Somali community may not have the technological proficiency to easily access information online. Participants described a technology divide primarily based on age:

> *Our younger generation are more tech savvy...I would like to pass it on verbally. Or to my friend or a neighbor. We are more oral people.* [Participant_004]

In-person communication, although unavailable during the current pandemic, was proposed as a future means of sharing health information. Many of the participants in this study represented organizations where parent information sessions are held. A participant involved with leading in-person parenting classes said,

> *When we did the parenting class with the Somali community in person, you wouldn't believe how much they keep discussing things around the course.* [Participant_008]

Participants believed that the parent sessions they hosted were successful in enriching members' learning experiences.

Theme 2: Representation

Overview

Participants suggested various ways through which KT tools could more accurately portray the lived experiences of Somali parents. The diverse daily lives of community members may not be fully represented in 1 version of illustrations, but the HCPs and KBs suggested that considering character depictions and home remedies would more accurately represent Somali families.

Character Depictions

Along with the importance of having Somali translations available through face-to-face parenting programs, participants suggested including representative characters, family structures, and environments in any visual KT product. Through relatable visuals, Somali community members might feel the content is relevant for their lives. For some families, having a multigeneration household or a single-parent household would increase relatability and improve information reception. One participant articulated the value of accurate character portrayal:

> *The more we showcase people that look like [Somali people] it just makes it a lot easier for them to relate.* [Participant_003]

Another consideration for culturally adapting KT tools is recognition of current health practices in communities.

Home Remedies

Rather than navigating barriers with language, culture, and tangible resources, parents may adopt home remedies suggested by friends and family. Several participants described alternative treatments Somali patients use, as "herbal remedies are very common." (Participant_009).

Understanding how Somali parents respond to their child's illness is an important consideration for KT tools. Moreover, physicians who are unfamiliar with home remedies that are common in Somali culture may not think to ask about existing treatments. One participant suggested that the key to understanding current health practices requires "just being very specific in asking what cultural practices have you done to try to help with your illness." (Participant_010). These practices of Somali parents shape the way they view acute childhood illnesses, and therefore change their information needs.

Theme 3: Trusted Others

Overview

Navigating health care in Canada may be particularly daunting for Somali parents. Numerous barriers prevent Somali families from accessing care and utilizing health care information resources. Participants explained that community leaders have an influential presence in the community, and could be helpful in bridging the gap between HCPs and community members. Understanding the role of community leaders would improve outreach and dissemination efforts. Similarly, participants suggested further exploring relationship dynamics with

physicians and the impact on help seeking and treatment adherence.

Physicians

Participants described the frustration some Somali parents feel when speaking with their physician. One participant described,

> *Many of my clients they tell me the doctor they just ask 1 minute question and they say okay take these medications sometimes they say there is no proper diagnoses.* [Participant_012]

When physicians were available for longer, participants explained that lack of cultural competency prevented meaningful care:

> *Physicians try to send the husband out and that doesn't really go well either because sometimes they don't want to leave the wife with a man physician in the room or something. There can be lots of little challenges and if the health professional have more understanding of the culture then it can be handled in a lot more positive ways.* [Participant_010]

Without appropriate levels of cultural competence, physicians may inadvertently alienate their Somali patients and reinforce distrust in Canadian health services. One participant furthered this point in saying,

> *When there is a cultural barrier there is also a power dynamic that plays. Within the Somali community HCPs are considered important people. And then they hold a sense of authority, so to challenge authority is kind of a taboo thing to do.* [Participant_004]

Somali parents hold physicians in high regard and feel as though they cannot voice concerns or speak frankly with medical professionals. One of the HCPs in this study explained that Somali people "don't want to seek assistance because they lost trust." (Participant_012). As barriers to access and negative experiences mount, Somali parents may be more reliant on community leaders for health advice.

Community Leaders

Rather than working against various barriers to seek professional medical advice, many Somali parents reach out to community leaders for support. In place of seeking medical attention, as a Somali parent, "you'd call family members to find out different cultural herbal remedies to kind of handle an illness." (Participant_010)

Community leaders were also mentioned during interviews as a viable avenue for information dissemination. One participant (Participant_005) suggested "community leaders can work with health care providers to initiate lectures and medical awareness" where Somali parents can learn from a trusted source. Navigating meaningful communication with community organizations was described as a sensitive process, as researchers and government agencies may be viewed an untrustworthy. Above all, participants emphasized recognizing Somali parent experiences:

> *Respect for that is important in gaining trust of families and really helping them benefit from the health care system.* [Participant_001]

Discussion

Principal Findings

Influence of Accessibility Barriers, Representation, and the Role of Trusted Others on KT Tool Development and Uptake

Through engaging with community HCPs and KBs, we aimed to explore the usability of 4 preexisting KT tools and understand what cultural adaptations should be considered to increase their usability with Somali parents and families. Community HCPs and KBs discussed the components of each KT tool through the perspective of using each tool with the Somali families they serve. Through this process, they described how accessibility barriers, representation, and the role of trusted others influence uptake of KT tools.

Accessibility Barriers

Participants suggested that Somali parents may have technological and language barriers that prevent them from accessing online tools in English. Although studies have found that parents often rely on the internet for health information [42], this may not hold true for Somali parents, particularly those that are new to Canada. Participants described parents and families having a spectrum of comfort with both English language and technology. The overwhelming preference voiced by HCPs and KBs was for communicating health information in Somali and in person. Participants described the strong oral culture of Somali communities where they preferentially sought information through peers rather than online or from health clinics. This finding aligns with a previously reported project with Somali refugees where they voiced a preference for 1-on-1 social support when navigating social services [43]. If oral communication and social support are the most impactful ways through which KT tools are presented to Somali parents, then the role of trusted community leaders should be further explored to help guide dissemination efforts.

Representation

It should be noted that the Somali community is diverse in and of itself. There is a great difference between the experiences of refugees and immigrants entering Canada [44]. Somali people may have gained permanent residency in Canada through family class, economic class, humanitarian relief, or through refugee status; others may have been born in Canada and have a greater understanding of the health care system [45]. Evidence suggests that immigrants from racialized groups are at risk of worsening health throughout their stay in Canada [46]. Compared with skilled workers, refugees reported a worse health status overall [47]. Additionally, length of residency in Canada may impact health resource needs (eg, established immigrants have had more exposure to harmful postmigration environments than recent immigrants [48]). Families just settling into their new life in Canada may have more needs related to how to access health care services, as many face barriers in navigating the health care system [45]. By contrast, families who are settled

may be wanting information on specific health-related topics such as nutrition and immunizations that have arisen over time. As Somali community members could represent a wide range of health literacy and have varying priorities, it is important for researchers to fully understand the information needs of the specific end user group.

Role of Trusted Others

The experiences of Somali parents relayed by HCPs and KBs in this study suggested that community leaders and family play a significant role in dissemination of health information. Similarly, participants in this study described that Somali parents who have lived in Canada for a longer period may also prefer seeking health information from friends due to negative experiences with the Canadian health care system. Home remedies and advice from friends may be more appealing and familiar than navigating barriers to health care access. As reported in this study, and by Clark and Missal [30], community leaders may be an impactful way of reaching Somali community members. Delivering this information via online media may be helpful, but only if it is accessible to the target audience. If community leaders could be involved with creating and disseminating KT products, there may be greater uptake. It should be noted that relying on community leaders also requires cultural sensitivity and reciprocity for ethical compensation of their time and effort [30].

Cultural Adaptation and KT Strategies

Bottom-up processes with participatory engagement may be the most impactful method for developing relevant and appropriate messaging [29], but these processes are often time-consuming and can be costly for researchers. Navigating appropriate and truly patient-driven health information campaigns is a nuanced process for each specific end user population [49]. Researchers who have previously developed KT tools for majority cultures may not have the time or resources to engage in this process for other cultural communities; instead, they may seek to adapt their current work for use with more diverse populations [50]. There are several processes of cultural adaptation that have been previously applied to adapt health intervention programs [51], decision aids [52], and patient-reported outcome scales [53]. When a niche community has a statistically higher prevalence of a certain disease or illness, an intervention may be designed to enact change on the behavior or environment [30]. However, little information or guidance exists on how best to adapt KT products that reach diverse end user needs. Additionally, the situational context regarding how cultural assimilation plays a role should be further explored. We recently set out to understand perspectives of French and Filipino parents in Alberta regarding our KT tools [54], who they themselves recognized that “their cultures were assimilated into a western Canadian lifestyle” and thus the needs of newcomer populations may be different.

Impactful KT goes beyond dissemination, and involves engagement, participation, and impact evaluation by knowledge users, alongside efforts focused on sustainability. Several studies emphasize the importance of consultation with specific cultural groups during KT activities and health promotion campaigns [28]. Of particular note, Telenta and colleagues [55] found that engaging directly with niche cultural communities allows stakeholders to invest in the research process, and respond more positively to KT products. Engaging with specific end users such as the Somali community to understand their unique needs and knowledge gaps can ensure that these tools are relatable, useful, and accessible by increasing cultural relevancy. In turn, utilization of these tools can potentially lead to improved health outcomes for Somali children.

A key driver of engagement with end users is the role KBs play as intermediaries within the community. Often they are flexible and responsive to both the researcher’s and community’s needs, building mutual understandings of goals and cultures to support the specific initiative [56]. Within their roles (including knowledge management and building capacity) KBs are essential to understanding how to access, adapt, and disseminate knowledge [31]. In the context of health care, this is integral to the success of moving evidence into action through the development of tailored KT products.

Limitations

This exploratory study involved HCPs and KBs, some of whom were community members, but others who were outsiders to the lived experiences of Somali parents. This insider knowledge with culturally and linguistically diverse communities has proved beneficial in KT projects [26,27]. Future research with integrated feedback from Somali parents would produce more relevant, impactful work. Additionally, only Albertan HCPs and KBs were recruited during this study, so the contextual pieces from other geographical areas may not be represented in their experiences. Undoubtedly the most effective method of producing relevant messaging would be truly participatory in nature, gaining insight from bottom-up data derivation [29]. Nonetheless, this formative study adds to the understandings of how health messaging could be conveyed more effectively to diverse communities. It also gives pause for thought to other researchers considering adapting or developing resources for linguistically and culturally diverse communities.

Innovation

Increasingly diverse populations in Canada necessitate greater effort in reaching culturally and linguistically diverse communities with KT strategies. As researchers become more interested in culturally adapting their KT tools, studies as described above will prove helpful for guidance.

These findings contribute to the evidence base regarding the need for early engagement with community members, and the need for cultural and linguistic adaptations of KT tools to improve accessibility for diverse communities. Furthermore, we advocate for an innovative approach to ensure adaptations go beyond the literal translation and encompass the fluid and dynamic phenomenon of culture.

When developing KT products there will undoubtedly be unique considerations specific to different cultural groups, but common threads for practice will help guide future efforts. This study represents an essential piece of understanding processes and resource needs for adapting KT products for culturally and linguistically diverse communities.

Conclusions

Community HCPs and KBs who serve Somali families believed that adding appropriate visuals, providing translated audio, and considering environmental contexts would improve KT tool usability. Prioritizing reciprocity and building relationships with trusted community members would also enhance the reach and trustworthiness of the tools.

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Authors' Contributions

All authors were involved in drafting the article and revising it, and all authors have approved the final manuscript before submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Examples of knowledge translation tools.
[DOCX File , 595 KB - formative_v6i4e36354_app1.docx]

Multimedia Appendix 2
Semi-structured interview guide.
[DOCX File , 15 KB - formative_v6i4e36354_app2.docx]

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Abbreviations

HCPs: health care providers
KBs: knowledge brokers
KT: knowledge translation

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Original Paper

Sleeping in an Inclined Position to Reduce Snoring and Improve Sleep: In-home Product Intervention Study

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Abstract

Background: Accurately and unobtrusively testing the effects of snoring and sleep interventions at home has become possible with recent advances in digital measurement technologies.

Objective: The aim of this study was to examine the effectiveness of using an adjustable bed base to sleep with the upper body in an inclined position to reduce snoring and improve sleep, measured at home using commercially available trackers.

Methods: Self-reported snorers (N=25) monitored their snoring and sleep nightly and completed questionnaires daily for 8 weeks. They slept flat for the first 4 weeks, then used an adjustable bed base to sleep with the upper body at a 12-degree incline for the next 4 weeks.

Results: Over 1000 nights of data were analyzed. Objective snoring data showed a 7% relative reduction in snoring duration (*P*=.001) in the inclined position. Objective sleep data showed 4% fewer awakenings (*P*=.04) and a 5% increase in the proportion of time spent in deep sleep (*P*=.02) in the inclined position. Consistent with these objective findings, snoring and sleep measured by self-report improved.

Conclusions: New measurement technologies allow intervention studies to be conducted in the comfort of research participants' own bedrooms. This study showed that sleeping at an incline has potential as a nonobtrusive means of reducing snoring and improving sleep in a nonclinical snoring population.

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KEYWORDS

snoring; sleep; sleep tracker; snoring tracker; adjustable bed; digital health; health technology; digital tracker; intervention; measurement

Introduction

Snoring is common and has been associated with poor sleep, increased risk of coronary artery disease, depressive disorders, and other health-related problems [1]. Changing one's sleeping posture has long been known as a way to reduce snoring [2]. This can include repositioning the upper body to an inclined position to open the upper airways, which can be achieved using specialized pillows, wedges, or bed bases.

These approaches have shown some effectiveness in patients with sleep apnea and other disorders [3]. For example, Skinner et al [4] reported mixed results after testing a shoulder-head elevation pillow for the management of obstructive sleep apnea (OSA). More recently, Souza et al [5] showed that head-of-bed elevation using a laboratory bed reduced the severity of OSA without interfering with sleep architecture. Similarly, a study of a bed that automatically lifted the trunk of the user upon detection of snoring found that it was able to reduce episodes of snoring in the laboratory [6].

However, evidence is lacking in nonclinical populations and settings. The accuracy of new unobtrusive sleep and snoring measurement technologies allows intervention studies to be conducted in research participants' own bedrooms and may contribute new evidence-based knowledge to the field of applied

sleep and snoring research. This method of in-home research using innovative digital health tools has an advantage over traditional sleep laboratory studies. It provides insight into the effectiveness of the intervention under real-life conditions, yielding ecologically valid results while still capturing objective data [7].

In this study, using an adjustable bed base to sleep with the upper body at a 12-degree incline was compared to sleeping in a flat position. The 12-degree angle is sufficient to elevate the head while still being comfortable for sleep. A mild degree of head-of-bed elevation, compared to larger angles, is most likely to be well tolerated while still being effective according to laboratory studies [5,6]. The inclined position was hypothesized to reduce snoring and improve sleep. This was measured objectively over 1000 nights of data collected using commercially available trackers as well as by self-report.

Methods

Participants

The sample included 25 users of SleepScore Labs technology who self-reported nightly snoring and screened negatively for sleep apnea based on the NoSAS (Neck Circumference, Obesity, Snoring, Age, Sex) screening tool, using a cut-off score of >8 [8], and/or had a BMI <30 kg/m^2. Users who reported having a partner who snored were excluded. Users with self-reported sleep disorders or other medical conditions (eg, hyperthyroidism) or lifestyle factors (eg, shift work) affecting sleep were excluded. Of the 25 participants, 60% (n=15) were male and the average age was 38 (SD 11.38) years, ranging from 21-62 years.

Ethics Approval

All participants provided written informed consent, and all procedures were conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki. Western Institutional Review Board-Copernicus Group reviewed the study under the Common Rule and applicable guidance and determined this to be exempt research.

Study Design and Procedures

A within-subjects pre-post design was used. During the baseline period, participants slept on their own mattress in a flat position for 4 weeks. During the intervention period, their bed base was replaced with the Dr Oz Good Life Adjustable Base Pro (2020 collection, Maven) to allow for sleeping in an inclined position for 4 weeks using their original mattress. Participants used the preprogrammed Anti-Snore position, resulting in an electrical motor elevating the head of the bed to a 12-degree incline prior to sleep. During the entire 8-week study, participants were instructed to record their snoring and sleep nightly and complete questionnaires daily. Data were collected during the same time period across all participants to account for weekday and weekend variation.

Measurement of Outcomes

Objective snoring was measured using the Do I Snore or Grind app (Version 1.2.4(2); SleepScore Labs) on an Apple iPod touch sixth generation (Model A1574; Apple Inc) with snoring sensitivity set to high and grinding sensitivity set to low. This consumer app captures sounds using the microphone of the mobile device and identifies snoring using artificial intelligence–based algorithms that filter out nonsnoring sounds. The app quantifies snoring duration exceeding the set level of sensitivity and transforms the percentage of the night during which the user snored into a snore score.

Objective sleep was measured with the SleepScore Max (SleepScore Labs), a noncontact monitoring device using respiratory and motion signals to detect sleep. It uses ultralow-power radiofrequency waves to monitor body movement while in bed; this measurement is unaffected by bedding or nightwear. High-resolution magnitude and duration data of gross movements, micromovements, and full breathing cycles are captured and transformed into 30-second epoch sleep stage data (Wake, Light, Deep, rapid eye movement [REM]) using proprietary algorithms. Studies have shown good agreement between this approach and polysomnography [9,10]. Using the 30-second epoch data, standard sleep metrics were calculated. In addition, the following 3 SleepScore Labs proprietary sleep measures reflecting sleep quality were calculated, all ranging from 0-100 and normalized for age and sex using reference values from the meta-analysis of quantitative sleep parameters by Ohayon et al [11]: SleepScore, which is an overall sleep quality metric that includes objectively measured total sleep time, sleep onset latency, and sleep stage durations; BodyScore, which reflects the age- and sex-normalized amount of deep (non–rapid eye movement stage 3 [NREM-3]) sleep; and MindScore, which reflects the age- and sex-normalized amount of REM sleep. The device's sensor is placed next to the bed and a companion app shows users their sleep data along with insights and advice.

Self-report items were developed for the current study. Perceived snoring (nights per week snored and frequency of waking from snoring) was measured before and after the intervention period and perceived sleep (time to fall asleep, number of awakenings during the night, amount of time spent awake after initially falling asleep, feeling well-rested in the morning, and overall sleep quality) was measured daily. These data were collected on the internet using SurveyMonkey (Momentive Inc).

Statistical Analyses

Statistical analyses were performed in R (version 3.5.2; R Foundation for Statistical Computing). Nightly objective snoring data, objective sleep data, and self-reported sleep data were analyzed using multilevel regression with a random intercept model, accounting for nights nested within participants and comparing nights during the baseline period to nights during the intervention period for each outcome. The regression model used was the following: $SleepMeasure_{ij} = Const_{0ij} + \beta \times TestPeriod_{ij}$; TestPeriod was coded as 0 for observations during the baseline and 1 for nights during the intervention period.

Self-reported snoring outcomes were analyzed with paired-samples *t* tests.

Discrepancies in sample sizes (N=1181 for snoring, N=991 for sleep, and N=1185 for self-report) occurred as the data sources were incomplete. Participants tracked their snoring and sleep

at home and at times were not fully compliant with using these measurement tools or completing daily surveys on the internet. All results reported reflect the largest sample available for each set of analyses.

Results

Snoring-Related Outcomes

Night-to-night objective measurement of snoring (1181 nights nested within 25 participants) revealed a 7% relative reduction in snoring duration (P=.001) when sleeping in the inclined position compared to the flat position (see Table 1).

Similar to the objective findings, self-report data indicated that participants felt they snored less often (decreasing on average from 6 nights per week to 5; P=.01) and were woken up by their snoring less often (decreasing on average from sometimes to rarely; P<.001) in the inclined position compared to the flat position. Participants with a bed partner (n=10) reported that their partner woke them less often to stop snoring (decreasing on average from sometimes to rarely; P<.01) when sleeping in the inclined position.

Table 1. Objective snoring and objective sleep multilevel regression results comparing the baseline to the intervention period.

Outcomes	Observed mean (SD)[a]		Estimated marginal means[b]		
	Baseline period	Intervention period	Intercept (SE)	β[c]	*P* value
Objective snoring (1181 nights)					
Snore score[d]	9.28 (4.29)	8.61 (3.64)	9.31 (0.24)	–0.756	.001
Objective sleep (991 nights)					
Time in bed in minutes	452.76 (76.35)	445.66(75.57)	450.24 (5.16)	–4.689	.18
Total sleep time in minutes	391.27 (69.05)	383.78(68.16)	388.79 (4.61)	–5.534	.12
Sleep efficiency[e]	85.43 (5.66)	84.02(5.92)	86.19 (0.41)	0.137	.37
Sleep onset latency in minutes	18.65 (14.81)	18.05(13.23)	18.54 (1.01)	0.095	.46
Number of awakenings	4.45 (1.99)	4.25(2.07)	4.43 (0.13)	–0.237	.04
Percentage of time spent awake after sleep onset	9.10 (4.87)	9.25(5.52)	9.10 (0.37)	0.032	.47
Percentage of time in light sleep	54.30 (7.07)	53.55(6.86)	54.40 (0.46)	–0.668	.07
Percentage of time in deep sleep	19.30 (6.55)	20.20(7.44)	19.30 (0.45)	0.905	.02
Percentage of time in REM[f] sleep	17.30 (5.37)	17.00(5.66)	17.20 (0.36)	–0.298	.21
SleepScore[g]	77.63 (9.73)	78.27(9.98)	77.40 (0.67)	0.633	.17
BodyScore[g]	78.93 (9.59)	81.10(10.13)	78.85 (0.63)	2.109	<.001
MindScore[g]	76.99 (12.99)	75.62(14.46)	76.61 (0.93)	–1.421	.06

[a]For the baseline and intervention periods, each mean was calculated by averaging nights across participants, then averaging those participants' averages to a single simple average.

[b]These are the outcomes of separate multilevel regression analyses. Each row shows results from a different single-predictor, single-outcome model.

[c]The beta values are unstandardized and can therefore be interpreted on the same scale as the original data.

[d]Snore score is reported as a percentage.

[e]Sleep efficiency is calculated as the ratio of time spent asleep to time spent in bed and reported as a percentage.

[f]REM: rapid eye movement.

[g]These scores range from 0 to 100.

Sleep-Related Outcomes

Night-to-night objective measurement of sleep (991 nights nested within 25 participants) revealed that when sleeping in the inclined position, participants woke up less often (4% decrease in number of awakenings; P=.04) and experienced a greater proportion of deep sleep (5% relative increase; P=.02), reflected by an improved BodyScore (3% increase; P<.001). Detailed sleep metrics are displayed in Table 1.

Multilevel analyses of the self-reported sleep data (1185 nights nested within 25 participants) showed that participants perceived that they fell asleep faster (20% decrease in sleep onset latency; P<.001), woke up less often (15% decrease in number of awakenings; P=.001), felt more rested in the morning (17% increase in the score on the 0-100 scale; P<.001), and experienced better sleep quality (14% increase in the score on the 0-100 scale; P<.001) in the inclined position compared to the flat position (see Table 2).

Table 2. Multilevel regression results for self-reported sleep (1185 nights), comparing the baseline to the intervention period.

Outcomes	Observed mean (SD)[a]		Estimated marginal means[b]		
	Baseline period	Intervention period	Intercept (SE)	β[c]	*P* value
Perceived sleep onset latency in minutes	16.38 (11.80)	13.13 (9.35)	16.23 (0.79)	–2.922	<.001
Perceived number of awakenings	2.33 (1.44)	1.97 (1.31)	2.31 (0.10)	–0.320	.001
Perceived amount of time spent awake after sleep onset in minutes	14.10 (14.43)	13.00 (13.36)	14.13 (1.38)	–0.898	.26
Feeling well-rested in morning[d]	56.29 (16.38)	66.09 (16.30)	56.60 (1.08)	9.651	<.001
Perceived sleep quality[d]	58.94 (15.52)	67.47 (16.78)	59.47 (1.06)	8.078	<.001

[a]For the baseline and intervention period, each mean was calculated by averaging nights across participants, then averaging those participants' averages to a single simple average.

[b]These are the outcomes of separate multilevel regression analyses. Each row shows results from a different single-predictor, single-outcome model.

[c]The beta values are unstandardized and can therefore be interpreted on the same scale as the original data.

[d]These outcomes are reported as a score ranging from 0-100.

Discussion

Recent technological advances enable the accurate digital measurement of sleep and snoring in the comfort and familiarity of one's habitual bedroom [12,13]. In this study, participants slept on their own mattresses in their homes for the duration of the study, recording their snoring and sleep nightly with commercially available trackers and by self-report. They slept flat for 4 weeks and then used the Anti-Snore setting (12-degree incline) of the Adjustable Base Pro for 4 weeks.

Analyses of over 1000 nights of data showed a significant improvement across all 4 areas measured: objective snoring, perceived snoring, objective sleep, and perceived sleep. When sleeping with the upper body in the inclined position, compared to when sleeping flat, objectively measured snoring duration decreased and self-reported snoring outcomes improved. Objective sleep measurements revealed fewer awakenings and more time in deep sleep when sleeping in the inclined position. Related to the increase in deep sleep, participants' average BodyScore increased. Self-reported sleep data showed fewer perceived awakenings and better sleep quality; additionally, participants felt more well-rested in the morning. Participants also felt that they fell asleep faster in the inclined position, but this finding was not confirmed by the objective sleep data. Taken together, these findings suggest that future in-home product intervention research using commercially available snoring and sleep trackers is merited.

In conclusion, sleeping with the upper body at an incline has potential as a simple nonobtrusive means of reducing snoring and improving sleep in a nonclinical snoring population. This sleeping position is thought to lead to benefits by decreasing upper airway collapsibility and increasing the upper airway area, compared to the flat position, leading to improved breathing and, in turn, better sleep [5]. Elevating the upper body at night is also frequently recommended to alleviate heartburn symptoms and improve sleep in individuals experiencing nocturnal gastroesophageal reflux [14]. This nonpharmacologic approach is preferred by many patients. Similarly, snorers might prefer this intervention because it is incorporated into their bedroom furniture, does not require extra pillows or devices, and may provide more comfort than nasal or oral appliances that can reduce snoring.

Study limitations include the need for further validation testing of the commercially available snoring app and the absence of a control group. Applied in-home product intervention studies have limitations compared to clinical trials; the key is to assess any change from no product use to product use as it would be experienced outside of a research setting. The design best reflecting this real-life experience is a baseline-controlled intervention. By using a within-subjects design with long-term use of the intervention, we have confidence that the observed changes are due to the intervention itself.

In this study, data were not collected regarding the sleeper's preferred body position (eg, supine or lateral) and therefore, possible interactions of sleeping position with the incline were not explored. These interactions have been shown to be relevant in determining optimal positional therapy for sleep apnea [15] and would be an interesting addition to future studies of snorers at home. Another useful future research direction could be measuring the sleep of snorers' bed partners because the elimination of snoring has been shown to benefit partners' sleep [16]. These types of research questions can now be studied using digital technology that is commercially available to consumers for home use.

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Conflicts of Interest

The authors are employed by SleepScore Labs. Dr Oz is an investor in SleepScore Labs.

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Abbreviations

NoSAS: Neck Circumference, Obesity, Snoring, Age, Sex screening tool
NREM-3: non–rapid eye movement stage 3
OSA: obstructive sleep apnea
REM: rapid eye movement

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Original Paper

Development of the Socioeconomic Screening, Active Engagement, Follow-up, Education, Discharge Readiness, and Consistency (SAFEDC) Model for Improving Transitions of Care: Participatory Design

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Abstract

Background: Transition to home after hospitalization involves the potential risk of adverse patient events, such as knowledge deficits related to self-care, medication errors, and readmissions. Despite broad organizational efforts to provide better care transitions for patients, there are challenges in implementing interventions that effectively improve care transition outcomes, as evidenced by readmission rates. Collaborative efforts that require health care professionals, patients, and caregivers to work together are necessary to identify gaps associated with transitions of care and generate effective transitional care interventions.

Objective: This study aims to understand the usefulness of participatory design approaches in identifying the design implications of transition of care interventions in health care settings. Through a series of participatory design workshops, we have brought stakeholders of the health care system together. With a shared understanding of care transition and patient experience, we have provided participants with opportunities to generate possible design implications for care transitions.

Methods: We selected field observations in clinical settings and participatory design workshops to develop transitional care interventions that serve each hospital's unique situation and context. Patient journey maps were created and functioned as tools for creating a shared understanding of the discharge process across different stakeholders in the health care environment. The intervention sustainability was also assessed. By applying thematic analysis methods, we analyzed the problem statements and proposed interventions collected from participatory design workshops. The findings showed patterns of major discussion during the workshop.

Results: On the basis of the workshop results, we formalized the transition of care model—the socioeconomic, active engagement, follow-up, education, discharge readiness tool, and consistency (Integrated Michigan Patient-centered Alliance in Care Transitions transition of care model)—which other organizations can apply to improve patient experiences in care transition. This model highlights the most significant themes that should necessarily be considered to improve the transition of care.

Conclusions: Our study presents the benefits of the participatory design approach in defining the challenges associated with transitions of care related to patient discharge and generating sustainable interventions to improve care transitions.

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KEYWORDS

care transition; discharge; readmission; patient-centered care; design; participatory design

Introduction

Improving Transitions of Care to Reduce Hospital Readmission

The US health care system has undergone a drastic shift in the past decade as payment to health systems has transitioned to rewarding value over the volume of care. Quality-based repayment programs incentivize hospitals through payment withholding or incentive-based payments based on outcomes instead of volume. Models such as the Hospital Readmission Reduction Program (HRRP), established in 2012 under the Affordable Care Act, financially penalize hospitals if they have higher than expected risk-standardized 30-day readmission rates [1,2].

Many quality reimbursement models focus on conditions that have a large morbidity and mortality burden, contribute to significant direct and indirect health care costs, and have clear and direct measures to target [3]. Many value-based purchasing programs, including HRRP, focus on improving the treatment of specific disease conditions such as acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, coronary artery bypass graft surgery, elective primary total hip arthroplasty, and total knee arthroplasty [4].

In particular, the HRRP has forced hospitals to recognize that the transition to home after hospitalization carries a significant risk of adverse patient events, readmissions, and increased costs [5]. Transition of care interventions refer to improvements developed to reduce readmission rates among populations transitioning from one care setting to another [6]. Despite ongoing organizational efforts to improve care transitions, there continue to be challenges in implementing interventions that consistently affect key care transition quality indicators such as 30-day readmission rates [7,8].

Although transitions involve multiple stakeholders in the care continuum, including physicians, nurses, hospitals, primary care organizations, and patients, the transition of care interventions were traditionally developed from the health care provider perspective [9]. These interventions are often limited to a single phase in the care continuum, involve only a single institution, and are often limited to interventions considered important from the provider's perspective [10]. Patients often remain passive participants in the health care system when discussing care transitions. As a result of these hierarchical approaches, developing and implementing effective interventions has been a significant challenge in improving care transitions.

As hospitals and physician organizations (POs) have recognized the benefits of working together to reduce readmissions through programs such as the HRRP [11,12], health care organizations have started to highlight the increased benefits of nonhierarchical collaborative efforts that bring health care professionals, patients, and caregivers together. This collaboration is necessary to identify gaps associated with transitions of care and generate effective interventions.

Health care organizations, private payers, the Centers for Medicare and Medicaid Services, and policy makers have been charged with the task of creating unique ways of incentivizing hospitals and POs to improve patient outcomes and reduce readmissions. An example of this collaborative approach is the Integrated Michigan Patient-centered Alliance in Care (I-MPACT) Collaborative Quality Initiative (CQI) [13]. I-MPACT is a patient-centered CQI that engages hospitals, POs, and patients throughout Michigan and supports the development and implementation of innovative approaches for improving care transitions. The collaborative is composed of numerous health system groups, or clusters, in the Michigan area, which comprise a hospital, a partnering outpatient PO, and patients and caregivers from the local community. Within the CQI, clusters are asked to identify the target population and implement interventions to reduce readmissions for the target population. This initiative offers a unique opportunity for hospitals and PO groups to collaborate to improve care and aligns seamlessly with value-based programs such as the HRRP.

Although the benefits of nonhierarchical collaborative efforts are acknowledged, the lack of effective tools to engage stakeholders often discourages collaborative, multidisciplinary solutions that bring together patients, hospital systems, and outpatient systems [14,15]. As a result, patients' voices are still marginalized and devalued when identifying problems or creating effective approaches to alleviate readmission [16]. There is a call for effective tools that will help hospitals, associated outpatient organizations, patients, and community caregivers in defining gaps associated with transitions of care.

Need for a Novel Approach to Identify Gaps Associated With Transitions of Care: Value of Participatory Design

Participatory design is often defined as the involvement of end users of services or products in the early phases of the development process [17-19]. The origins of the participatory design approach are from the 1970s Scandinavian cooperative design movement. When computers were first introduced in the work environment, workers were concerned that they would no longer have the agency to control their tasks and that they would be replaced by newly implemented technologies [17]. To respond to these changes, they aimed to take an active role in managing their work environment. This workplace democracy movement influenced the origin of the participatory design approach and yielded detailed design techniques to invite users throughout the design process [19]. Activity-based methods, including collaborative workshops, brainstorming, and drawing activities, are effective in understanding end users' expertise and experiences [20,21]. As participatory design has emerged beyond the field of design and human-computer interaction, researchers in other fields, including health care, have started

to apply different participatory methods and tools during projects [18,22]. As health care interventions are often designed and implemented from providers' perspectives, participatory design approaches are considered effective cocreation methods when they include the patient's perspective.

One of the most widely used participatory design methods is the collaborative design workshop. During the workshops, participants with different perspectives often form subgroups and discuss experiences, insights, and ideas regarding health care interventions through collaborative activities [17,23]. In these collaborative workshops, participants are recognized as knowledgeable stakeholders and experts on particular health issues (eg, disease-specific experiences). Recent health care and human-computer interaction literature has highlighted the benefits of a participatory design workshop with people with special needs in health care contexts (eg, older adults [24], people with dementia [25], pediatric patients, and their caregivers) [24-28]. By participating in different activities, participants can open up conversations regarding complex and unfamiliar social issues during participatory design sessions. For example, Harrington et al [26,29] conducted 2 community-based workshops with underserved populations in the United States. They identified how participants managed their health and the function of design workshops as facilitators for health-related discussions in their communities. Different activities were considered, including mapping activities, to draw participants' insights into their health management. Similarly, Unbehaun et a [30] conducted participatory, co-design sessions with 14 people with dementia and their caregivers to understand how exergames can be integrated into their daily routines. From multiple design sessions, researchers were able to iteratively modify their design ideas toward users' motivations and interests. As these examples show, participatory design approaches helped health care researchers develop a deeper understanding of the lived experiences of technology users and engage them in the design of interventions.

To our knowledge, this study is the first to apply participatory design approaches in the context of care transition. As care transitions are a series of events throughout the care continuum rather than a single event, professionals who are engaged in a patient's care transition typically witness only a part of the whole process. As participants perceive care transitions from multiple perspectives, the authors sought to develop a shared understanding of the care transition. A participatory design workshop was proposed as an effective approach to build a consensus on the care transition processes among different stakeholders.

Building on previous studies that showed the benefits of participatory design methods in different health care settings, this study suggests expanding the application of participatory design workshops beyond a single institution and a single trial. The authors set out to examine the usefulness of inviting multiple health care institutions into the participatory design workshop and the sustainability of the interventions, including long-term follow-up with the participants.

Research Aims

The overall purpose of this study is to identify the design implications of transition of care interventions derived from the participatory design workshop series. On the basis of qualitative analyses of ideas collected during the workshop, we discuss the major themes of transitional care interventions developed by the project clusters. Our study will contribute to improving methodological innovations in developing a shared understanding of the transition of care that encompasses the patient's perspective.

Methods

Study Design

The goal of this study was to apply participatory design approaches in the context of care transition and generate emerging themes for interventions across different hospitals. We highlight the benefits of gathering stakeholders from a local hospital for collaboration, using patient-centered perspectives, and incorporating participant observation in the hospital setting. During the postworkshop period, we also captured the following: (1) the status of the intervention (active or inactive, modifications, and maintenance), (2) the status of the cluster (participated or dropped out during the study), and (3) whether the cluster conducted an observation. In the *Intervention Sustainability Follow-up* section, we summarize the data collected from 2016 to August 2020.

Ethical Considerations

I-MPACT's quality improvement efforts were reviewed by the Institutional Review Board at the University of Michigan (IRB# HUM00126940) and determined to be exempt.

Data Collection

Observation and Patient Journey Maps

Within each cluster, on the day of discharge, a charge nurse identified each patient for observation from the target population. Observations were conducted before discharge from early morning to when the patient physically left the hospital, by an I-MPACT representative not affiliated with the hospital, after obtaining consent from the patient [17]. Observations lasted between 2 and 8 hours and were primarily focused on the patient's perspective during the process. Timestamps were recorded of patient-provider interactions; patients' and caregivers' behaviors; and details surrounding any type of patient instruction or education, including medication administration, self-care activities, mobility restrictions, and wait or idle time. On the basis of the observation data, we created a journey map that shows an overview of each patient's day of hospital discharge [31]. As a result, 26 unique patient journey maps were created from these observations, with at least one or more patient journey maps from each cluster (Multimedia Appendix 1). The 26 patient journey maps were generated from each participating hospital and shared with all stakeholders at the start of participatory design workshops. These patient journey maps represented a discharge timeline from the patient's perspective and included all events associated

with the discharge process that were considered significant (Multimedia Appendix 1).

Participatory Design Workshop

When each cluster joined I-MPACT, they were required to attend a participatory design workshop. This all-day commencement event was intended to bring a cluster together to discuss the local transition of care data and share ideas and insights around the patient's perspective from various points along the care continuum. Clusters were asked to use this workshop to generate ideas about the problems that the local cluster would target during their participation in I-MPACT over the next several years to improve transitions of care and patient experiences. To create a more collaborative environment and draw rich insights from multiple stakeholders, each commencement event was organized to create a collaborative environment, draw rich insight from multiple stakeholders, and highlight the patient perspective.

A total of 5 participatory design workshops were held between 2016 and 2018 (Table 1). With each cluster attending this commencement event, the aim was to foster discussions where participants could share multiple perspectives, capture the full scope of the care transition process, and generate practical design implications for improvement in care transitions. Each workshop had approximately 40 to 65 participants. During the full-day workshops, participants, comprising patients, caregivers, physicians, nurses, administrators, and designers, worked in groups of 7 to 9 people within their cluster to generate problem statements and begin initial discussions regarding interventions. Each cluster cohort participated in 1 workshop.

Table 1. Study cohorts and their commencement dates.

Cohort	Clusters involved in the cohort	Start date
Cohort 1	1 CHF[a] and 1 SNF[b]	February 2016
Cohort 2	4 CHF	September 2016
Cohort 3	1 SNF and 5 CHF	February 2017
Cohort 4	2 COPD[c] and 1 CHF	September 2017
Cohort 5	1 CHF and 3 SNF	September 2018

[a]CHF: congestive heart failure.

[b]SNF: skilled nursing facility.

[c]COPD: chronic obstructive pulmonary disease.

At each commencement workshop, participants were provided with patient journey maps created from the observation of a patient discharged from the hospital within their cluster (Multimedia Appendix 2). The details shared from each of the 26 observed discharges focused on the transition of care discussion from the patient's perspective in an effort to enable participants to gain a better perspective on problems that may otherwise have gone unnoticed by others. Participants also shared their individual experiences regarding care transition, which contributed to a shared understanding of the entire discharge process.

After reviewing the patient journey map and initial discussions, participants were asked to collaboratively generate major problem areas that they aimed to improve through transitions of care interventions. Inspired by service blueprint mapping in service design [32], we encouraged participants to create their own hospital's discharge timeline that detailed the core activities of a typical patient's care transition. This process enabled the participants to create a broader representation of the discharge process and consider the major barriers and details that affect a patient's experience during the care transition (Multimedia Appendix 3). During this process, each group was able to identify barriers, draft problem statements, and generate potential design interventions aimed at improving patient experiences throughout the care transition. If brainstorming was not completed during the workshop, each hospital finalized their brainstormed ideas for transitional care interventions during the postworkshop phase. As a result, 47 original interventions were generated with the aim of facilitating and improving care transitions. Each cluster was required to update its progress in a biannual report called the quality initiative (QI) log, and the August 2020 report was used to assess the status of their interventions. In the *Results* section, we have provided an overview of postworkshop progress to gauge the sustainability of these interventions.

Data Analysis

We followed a constructivist grounded theory approach for data analysis [33]. Without a predetermined conceptual frame, we iteratively read the participants' problem statements and identified commonly addressed themes in a collaborative manner. This methodology enabled the team to understand participants' experiences and views on care transition rather than our views or the preconceptions of health care researchers. To identify the patterns of major discussion during the participatory design workshop, we analyzed problem statements and proposed interventions collected from 79% (19/24) of the hospitals after the workshop. A total of 5 hospitals were not included in the study as 3 (60%) hospitals did not conduct an observation to generate a patient journey map, and the other 2 (40%) hospitals opted out of I-MPACT before August 2020. The lead author (JYS) performed open coding using NVivo Pro 12. While data analysis was performed, the team discussed the general direction and primary focus to create a shared understanding. The team iteratively reviewed the data to identify the major themes for open coding. This resulted in the following topic areas: (1) emerging obstacles during the discharge processes, (2) problem statements that represent the most

significant and feasible areas for improving care transitions among identified issues, and (3) generated design opportunities that could be turned into practical interventions. With these themes, we aggregated the problem statements until they did not overlap. This open coding yielded 206 codes, including 106 (51.5%) emerging problems of care transition and 100 (48.5%) opportunities to contribute to interventions. Some examples of coded problems included *lack of patient's involvement in managing their health* and *lack of consistent scheduling of follow-up appointments*. Opportunities for interventions included the following: *ensure that patient and family caregivers understand education* and *encourage patients to take control over their care*. We used affinity clustering to identify the commonalities and hierarchies of the 206 codes. The lead author (JYS) performed the affinity clustering based on the commonalities and relationships between themes, identifying the most salient emerging themes. The results were presented to the rest of the team to resolve any lack of agreement on the themes. Affinity diagramming resulted in themes with 3 different levels, which allowed the team to capture overarching themes that encompassed the lower-level themes. Themes at the third or lowest level included *patients cannot afford prescriptions* and *differences in the role of social workers and case managers at a hospital.* Second-level themes included *lack of early communication among providers* and *documenting patients' goals.* Top-level themes included *needs for screening tools* and *the importance of consistency.* This iterative analysis allowed the team to identify themes that workshop participants deemed most critical and recognized as areas needing significant transitions of care improvement.

Results

Overview

Six major themes emerged from the 206 codes that were developed out of open coding and affinity clustering: (1) screening tools for identifying social determinants of health (SDOH) barriers after discharge, (2) active patient and caregiver engagement in the discharge process, (3) follow-up postdischarge phone calls, (4) patient comprehension of discharge education, (5) team-based readiness tools to assess patient readiness for safe discharge from the hospital, and (6) consistency across the care continuum.

On the basis of these 6 themes, we formalized the transition of care model—the socioeconomic screening, active patient engagement, follow-up, education, discharge readiness tool, and consistency (SAFEDC) model (I-MPACT transition of care model)—that future initiatives can adopt and use to improve patient experience in care transitions (see Multimedia Appendix 4).

Theme 1: SDOH Screening—Screening Tools to Identify Specific Health or Socioeconomic Barriers After Discharge

One of the critical factors identified for transitions of care improvement is the need for tools to better identify SDOH factors that affect patients after discharge. The lack of such screening tools was identified as a barrier to optimizing tailored care for patients. For example, targeted interventions for patients with specific health conditions are difficult to conduct if some of these conditions are not appropriately identified until after hospital discharge. One such intervention developed by workshop participants involves a multilevel, team-based screening system that captures feedback from multiple clinicians at different points along the care continuum. The screening system would help identify patients with lower socioeconomic status and ensure that a patient has the means to obtain medications, adhere to their prescribed treatment plan, and make it to their follow-up appointments after discharge. Another intervention highlights the importance of screening all patients who transfer to a skilled nursing facility with a standardized SDOH screening tool before discharge. Once the standardized SDOH screening is completed, the hospital-based care coordination team can determine whether patients need further assistance. If a need for assistance is identified, care coordinators will communicate with each facility independently based on the patient's needs so that they can offer aid with the necessary resources (eg, options for medications). Screened information and identified needs can be integrated into the electronic health record (eg, Epic) and transferred to respective care coordination programs or other hospitals. See Multimedia Appendix 5 for an example of the SDOH Assessment Screening Tool that was implemented by one of the hospitals participating in the workshop.

Theme 2: Active Patient Engagement—Active Patient and Caregiver Engagement in the Discharge Process

Another barrier identified in care transitions is the lack of patient and caregiver involvement in the discharge process. Participants noted that the current discharge process often does not provide enough options for patients and their caregivers to communicate their specific health care needs with providers after hospital discharge. The lack of active patient and caregiver involvement negatively affects the patient's care transition experience.

To effectively engage patients and caregivers across the care continuum, participants highlighted the necessity of creating explicit systems to better allow patients to engage in their care. The use of practical tools for providers to better understand and support patients' specific health-related goals and motivations was theorized to lead to a more effective and patient-tailored care plan. For example, providers pointed out the need for more patient-friendly communication tools that can better empower patients to improve medication adherence when medication noncompliance has been identified. In addition, a patient-tailored tool could invite and empower patients to engage in advanced care planning conversations at various stages of their illness and better equip clinicians to deliver care personalized to meet individual patients' needs. During the workshop, providers shared that when they perceive barriers to patient or caregiver engagement, the providers feel less equipped, are less motivated, and perceive that there is more bias when offering additional support to their patients at the time of discharge. A standard protocol for patient engagement may help reduce these barriers and better engage patients and caregivers in patient-centered care plans.

In addition, participants suggested technology-mediated interventions that could facilitate goal planning and tracking. One of the examples presented by the participants was to provide ways of generating personal goals and regularly document them in their heart failure symptom tracker (eg, Heart Smart Calendar and My Heart Failure Action Plan). See Multimedia Appendix 5 for an example of an intervention aimed at promoting active patient and caregiver engagement during the discharge process.

Theme 3: Follow-up—Improving Postdischarge Follow-up

A prerequisite for participation in the I-MPACT workshops was a commitment to increase rates of the 7-day posthospital follow-up for patients. In addition to improving the postdischarge follow-up, participants also identified the need for more complete postdischarge follow-up protocols. Although many hospitals noted that they often call patients after discharge, it was determined that current phone calls are often unstructured and uncoordinated between the different organizations that provide posthospital care. The lack of an integrated call process between the hospital and POs results in fragmentation of care, creating difficulties in ensuring whether patients receive appropriate follow-up assistance, as well as important information (eg, follow-up clinic appointment schedule) from their care providers.

To alleviate this problem, our participants emphasized the need to have clear goals, protocols, and improved structures for follow-up phone calls. For example, the participants suggested that there would be value in having a standard approach to close follow-up phone calls with patients in both the immediate postdischarge period (eg, within 2 days of discharge) and the early postdischarge period (eg, within a week). See Multimedia Appendix 5 for an example of a structured postdischarge phone call, which was implemented by one of the hospitals that participated in the workshop.

Theme 4: Education—Patient's Comprehension of Discharge Education

We also identified that a patient's comprehension of discharge education was a potential factor that affects the effectiveness and quality of care transition. Workshop participants raised concerns that patients often do not comprehend the educational materials and are given an extensive amount of information (eg, precautions, safety protocols, and medication instructions) in later phases of their hospital stay and at the time of discharge. Patients often receive lengthy handbooks and materials to review after they leave; however, the patients participating in the workshop stated that these materials are often unread. Participants noted that patient education materials could be ineffective as they are often generic and not tailored to each patient's individual circumstances.

It was further noted that current discharge processes do not involve effective methods to ensure that patients comprehend the information that they are given. Workshop participants pointed out the need for effective strategies to deliver core discharge information, such as medication teaching, to patients and their caregivers earlier during hospitalization. Examples of recommended interventions included applying teach-back methods with tailored tools and simplified educational materials. Re-educating nursing staff about teach-back methods and clarifying caregivers' roles and responsibilities for patient education were proposed as ways of improving the effectiveness and quality of discharge education. Multimedia Appendix 5 provides an example of an intervention to promote patient comprehension of discharge education—a simplified, patient-centered education that was implemented by one of the hospitals participating in the workshop.

Theme 5: Discharge Readiness—Team-Based Tools That Assess Readiness for Safe Discharge

The findings highlight the importance of having a standardized, multidisciplinary discharge readiness assessment, in which all team members can provide input and receive feedback regarding the patient's readiness for safe hospital discharge. The participants agreed that, currently, there is limited availability of such a tool; however, its creation and use would allow the multidisciplinary team to better understand and communicate discharge readiness.

Participants discussed the value of a team-based perspective to determine whether the patient is ready for discharge and a multidisciplinary approach for how to best minimize risk and improve safety for the patient. Participants hypothesized that using a team-based readiness tool would improve communication, optimize workflow, and allow an improved multidisciplinary approach to identifying potential barriers and the action plans needed to overcome them. By prioritizing and adjusting the workload for a multidisciplinary team, a team-based readiness assessment tool could assist in the evaluation of safe discharge. See Multimedia Appendix 5 for an example of implementing a team-based discharge readiness assessment tool that was implemented by one of the hospitals.

Theme 6: Consistency—Consistent Transition of Care Processes Across the Care Continuum

One of the most frequently mentioned themes across the clusters was that patients and caregivers experience a lack of consistency as they move from one episode of care to the next. The workshop participants noted that inconsistency could significantly affect patients' experiences. Participants shared how uncoordinated and inconsistent information received from different providers negatively affected a patient's comprehension and interfered with their ability to actively engage and participate in their own care. Examples of inconsistent care included conflicting information from the provider (eg, discrepancies in discharge instructions), uncoordinated phone calls from multiple providers after discharge, incongruent follow-up appointments, and incomplete information or misinformation from different clinics (eg, incorrect physician names). In addition, the multitude of inaccessible electronic health records across the continuum of care prevents patients from accessing important records and impedes their awareness and comprehension. These findings challenged our participants to consider the use of a standard communication process between providers and patients and the implementation of active collaboration across multidisciplinary teams to proactively plan discharge.

The proposed intervention involved a hospital notifying the PO that their patient had been admitted to the hospital and the PO then providing a longitudinal care management program for the patient to follow for 90 days after discharge. Another intervention involved a care management program for all patients transferred from the hospital to a skilled nursing facility. See Multimedia Appendix 5 for an example of an intervention aimed at improving consistency across the care continuum.

Intervention Sustainability Follow-up

In this section, we summarize the current status of intervention implementation in hospitals during the postworkshop phase. Initial interventions were conducted during or shortly after the workshop. Furthermore, each cluster updated the QI log biannually, recording how the intervention was adopted, modified, or maintained. Interventions could be adopted depending on the hospital's resources, patient needs, and what could be sustainable and widely disseminated for that cluster's target population. To receive points in the program, the cluster must meet a certain threshold for intervention dissemination. Each hospital generated the most feasible care transition intervention tailored to the needs of its health system during the postworkshop period based on the 6 themes. Examples of practical interventions included a 90-day PO care management enrollment program, advanced care planning, and follow-up phone calls after discharge (see Multimedia Appendix 4 for example interventions). Although our primary aim was to present the impact of the participatory design process on brainstorming interventions for care transition rather than longitudinally following up on the implementation process, we also captured postworkshop progress to assess the sustainability of these ideas. Each cluster updated its progress in a biannual progress report called the QI log. We used the August 2020 progress report to gauge the intervention's sustainability.

Of the 24 hospitals that joined the I-MPACT and participated in the workshop, 5 (21%) were not included in the study as 3 (60%) hospitals did not conduct an observation to generate a patient journey map, and the other 2 (40%) hospitals opted out of the I-MPACT before August 2020. As a result, 79% (19/24) of hospitals remained in the project for follow-up and were analyzed in this study. Each of the 19 hospitals generated and implemented at least two feasible transition of care interventions, resulting in a total of 47 original interventions. From the August 2020 progress report, there were 47 total interventions, of which 24 (51%) were original interventions generated during or after the workshop, 10 (21%) interventions changed but were related to the originally proposed interventions, and 13 (28%) interventions were new interventions that hospitals generated by themselves during the postworkshop period. Of the 19 clusters that participated, 13 (68%) sustained at least one of their original interventions, 2 (11%) sustained all of their original interventions, and 4 (21%) did not sustain any of their original interventions. In summary, it was found that most clusters currently implemented the same interventions or those incorporated themes similar to the original interventions.

Discussion

Principal Findings

This study aimed to explore the effectiveness of the collaborative design approach in creating transition of care interventions that can potentially improve the hospital discharge experience for patients and reduce adverse outcomes, including readmissions. Through our qualitative analysis, six primary themes that facilitate patient care transitions emerged: (1) screening tools for identifying SDOH barriers after discharge, (2) active patient and caregiver engagement in the discharge process, (3) follow-up postdischarge phone calls, (4) patient comprehension of discharge education, (5) team-based readiness tools that can assess a patient's readiness for safe hospital discharge, and (6) consistency across the care continuum. On the basis of these themes, each hospital developed tailored interventions to improve patients' care transition experiences in their hospitals. During the follow-up period, all hospitals implemented at least one intervention originating from the initial workshop.

The SAFEDC model can be applied to improve patients' experiences during care transitions. Our findings support the usefulness of gathering stakeholders from a local hospital and involving the patient perspective to help identify local gaps associated with transitions of care.

By presenting how collaborative efforts can be transformed into practical interventions, our study makes two main contributions: (1) generated insights and useful innovations for transition of care interventions by forming multidisciplinary teams involving patients, hospital systems, and outpatient systems across the care continuum and (2) established the usefulness of the participatory design approach in the context of health care quality improvement.

Implications for Transitional Care Interventions

Given the number of health care interventions developed by workshop participants to improve care transitions, our study contributes to the current literature by highlighting the types of interventions that have been developed to improve care transitions and reduce hospital readmission rates. Previous studies in the context of care transition often involved 1 to 2 institutions as the target site [9,34,35]. However, in this study, close to 300 people from 19 health systems generated major concerns that should be considered when designing transition of care interventions. This study is an example of a large-scale project addressing care transitions using a participatory design approach. On the basis of workshop participants' insights and interventions, we established 6 major themes that health systems could address when establishing transitional care interventions.

Patient-targeted approaches (eg, interventions directly involving the patient), provider-targeted approaches (eg, interventions aimed at better equipping the provider with information), and system-targeted approaches (eg, interventions aimed at improving care consistency) were generated. For example, 33% (2/6) of the important themes, including the team-based assessment of a patient's readiness for safe discharge and screening to better identify vulnerable patients with particular conditions, particularly emphasized the provider role, which is

historically less visible to patients. Alternatively, 3 themes were patient centered: active patient and caregiver engagement in the discharge process, postdischarge follow-up to ensure patients are on the right track, and patient comprehension of discharge education. The last theme highlights improving consistency across the care continuum, requires a more integrated view of the health system, and emphasizes the importance of cohesive work within hospitals and between health organizations. This study highlights the need for a multipronged approach to transition of care interventions.

These themes show that transitions of care should be regarded as an ongoing and continuous process rather than a series of intermittent events, which aligns with previous literature highlighting the importance of multidisciplinary, patient-centered approaches to care transitions that span the care continuum [36-39]. There is no one size fits all intervention that can facilitate care transitions for every individual or context. Depending on each hospital's unique situation, including the available resources, targeted population, and prioritized problems, the specific details of an intervention should be carefully considered.

Using the SAFEDC model, future studies might propose simple collaborative activities or educational materials (eg, predesigned format to fill out and view multimedia content explaining the SAFEDC model) for health care institutions seeking to determine the six salient areas needing improvement within their specific context. For example, multiple stakeholders from health care institutions can apply the SAFEDC model to their situation and exchange perspectives to generate in-depth discussion.

Sustainability of Participatory Design in the Health Care Environment

By highlighting the various roles of the stakeholders involved in transitions of care who developed sustainable interventions, this study shows the benefits of using a participatory design workshop in large-scale quality improvement efforts.

Implementing interventions within health care systems beyond the project timeline has been an important focus of recent studies on participatory design [40]. Although valuable insights and discussions were generated during the workshop, previous studies noted that many useful outcomes were minimally incorporated into the organization or community after the events because of the lack of follow-up and sustained methods of implementing outcomes [40,41]. Consequently, participatory design outcomes are often poorly diffused to the organization or community when a research project ends [40,41]. In complex social settings such as hospitals, limited use of available resources (eg, human resources and infrastructure) has become the main barrier that negatively affects the impact of participatory design recommendations. As we followed up with each hospital to understand their postworkshop practices, we shed light on the improved sustainability of participatory design outcomes.

We brought together various stakeholders of the health care environment, including patients and caregivers, and successfully generated transition of care interventions. We confirmed from our follow-up review that of 47 interventions implemented across 19 hospitals, 24 (51%) of the 47 interventions had remained the same over a period of approximately 3 years. As long-term outcomes (eg, 3 years) of participatory design efforts have been infrequently discussed in previous studies, our study demonstrates that participatory design as a sustained approach is capable of generating large-scale interventions that can be implemented in hospitals and health care systems.

Limitations

Our study has some limitations. First, the lack of measurement tools to understand sustainability across hospitals was one of our limitations. Although we did our best to provide details of the intervention evaluation process across hospitals, this study does not offer an effective tool for the in-depth understanding of the long-term effectiveness of the intervention. Second, we did not collect sufficient information on why the clusters no longer used their interventions at certain points. Despite the specific number of clusters that continued with their original interventions, we have limited information on the specific factors that did not work in certain situations or contexts. Future studies should address these issues and generate contextual implications from long-term follow-ups using practical measurement tools.

Conclusions

We conducted observations aimed at understanding patient discharge experiences and held a participatory design workshop to gather rich end user perspectives of stakeholders, including health care professionals and patients. Patient journey maps were used as useful triggers for conversations among various stakeholders during the workshop. On the basis of these findings, we proposed the use of a transition of care model, SAFEDC, in which future research and practices can be used to improve patient experiences in care transitions. As the study did not examine the direct opinions of workshop participants or intervention users, future studies may gain additional insights by following up with intervention user experiences, real use cases, and factors that may aid in understanding the facilitators and challenges for each implemented intervention. Given the increasing interest in quality improvement through patient-centered approaches to designing health care interventions, this study demonstrates ways of enhancing care transitions through user-centered interventions.

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Authors' Contributions

JYS, AP, and DB were involved in writing the original draft, data curation, and data analysis. JYS, NO, and DB were involved in visualization. NO and KH were involved in data collection, data curation, data analysis, reviewing, and editing of the paper. KH, AP, GJ, and DB were also involved in reviewing and editing the paper. AP also performed data collection. GJ was involved in data interpretation and supervision. DB was involved in investigation, methodology, data analysis, resources, and supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient journey map generated from the observation study.
[DOCX File , 536 KB - formative_v6i4e31277_app1.docx]

Multimedia Appendix 2
Participatory design workshop held in February 2017.
[DOCX File , 96 KB - formative_v6i4e31277_app2.docx]

Multimedia Appendix 3
Discharge timeline creation during the workshop.
[DOCX File , 123 KB - formative_v6i4e31277_app3.docx]

Multimedia Appendix 4
Socioeconomic screening, active patient engagement, follow-up, education, discharge readiness tool, and consistency model (Integrated Michigan Patient-centered Alliance in Care Transitions transition of care model).
[DOCX File , 68 KB - formative_v6i4e31277_app4.docx]

Multimedia Appendix 5
Example interventions.
[DOCX File , 14 KB - formative_v6i4e31277_app5.docx]

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Abbreviations

CQI: Collaborative Quality Initiative
HRRP: Hospital Readmission Reduction Program
I-MPACT: Integrated Michigan Patient-Centered Alliance in Care Transitions
PO: physician organization
QI: quality initiative
SAFEDC: socioeconomic screening, active patient engagement, follow-up, education, discharge readiness tool, and consistency
SDOH: social determinants of health

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Original Paper

Characteristics and Outcomes of Clinical Trials on Gene Therapy in Noncongenital Cardiovascular Diseases: Cross-sectional Study of Three Clinical Trial Registries

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Abstract

Background: Cardiovascular diseases remain the leading cause of morbidity and mortality worldwide. Gene therapies (GTs) may become a novel therapeutic option for cardiovascular diseases.

Objective: We aimed to characterize all trials involving human subjects utilizing GT to treat noncongenital cardiovascular diseases.

Methods: In March 2021, we searched for clinical trials on the ClinicalTrials.gov (CT), International Clinical Trials Registry Platform (ICTRP), and International Standard Randomised Controlled Trials Number (ISRCTN) databases. Two authors screened the titles and registry notes of all the searched studies. We collected details of the included studies regarding their design, location funding source, treated conditions, completion, publication statuses, and final outcomes.

Results: We generated a total of 3508 records, and 50 unique clinical trials met our eligibility criteria. Of these, 20 (40%) concerned peripheral artery disease, and 18 (36%) concerned coronary artery disease. Most studies were randomized (34/50, 68%) and were performed in multiple locations (30/50, 60%), and around half of the trials compared GT with a placebo (27/50, 54%), while one in four were single-arm (14/50, 28%), and the rest concerned dose-finding (22%). More than half of the trials (29/50, 58%) were funded by industry. Of the 50 clinical trials, 28 (56%) published their results by the data collection date (March 2021), and 22 of 31 (71%) were slated to be completed before 2021. Overall, 12 of 28 (42.9%) clinical trials showed favorable outcomes of the intervention.

Conclusions: Among noncongenital cardiovascular diseases, GTs are mostly investigated in peripheral artery disease and coronary artery disease. Many clinical trials on GT use in noncongenital cardiovascular diseases did not disclose their results. Regardless of the trial phase, less than half of published studies on GT in noncongenital cardiovascular diseases showed promising results.

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KEYWORDS

gene therapy; cardiovascular disease; clinical trials; trial design; heart disease; clinical trial; therapy; cardiac risk factor; health intervention

Introduction

Cardiovascular diseases remain the leading cause of morbidity and mortality worldwide, despite developments in treatment and diagnostics. In 2005, they were responsible for 29.7% of global deaths and for 32.1% in 2015 [1]. Therefore, there is a need for novel strategies to prevent and treat cardiovascular diseases and mitigate their consequences. Gene therapies (GTs) are methods of gene modification or expression to achieve specific cellular effects [2]. This novel class of therapeutics may improve the prevention and treatment of many diseases, including cardiovascular diseases. One of the first approved GTs was alipogene tiparvovec (Glybera; AMT-011,

AAV1-LPLS447X), aimed at adults with familial lipoprotein lipase deficiency [3,4]. The potential of GT in noncongenital cardiovascular diseases was studied from the early 21st century, but its efficacy was limited [5,6]. In the past 15 years, several promising phase II randomized controlled trials (RCTs) of GT in heart failure (HF) [7,8] and peripheral artery disease (PAD) [9-11] were published. However, none of those GTs are currently approved (eg, NV1FGF for PAD failed to reduce major amputation or death in a phase III RCT [12]). In 2011, GT (Neovasculgen; cambiogenplasmid, PL-VEGFR165) for PAD was approved in Russia [13]. A postapproval observation of PL-VEGFR165 (Neovasculgen; cambiogenplasmid) suggested persistence of the therapeutic effect for individuals with PAD [13]. However, in the United States and Europe, there is currently no GT approved for noncongenital cardiovascular diseases. RCTs are considered the most reliable method for assessing the efficacy of therapeutics [14,15] and should also be used in gene therapy research. However, interventional trials may have many limitations in terms of design, sample selection, and end points. Moreover, it has been observed that many scientific groups do not publish the results of their clinical trials [16-20]. Nonpublication wastes scientists' funds and efforts to generate data. Clinical trials are expensive, and participants are exposed to adverse events; thus, they should be precisely designed and their results published. If the results of previous trials are unavailable, other scientists have limited opportunities to assess the benefits and risks of similar interventions. Performing a study with a similar intervention may expose participants to unnecessary risk. Taken together, the publication of clinical trial results, even if negative, is not only an important part of the scientific process but also an ethical imperative. Gupta et al [20] analyzed obstetrical and gynecological RCTs registered on ClinicalTrials.gov between 2009 and 2013 and found that less than two-thirds of the trials were completed and only one-third published. The last known review of previous and ongoing clinical trials of GT in PAD, coronary artery diseases (CAD), and HF was performed in 2017 [6]. Since then, no study has described all clinical trials using GTs among noncongenital cardiovascular diseases.

In this cross-sectional study, we aimed to characterize all trials involving human participants utilizing GT for the treatment of noncongenital cardiovascular diseases.

Methods

Ethics Approval

This is a cross-sectional analysis of clinical trial registries and processes found in publicly available data and does not involve human or animal subjects. Therefore, the project did not require Ethical Committee approval. The analysis does not violate the terms of service of the registries used.

Data Collection

We generated a list of clinical trials involving those registered at ClinicalTrials.gov (CT), the International Clinical Trials Registry Platform (ICTRP), and the International Standard Randomised Controlled Trial Number (ISRCTN) databases. We included all studies up to March 15, 2021, which was the date of the data collection. We included only trials that met the following eligibility criteria: (1) those that involved human participants, (2) where at least one of the study arms received gene therapy, and (3) where the study aimed to treat noncongenital cardiovascular disease according to the World Health Organization (WHO) definition [21].

In the CT database, we used the available filters as follows: other terms: "gene therapy," study type: "interventional (clinical trial)," and conditions by category: "heart and blood diseases." In other databases, we typed the phrase "gene therapy" into the search engine. We removed all "noninterventional" studies from .csv file generated from the ICTRP search engine. Furthermore, duplicated registered clinical trials were excluded.

Two authors (WP and ST) independently screened the titles and registry notes of all the generated studies. A third researcher (author MK) resolved any disputes or discrepancies after the initial classification. Additionally, we removed duplicated registered clinical trials.

Data Processing and Statistical Analysis

We read the clinical trial design (study record details) published on the registry and publication if available. We then extracted self-reported study characteristics (eg, study design, trial location, funding source, treated condition, intervention, comparator, age of participants, sample size, initiation date, completion date, completion status, publication status, and outcome measures). In the case of incomplete reporting in some study records, we checked publications for missing information. Trials that were not categorized as single or multicenter were assigned to appropriate groups based on location. If the study claimed to be completed but no publication was linked in the registry, we searched for the registry number, study title, or keywords in PubMed and Google Scholar. We analyzed probable matches for trial design, location, sample size, therapy name, and date of publishing results. We considered those studies with posted results in the registry record or publication in a peer-reviewed journal as published. For all papers with published results, we searched for favorable outcomes. Favorable outcomes were defined as reaching either of the following primary aims: (1) optimal dose was established in early clinical trials, (2) GT showed acceptable safety profile, or (3) GT was better than the comparator in the primary aim or reached the primary aim in single-arm studies. We did not perform a risk of bias assessment on individual studies. In addition, we performed descriptive statistics. The primary outcome was the proportion of completed studies with favorable outcomes. The secondary outcomes included descriptive statistics of the studies' analyzed features. Furthermore, we compared features of clinical trials that either published or did not publish their results. We included only trials that aimed to be completed before the day of data collection, which was March 15, 2021. We used the chi-square test for categorical variables and the Mann-Whitney U test for numerical variables.

Results

We generated a total of 3508 records through database searching: 1032 records from CT, 2279 from ICTRP, and 197 from ISRCTN (Figure 1). We screened 2711 records based on

titles and registry notes. A total of 50 trials with 4436 total participants ultimately met our eligibility criteria. In Table 1, we present the characteristics of the included studies. We distinguished four groups depending on the treated disease: (1) PAD, (2) CAD, (3) HF, and (4) Other (pulmonary hypertension, ischemic cardiomyopathy, and secondary Raynaud's phenomenon). The predominant group was PAD, represented by 20 out of 50 (40%) studies, followed by CAD, with 18 (36%) studies. Most studies (34/50, 68%) were randomized and were performed in multiple places (30/50, 60%), and around half of the trials compared GT with the placebo (27/50, 54%), while one in four were single-arm (14/50, 28%), and the rest concerned dose finding (22%). More than half of the trials (29/50, 58%) were funded by industry. To date, 28 (56%) of the 50 clinical trials published their results (NCT02016755, JPRN-jRCTs053180162, JPRN-UMIN000014918) [7-13,22-40]. Of these, 12 (42.9%) revealed a favorable outcome of the interventions.

We present the results for all analyzed trials in Multimedia Appendices 1-4. One study (NCT00438867; AWARE study; phase III) only recruited females, while the rest included both sexes. All the studies involved only adults. Most studies had wide age ranges, but 2 studies (NCT00956332, NCT00566657) included individuals at least 50 years old. Most of the studies (34/50, 68%) were initiated within the last 10 years (2012-2021). A total of 31 trials were slated to finish before the date of data collection (March 2021). Of these, 22 (71%) were published. Three publications came from ongoing trials with completion dates after 2021 and three from projects with unknown completion dates. The most prevalent vectors were plasmids (25/50, 50%) and adenoviruses (18/50, 36%). GTs were mostly delivered via intramuscular injection (19/50, 38%), intramyocardial injection (17/50, 34%), and intracoronary infusion (11/50, 22%). Eighteen of 50 (36%) GTs transferred vascular endothelial growth factor (VEGF) genes. We did not find information about deaths related to the used GT. All collected variables are presented jointly in Multimedia Appendix 5.

We performed a comparison between published and unpublished clinical trials that should be completed before March 2021 (Table 2). We identified that the published clinical trials were initiated and completed in later years than those that were unpublished. We did not detect any significant differences in the other analyzed variables.

Figure 1. Data collection flowchart. ICTRP: International Clinical Trials Registry Platform, ISRCTN: International Standard Randomised Controlled Trials Number.

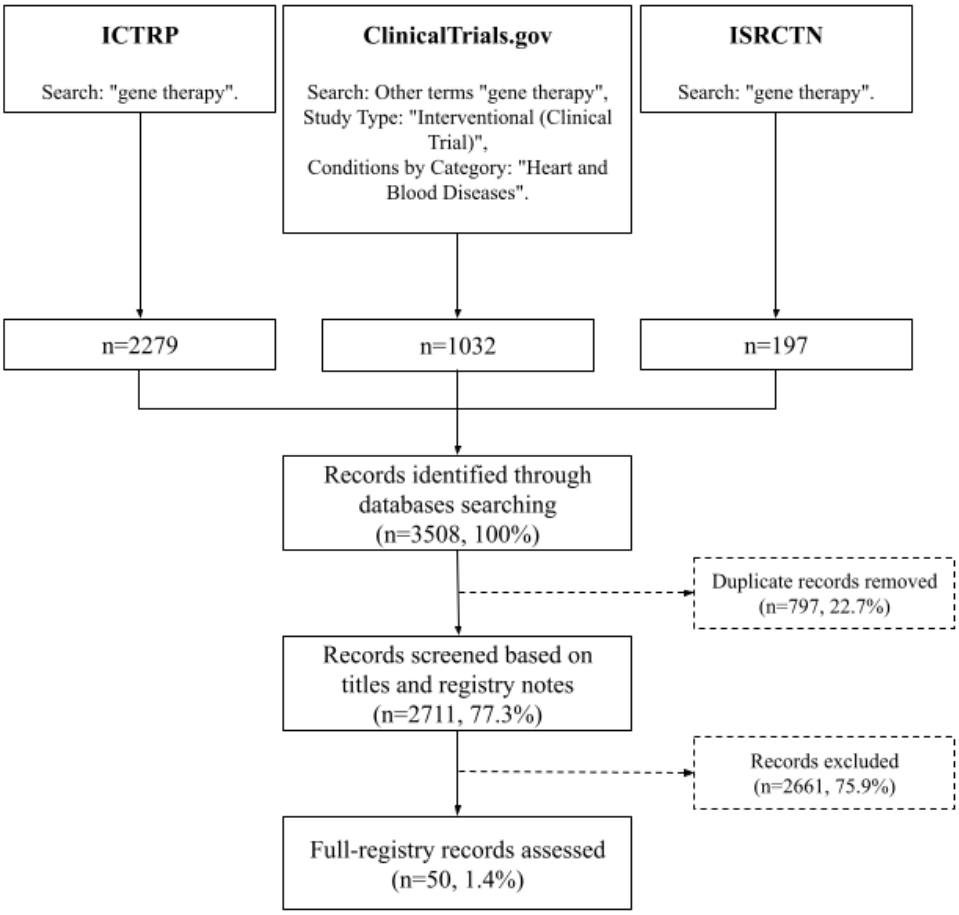

Table 1. Characteristics of included studies on gene therapies in noncongenital cardiovascular studies.

	Total	Peripheral arterial disease	Coronary artery disease	Heart failure	Other
Studies, n (%)	50 (100)	20 (40)	18 (36)	10 (20)	2 (5)
Total participants, n (%)	4436 (100)	2136 (48)	2034 (46)	216 (5)	50 (1)
Study status, n (%)					
Completed	24 (48)	14 (70)	6 (33)	4 (40)	0 (0)
Not completed	18 (36)	5 (25)	7 (39)	5 (50)	1 (50)
Terminated	2 (6)	0 (0)	1 (6)	1 (10)	0 (0)
NA[a]	6 (12)	1 (5)	4 (22)	0 (0)	1 (50)
Funding, n (%)					
Industry	29 (58)	15 (75)	8 (44)	6 (60)	0 (0)
Other	18 (36)	5 (25)	10 (56)	1 (10)	2 (100)
Both	3 (6)	0 (0)	0 (0)	3 (30)	0 (0)
Randomization, n (%)					
Yes	34 (68)	13 (65)	13 (72)	7 (70)	1 (50)
No	13 (26)	5 (25)	5 (28)	3 (30)	0 (0)
NA	3 (6)	2 (10)	0 (0)	0 (0)	1 (50)
Center, n (%)					
Single center	15 (30)	6 (30)	5 (28)	2 (20)	2 (100)
Multicenter	30 (60)	12 (60)	12 (67)	6 (60)	0 (0)
NA	5 (10)	2 (10)	1 (6)	2 (20)	0 (0)
Published, n (%)					
Yes	28 (56)	13 (65)	8 (44)	6 (60)	1 (50)
No	22 (44)	7 (35)	10 (56)	4 (40)	1 (50)
Comparator, n (%)					
Placebo	27 (54)	11 (55)	10 (56)	6 (60)	0 (0)
Dose finding	11 (22)	5 (25)	4 (22)	2 (20)	0 (0)
None	14 (28)	5 (25)	4 (22)	3 (30)	2 (100)
Study phase, n (%)					
I	9 (18)	4 (20)	2 (11)	3 (30)	0 (0)
I/II	11 (22)	2 (10)	4 (22)	4 (40)	1 (50)
II	19 (38)	8 (40)	8 (44)	2 (20)	1 (50)
II/III	2 (5)	1 (5)	1 (5.6)	0 (0)	0 (0)
III	6 (12)	3 (15)	2 (11)	1 (10)	0 (0)
NA	3 (6)	2 (10)	1 (6)	0 (0)	0 (0)
Continent, n (%)					
North America	17 (34)	5 (25)	6 (33)	6 (60)	0 (0)
Asia	13 (26)	9 (45)	4 (22)	0 (0)	0 (0)
Europe	12 (24)	1 (5)	7 (39)	2 (20)	1 (50)
South America	2 (4)	1 (5)	0 (0)	0 (0)	1 (50)
Intercontinental	4 (8)	3 (15)	1 (6)	0 (0)	0 (0)
NA	2 (4)	0 (0)	0 (0)	2 (20)	0 (0)
Favorable outcomes (n=28), n (%)					
Yes	12 (43)	5 (36)	3 (38)	4 (67)	0 (0)

	Total	Peripheral arterial disease	Coronary artery disease	Heart failure	Other
No	16 (57)	9 (64)	5 (62)	2 (33)	0 (0)

[a]NA: nonavailable

Table 2. Comparison between published and unpublished clinical trials on gene therapy in noncongenital cardiovascular diseases completed before data collection (March 2021).

Features	Published (n=22)	Unpublished (n=9)	*P* value
Conditions, n (%)	• Peripheral artery disease, 11 (50) • Coronary artery disease, 5 (23) • Heart failure, 5 (23) • Other, 1 (5)	• Peripheral artery disease, 4 (44) • Coronary artery disease, 3 (33) • Heart failure, 1 (11) • Other, 1 (11)	.58
Number of participants, median (IQR)	• 49.5 (11-100)	• 12.0 (10-52)	.29
Phases, n (%)	• I, 4(18) • I/II, 3 (14) • II, 10 (46) • II/III, 2 (9) • III, 1 (5)	• I, 4 (44) • I/II, 2 (22) • II, 2 (22) • II/III, 0 (0) • III, 0 (0)	.53
Funded by, n (%)	• Industry, 12 (55) • Other, 7 (32) • Both, 3 (14)	• Industry, 6 (67) • Other, 3 (33) • Both, 0 (0)	.50
Randomized	• 14 (70)	• 5 (56)	>.99
Start date, median (IQR)	• 2007 (2004-2012)	• 2015 (2010-2018)	.02
Completion date, median (IQR)	• 2012 (2009-2015)	• 2016.0 (2013-2020)	.03
Continent, n (%)	• Asia, 4 (18) • Europe, 7 (32) • North America, 8 (36) • South America, 1 (5) • Intercontinental, 2 (9)	• Asia, 2 (22) • Europe, 1 (11) • North America, 4 (44) • South America, 1 (11) • Intercontinental, 1 (11)	.80
Single center study, n (%)	• 11 (50)	• 3 (33.3)	.58
Vector, n (%)	• Plasmid, 14 (64) • Virus, 4 (18)	• Plasmid, 7 (78) • Virus, 2 (22)	>.99

Discussion

Principal Findings

In this paper, we characterized all clinical trials on GTs for noncongenital cardiovascular diseases. The trials concerned mostly PAD and CAD, and most had positive traits in terms of good design, including randomization, multicenter design, and placebo as the comparator. Over half of all included clinical trials disclosed their results.

We found that most trials searched for efficient GTs for the atherosclerotic cardiovascular diseases PAD and CAD. GT in PAD was used to stimulate angiogenesis to heal ulcers or increase pain-free distance [6]. The pathophysiology of PAD and CAD results from atherosclerotic cardiovascular disease. Progressive occlusion of small vessels in the heart or limbs causes a decrease of tissue perfusion and consequently cell hypoxia and necrosis. Angiogenesis stimulated by VEGFs offers a potential approach for improving ischemic tissue function by inducing blood vessel growth to restore perfusion and regeneration. Similarly, the stimulation of angiogenesis CAD can improve myocardial perfusion and tolerability of physical activity. However, GT has limited success against these diseases [6]. The most recent meta-analysis from 2013 on GT in PAD did not find clear benefits from the treatment [41]. However, the high number of clinical trials on GT atherosclerotic cardiovascular diseases provides hope that effective GTs will be developed.

The primary cause of HF is a progressive loss of contractile function, which can be caused by both ischemic and nonischemic factors. Understanding how these factors affect heart function is key to developing an effective and targeted treatment. Regardless of its etiology, there is decreased sarcoplasmic reticulum Ca2+-ATPase (SERCA2a) activity in heart failure [42]. Abnormalities in the relaxation and contraction of cardiomyocytes are associated with calcium levels and reduced SERCA2a activity, and they can be treated by

increasing the SERCA2a activity. In the database, we found six studies that used GT with adenoviral vector gene transfer to improve SERCA2a function. A leading cause in HF pathophysiology is an ischemic factor—CAD. The progression of atherosclerosis causes a decrease in the blood supply to cardiomyocytes, tissue damage, and decreased cardiac contractility. Potential treatment methods are VEGFs, which enhance angiogenesis in the ischemic heart [5]. These studies were conducted without favorable clinical outcomes. Another potential GT to treat ischemic cardiomyocytes is stem cell-derived factor 1 (SDF-1). SDF-1 recruits bone marrow-derived stem cells to the site of myocardial injury in a failing heart, where it induces tissue repair [43]. Desensitization of β-adrenergic receptors is another cause of HF, which could be targeted at the molecular level. Downregulation of receptors causes a weaker contraction response and lower levels of cAMP inside cardiomyocytes. This was treated by administering an adenoviral vector, which improved cAMP expression and activation of adenyl cyclase type 6 [44], showing promising results. GT in HF relies mostly on optimizing myocardial contraction and excitation processes and reducing myocardial wall remodeling [5,6,45]. To date, there are no registered GTs on HF, but this area of research is intensively developed, with 4 of 6 published clinical trials on GT in HF revealing favorable outcomes. Therefore, we can expect that future trials will bolster the possibilities of GT in cardiology.

Furthermore, we analyzed the publication rate of the included clinical trials. Approximately one in four completed clinical trials in urology reported results [46]. Liu et al [47] found that only 34% of oncology interventional trials registered on ClinicalTrials.gov published their results. A similar proportion of published clinical trials were noted for obstetrical and gynecological RCTs [20]. A higher publication rate was observed in orthopedic trauma trials (43.2%) [48], National Institutes of Health–funded trials (46%) [18], and RCTs involving patients with rare diseases (48.3%) [49]. However, Bourgeois et al [50] found that up to 66.3% of clinical trials conducted between 2000 and 2006 on anticholesteremics, antidepressants, antipsychotics, proton-pump inhibitors, and vasodilators were published. Moreover, the majority (71%) of large RCTs were published [16]. Considering publication rates from the aforementioned trials, 71% (22/31) of the disclosed results of clinical trials on GT in noncongenital cardiovascular diseases were very high. We speculate that this may be the result of: (1) a high priority given to trials on GT, (2) pressure from sponsors, and (3) the high citation potential of GT trials. However, ~30% of clinical trials that were planned to be completed before 2021 did not disclose their results. We found that unpublished trials were initiated and completed later than those published, which is similar to the previous observations [49]. Moreover, we found that many variables were not described in <10% of the clinical trial records.

In addition, we found that most clinical trials revealed positive traits of good design: 68% (34/50) were randomized, 60% (30/50) were multicenter studies, and 54% (27/50) used a placebo as a comparator. Interestingly, the reported outcomes were mostly negative (16/28, 57%). In the study by Bourgeois et al [50], drug trials funded by industry showed positive outcomes in 85.4% of publications, nonprofit or nonfederal organizations in 71.9%, and government-funded in 50%. However, a higher number of negative trials on GT in noncongenital cardiovascular disease may be caused by the relatively high rate of trials disclosing results.

Future Directions

Further studies may deploy contemporary technologies, including artificial intelligence (AI), to simplify medical data processing. Human-like tasks can now be performed by machines (eg, image analysis, computer-aided diagnosis, patterns, and cost of health care studies), augmenting clinicians' and researchers' work. The power of AI may discover unmeasured confounders and associations impacting publication rates. Therefore, such analyses may help reduce health care costs while improving the overall morbidity and mortality associated with noncongenital cardiovascular diseases [51]. For that to be accomplished, there is a need for a large-scale study based on a database dedicated specifically for RCTs on novel gene therapies instead of several noncompatible databases containing incomplete information about RCT characteristics [52]. It should contain complete data to enable research on factors affecting the publishing rate, outcomes of treatments, quality, and costs of RCTs.

Limitations

We acknowledge several limitations of the study. First, many of the analyzed clinical trial records had missing information. Second, the number of trials that should have been completed before the data collection date was low. For this reason, we could not perform a multivariate logistic regression analysis to indicate independent factors associated with results disclosure. Finally, we did not contact investigators of the trials to verify the status of the projects and the reason for termination or nonpublication of the trial.

Conclusions

Among noncongenital cardiovascular diseases, GTs are mostly investigated in PAD and CAD. Many clinical trials on GT use in noncongenital cardiovascular diseases did not disclose their results. Regardless of the trial phase, less than half of published studies on GT in noncongenital cardiovascular diseases showed promising results.

Data Availability

The data sets used and analyzed in this study are available from the corresponding author on reasonable request.

Authors' Contributions

WP and ST collected the data, performed the formal analysis, prepared the tables, drafted the initial manuscript, and reviewed and revised the manuscript. MK conceptualized and designed the study, collected data, performed formal analysis, performed statistical analysis, prepared tables, interpreted the data drafted the initial manuscript, and reviewed and revised the manuscript. All authors have approved the final manuscript and agree to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of included studies on gene therapies in peripheral artery disease.
[DOC File , 78 KB - formative_v6i4e33893_app1.doc]

Multimedia Appendix 2
Characteristics of included studies on gene therapies in coronary artery disease.
[DOC File , 56 KB - formative_v6i4e33893_app2.doc]

Multimedia Appendix 3
Characteristics of included studies on gene therapies in heart failure.
[DOC File , 31 KB - formative_v6i4e33893_app3.doc]

Multimedia Appendix 4
Characteristics of included studies on gene therapies in ischemic cardiomyopathy and secondary Raynaud's phenomenon.
[DOC File , 22 KB - formative_v6i4e33893_app4.doc]

Multimedia Appendix 5
Detailed characteristics of included studies on gene therapies in noncongenital cardiovascular studies.
[XLS File (Microsoft Excel File), 301 KB - formative_v6i4e33893_app5.xls]

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Abbreviations

AI: artificial intelligence
CAD: coronary artery disease
CT: ClinicalTrials.gov
GT: gene therapy
HF: heart failure
ICTRP: International Clinical Trials Registry Platform
ISRCTN: International Standard Randomised Controlled Trials Number
PAD: peripheral artery disease
RCT: randomized controlled trial
SDF-1: stem cell-derived factor 1
SERCA2a: sarcoplasmic reticulum Ca2+-ATPase
VEGF: vascular endothelial growth factor
WHO: World Health Organization

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Original Paper

Critical Care Nurses' Knowledge of Correct Line Types for Administration of Common Intravenous Medications: Assessment and Intervention Study

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Abstract

Background: There is a paucity of information in the literature on core nursing staff knowledge on the requirements of specific intravenous administration lines for medications regularly given in critical care. There is also a lack of well-researched and appropriate information in the literature for intravenous administration line selection, and the need for filtration, protection from light, and other line-material selection precautions for many critical and noncritical medications used in these settings to maintain their potency and efficacy.

Objective: We aimed to assess the knowledge gap of clinicians with respect to intravenous administration line set material requirements for critical care medications.

Methods: Data were drawn from a clinician knowledge questionnaire, a region-wide database of administered infusions, and regional data on standard and special intravenous administration line consumption for 1 year (2019-2020) from an enterprise resource planning system log. The clinician knowledge questionnaire was validated with 3 groups (n=35) and then released for a general survey of critical care nurses (n=72) by assessing response dispersal and interrater reliability (Cronbach α=.889). Correct answers were determined by referencing available literature, with consensus between the team's pharmacists. Percentage deviations from correct answers (which had multiple possible selections) were calculated for control and test groups. We reviewed all 3 sources of information to identify the gap between required usage and real usage, and the impact of knowledge deficits on this disparity.

Results: Percentage deviations from correct answers were substantial in the control groups and extensive in the test group for all medications tested (percentage deviation range –43% to 93%), with the exception of for total parenteral nutrition. Respondents scored poorly on questions about medications requiring light protection, and there was a difference of 2.75% between actual consumption of lines and expected consumption based on medication type requirement. Confusion over the requirements for low-sorbing lines, light protection of infusions, and the requirement for filtration of specific solutions was evident in all evidence sources. The consumption of low-sorbing lines (125,090/1,454,440, 8.60%) was larger than the regional data of medication usage data would suggest as being appropriate (15,063/592,392, 2.54%).

Conclusions: There is no single source of truth for clinicians on the interactions of critical care intravenous medications and administration line materials, protection from light, and filtration. Nursing staff showed limited knowledge of these requirements.

To reduce clinical variability in this area, it is desirable to have succinct easy-to-access information available for clinicians to make decisions on which administration line type to use for each medication. The study's results will be used to formulate solutions for bedside delivery of accurate information on special intravenous line requirements for critical care medications.

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KEYWORDS

critical care, intravenous medication, compatibility, administration error, infusion maintenance, medication interaction; knowledge; survey

Introduction

Background

There is a paucity of information in the literature on core nursing staff knowledge on the requirements of specific intravenous lines for medications regularly administered in settings such as critical care, coronary care, and high-dependency units. This is matched by the lack of well-researched and appropriate information in the literature on material compatibility, the need for filtration, protection from light, and other selection precautions for many medications administered intravenously in these settings.

Within critical care, and particularly in pediatric and neonatal critical care, evidence is beginning to emerge that incompatibility between medications can cause the precipitation of medications in the venous access device [1], which may result in intravenous access failure or partial occlusion of peripheral access devices and central lines. A recent study [2] showed that venous access occlusion alarms are responsible for 55% of all intravenous infusion pump alarms in neonatal intensive care units and that noninfusion of critical short–half-life infusions (due to such occlusions) has the potential to cause severe cardiovascular instability in critical care patients receiving vasoactive medications. Maintaining line patency and ensuring noninterruption of medications such as inotropes and cardiac glycosides are very much patient safety issues [3].

The problem of limited access and multiple infusions running into a single venous access device is common in critical care, particularly in pediatric and neonatal critical care settings. Fonzo-Christe et al [1] suggested that the filtration of medications might be one method of reducing the risk of precipitation during multiple concurrent infusions; however, the questions—for which medications? and how can we ensure that nursing staff are aware of and able to comply with such requirements?—should be asked.

Critical care costs are high and increasing. Pharmaceutical costs are a sizeable component of these costs. Indeed, in all hospital areas, the price of pharmaceuticals is increasing rapidly year-on-year with a 30.1% rise in per capita spending (adjusted for purchasing power parity) between 2010 and 2018 across Organization for Economic Cooperation and Development nations, despite overall consumption only increasing by 7.1% in the same period [4,5]. Cost reduction approaches undertaken by health care systems, however, often ignore the actual use of these medications once they are purchased; storage, compounding, and administration of these medications are areas in which value and efficacy can be lost and waste can be generated through incorrect medication management.

With some medications, the manufacturer's instructions for administration are clear, but with others, the manufacturer's instructions may give information on storage only, for example, Pfizer's package insert for sodium nitroprusside has very clear statements about the requirement for light-protected administration postdilution [6]; however, the same active molecule marketed as a generic by another manufacturer does not discuss protection during administration [7].

Even if pharmaceutical manufacturers do give adequate guidance on storage and protection of base medications, there is generally much more sparse information available to the end-user postreconstitution or after compounding processes have been undertaken. Furthermore, package inserts will usually remain within the central pharmacy if compounding is undertaken in isolated intravenous clean rooms, as per many accreditation bodies and pharmaceutical safety societies' recommendations for medication compounding and reconstitution [8], and therefore, may be unavailable for consultation by the nursing staff who administer the medication.

The diluent used for intravenous medication compounding and can also change the requirements for protection from light and filtration, for example, epinephrine (adrenaline) is photostable when mixed in normal saline, but it is photolabile when mixed in dextrose solutions [9]. Even well-constructed and researched bedside intravenous administration manuals, such as those of the Royal Children's Hospital in Melbourne [10] and the British National Formulary [11], do not generally include information on material selection, guidance on protection from light, and required filtration of the compounded medication for intravenous administration lines.

Clearly, more could be done in terms of labeling medications requiring special administration lines during centralized compounding processes to give nurses better information on administration. Some intravenous smart pumps carry clinical advisories on their user interfaces, which are customizable for individual medications, and these have been successfully used in failure modes and effects analysis of intravenous medication safety strategies for reducing medication administration errors by users. The user cannot proceed with programming without confirming that they have read the advisory. In one study [12], a medication safety strategy that used centrally applied medication labels from the central compounding service to match the dose, dilution, advisories, and warnings as presented on the patient's electronic medication administration record (aligned with the medication information available on the

automated dispensing cabinet and integrated refrigeration unit and on the intravenous smart pump) was described. The drawback of this approach is that the nurse has often primed the intravenous administration line manually (either by gravity for a volume pump or by manual purge in the case of a syringe driver); therefore, the clinical advisory may be ignored in the interest of convenience, either because a considerable amount of pump programming has already taken place to get to the clinical advisory or in order to avoid wasting the medication that has already travelled through the intravenous administration set (this can be around 20 mL with most volume pump intravenous administration sets, thus, not an inconsiderable amount, particularly in the case of pediatric and neonatal patients).

A second issue is that despite the growth of central intravenous additive services in many facilities many critical care medications are still compounded by nurses at the bedside or in the medication room. Critical care prescriptions are not uncommonly urgent orders, and the consumption of medications can be so large and rapid that even a well-functioning central compounding unit may struggle to keep up with demand.

The above is also based on the assumption that connected and integrated intravenous smart pumps are available to update clinical advisories to match compounding changes. This scenario is rare. Many intravenous smart pumps are not connected to a central server, particularly when they are deployed to dispersed high-dependency beds or to infection-isolation units. Wireless connectivity can facilitate updates, but with older intravenous pumps, updates are dependent on biomedical engineers uploading new libraries manually to each intravenous smart pump [12,13].

A recent survey of sterile compounding errors indicated that 74% of survey respondents were aware of at least one pharmacy sterile compounding error in the preceding 12 months, for the purposes of the current study what was particularly pertinent in the survey was that 41% of these errors involved labelling of a compounded sterile preparation (including omission of administration guidance) and that wrong preparation techniques, including the attachment of an incorrect administration line, were found in 26% of compounding errors [14]. Approximately 30% of the degradation of clear medication solutions due to light occur in the line or tubing of the infusion set [9].

It is a common misconception that all intravenous administration lines are the same. They are not. Incorrect administration line selection by the clinician can cause deleterious changes to the active ingredients in the medication being given. Not only is this potentially harmful to the patient, as chemical change may take place in the medication upon contact and interaction with administration line material (for example, the creation of peroxides when total parental nutrition is exposed to light during administration), but there may also be a significant loss in the efficacy of the medication and degradation of its therapeutic value. Not only is this equivalent to incorrect administration of the medication, it is also potentially a waste of the full monetary value of the medication. There are a small number of papers delineating a significant financial impact to organizations from incomplete intravenous medication dosing and subsequent requirement for redosing [15,16].

Up to 80% of most facilities' infusion activities take place in critical care. This is also an area where stat-prescribing is common, where first doses of many medications are commonly not prepared in pharmacy, and where compounding by nursing staff is also common.

Objectives

The study had 4 goals. First, we wanted to create a verified, reliable, dependable, and easily replicated survey tool to assess the knowledge gap of clinicians in terms of their abilities to select the correct administration set for medications commonly encountered in their care area. Second, we wanted to investigate the gap between what clinicians should seek to apply, in terms of infusion protection through the use of special administration sets and what, in fact, takes place in terms of consumption of these lines across average uses of critical care medications with known requirements in terms of material, filters and light protection. Third, we wanted to be able to use this information to consider solutions in terms of information availability and education leading to consistent and accurate selection of special intravenous administration lines. Finally, we wanted to suggest a strategy to ensure that the medication administration line information given to end users is up-to-date, pertinent, evidence-based, and appropriate for their specific needs.

Methods

Study Design and Data

We collected data using a clinician knowledge questionnaire via web-based survey, direct email request, and in-person (at critical care conferences). To compare perceived or potential usage based on survey responses with real-world critical care usage, regional data on standard and special intravenous administration line consumables for a 1-year period (2019-2020) and the amount of critical care medications, for which special intravenous lines (light-protective, filtered, or low-sorbing) were necessary, were obtained from two sources. We used an enterprise resource planning system log for the Middle East and North Africa. This database comprises 2.2 million infusions given across Europe and the Middle East, which has been previously used in a study on infusion pump alarms [2]. In addition, we reviewed individual hospital accounts.

Clinician Knowledge Assessment Survey

Inclusion and Exclusion Criteria

Nurses working in critical care areas (adult intensive care units, pediatric intensive care units, neonatal intensive care units, high-acuity high-dependency units, and coronary care units) where parental drug administration of the medications addressed in the survey are commonly used were included.

Nursing staff working outside of critical care settings, with the exception of nurse educators and clinical leads with crossover roles within clusters of care areas (applied generally to critical care directorates), were not included.

First Pilot

We prospectively validated the clinician knowledge assessment survey. Prospective validation is widely used in such areas as the production of new and innovative practice guidelines, policies, and clinical decision-making tools to assess them for dependability [17].

The questionnaire was pretested among a convenience sample of clinicians, who were divided into 2 groups (A and B), with moderate to extensive experience with infusion therapy. Clinicians received an email invitation to take part in the survey. Reminder invitations were sent out at 3-day intervals to improve response rates. Our aim was to assess the clarity of wording and to verify the coherence of the questions. The groups were drawn from European, west Asian, and African countries where English was a second language. We evaluated answer groupings from each group and clustering or dispersal of answers. Overall, response dispersal for the survey (Cronbach α=.889) indicated interrater consistency (Cronbach α>.7 is acceptable).

Some minor changes to question language were made at this point in response to differences in answer clustering that may have been related to poor understanding of individual questions. For example, the nomenclature *epinephrine* was added to the survey tool with the original *adrenaline*. Overall, the questionnaire was deemed to be valid because the groups showed similar selection grouping and consistency in their answers. We discussed changing the phrase *light-protective* to *light-sensitive* because a lot of regional educational and guidance materials for nurses use the phrase *light-sensitive* to describe this special type administration line, but for clarity, we rejected the change—although medications may be described as *light-sensitive*, most authoritative texts use *light-protective* to describe administration lines [18]. We also discussed removing the question pertaining to the medication *epoprostenol*, because several respondents had commented that they were not familiar with this medication. We decided to retain the question based on its use in extracorporeal circuit management in many critical care units and its use in neonatal intensive care.

The response rate was 100%; we believe this was due to the succinct nature of the assessment, because respondents could complete it quickly.

Second Pilot

An introduction was added, to give respondents an impetus for completing the survey and to act as informed consent, and the questionnaire was released (Multimedia Appendix 1) in 20 countries via Google Forms, as a second-stage pilot. A total of 15 responses (Group C) were obtained. No further changes were made because good internal consistency was demonstrated and there was no evidence of spurious answers; the pattern of answers was similar to those in the initial pilot (Table 1). Though the number of respondents was small, this group was a useful adjunct because they, like the initial test groups, potentially had access to medication information from the internet. Although they were asked to complete the survey using their own knowledge, there was an opportunity for cheating. Groups A, B, and C formed the control group (n=25).

Table 1. Response dispersal during questionnaire validation.

Question	Medications assessed, n	Group A (n=10)	Group B (n=10)	Group C (n=15)
1	10	Dispersed over 5 choices	Dispersed over 6 choices	Dispersed over 5 choices
2	10	Dispersed over 5 choices	Dispersed over 5 choices	Dispersed over 5 choices
3	4	Concentrated over 2 choices	Mildly dispersed over 3 choices	Concentrated over 2 choices
4	4	Concentrated over 2 choices	Concentrated over 2 choices	Concentrated over 2 choices
5	4	Mildly dispersed over 3 choices	Dispersed over 4 choices	Dispersed over 4 choices
6	4	Mildly dispersed over 3 choices	Dispersed over 4 choices	Dispersed over 4 choices

Test

A test group of respondents (n=72) completed the survey independently. No access to internet information sources was permitted, and respondents were asked to complete the survey independently. The surveys were conducted in 2021 at the World Federation of Critical Care Nurses Congress and the Emirates Critical Care Congress, which were held in Dubai. Analysis of survey results for interrater reliability was undertaken using Minitab (version 18).

In assessing respondents' answers as either correct or incorrect, we defined standard lines as those not made with di(2-ethylhexyl) phthalate, because infusion therapy is moving toward not using the plasticizer *di(2-ethylhexyl) phthalate* due to concerns over its interaction with multiple medications and fluids in even, what may be considered to be, nonspecial infusions [18] and special lines (Table 2), in accordance with definitions used by the other data sources.

Correct answers were defined based on the findings of an extensive literature search (Multimedia Appendix 2), and consensus between the team's pharmacists (RAJ and AC) was required.

Answers from the control and test groups were calculated as percentage deviations from a fully correct selection. This approach was taken due to the nature of the questions, wherein multiple item selections could be made, leading to the chance of multiple wrong and correct selections. The selection of all medications correctly was scored as 0; an incorrect selection was scored –1, and the omission of a correct selection was scored as +1.

Table 2. Definitions and characteristics of standard and special intravenous administration lines [19-22].

Administration line type	Definition	Characteristics	Comments or usage example
Nonspecial line	Standard	• Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride	General medication administration
Low-protein binding 0.2-micron filter	Specialty	• Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride • Polyurethane filter	Amiodarone, total parental nutrition (lipid-free, crystalloid, vamin)
Low-protein binding 1.2-micron filter	Specialty	• Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride • Polyurethane filter	Total parenteral nutrition containing lipid emulsion or lipid infusions
Low-sorbing line	Specialty	• Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride • Polyethylene lined	Insulin, nitroglycerin, alemtuzumab, bleomycin, cabazitaxel, docetaxel, ifosfamide
Low-sorbing line with low-protein binding 0.2-micron filter	Specialty	• Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride • Polyethylene lined • Polyurethane filter	Epoprostenol, alemtuzumab, thiotepa, ofatumumab, panitumumab, cetuximab, paclitaxel
Light-protective	Specialty	• Amber • Not made with di(2-ethylhexyl) phthalate • Made with polyvinylchloride	Adrenaline (epinephrine), amiodarone, labetalol, digoxin, bleomycin, doxorubicin, methotrexate, rituximab, vincristine

Analysis of Intravenous Line Usage and Medication Usage Data

Regional data on standard and special intravenous line consumable usage were grouped by specific characteristics. The amount of medication for which special intravenous administration lines would be required was assayed using a software program (Alaris CQI, version 4.3; Becton, Dickinson and Company).

Mapping between these 2 sources of information was undertaken for evidence of the degree of discrepancy between actual use of special intravenous administration lines in the region and what should have been used assuming full knowledge of the intravenous administration line requirements for the total number of medications requiring special intravenous administration lines given. We suggest that any knowledge deficit identified in the survey of nurses could be an important cause for incorrect use (under or overuse) of special intravenous administration lines identified in the database contrasting.

Results

It became evident that the test group found question 3 to be problematic, despite its interrater consistency; the interrater consistency was acceptable for all other questions (Table 3). Many respondents gave rapid feedback that the question was confusing, because they were confident that none of the medications required filtering. Respondents therefore appeared to have randomly selected 1 incorrect option. The question was, therefore, removed from final survey results.

There was a substantial discrepancy between actual usage (enterprise resource planning data on standard and special intravenous administration line consumable use) and correct usage of medication with special line requirements (Table 4).

Table 3. Interrater consistency (control and test groups).

Question	Item-adjusted total correlation	Squared multiple correlation	Cronbach α
1	0.2299	0.4336	.7923
2	0.7281	0.7493	.6978
3	0.1693	0.5101	.7966
4	0.6414	0.5419	.7117
5	0.6508	0.7266	.7045
6	0.7678	0.6426	.6636

Table 4. Enterprise resource planning and facility consumption and intravenous medication administration requiring special lines.

Specialty line type	Intravenous consumables usage (n=1,454,440), n (%)	Required usage based on medications administered (n=592,392), n (%)
Low-protein binding 0.2-micron filter	0 (0.00)	27,428 (4.63)
Low-protein binding 1.2-micron filter	6600 (0.45)	2987 (0.50)
Low-sorbing line	125,090 (8.60)	15,063 (2.54)
Low-sorbing line with low-protein binding 0.2-micron filter	6000 (0.41)	3407 (0.58)
Light-protective	109,400 (7.52)	60,812 (10.27)

Discussion

Principal Findings

A good example of the absolute need for the correct selection of administration line for a particular medication is that of epoprostenol. This medication requires light protection and 0.2-micron filtration and reacts with polyethylene (which is commonly used in low-sorbing lines). Question 6, which was related to this medication was poorly answered by respondents in the control group (percentage deviation range –19% to 41%) and answered particularly poorly in the test group (percentage deviation range –43% to 93%). Given its extremely short half-life and use of this medication for critical interventions such as extracorporeal circuit management and pulmonary hypertension treatment, degradation of the active molecule due to incorrect line selection has potentially serious effects.

Question 1, which was about medications requiring protection from light, also showed a large deviation in the test group (percentage deviation range –25% to 92%), with multiple omissions including short half-life vasopressors and cardiac medications. The control group (percentage deviation range –13% to 47%) performed far better on this question. Each group was asked to not use internet resources while answering each question, but individuals in the control group were unsupervised during the completion of the survey and may have submitted to the temptation to use medication guides on the internet.

In fact, the test group (Figure 1) consistently performed worse than the control group (Figure 2) for every question (Figure 3). There was no time limit applied to completion of the questionnaire for either group, but the opportunity to review medication guides on the internet or medication manufacturers' package inserts cannot be discounted, and in the study, demonstrates that, although access to information improves performance, there is conflicting information and a lack of hierarchy associated with information on this topic. Reducing clinical variability has been a goal in health care for a considerable amount of time. It is desirable that we verify, concentrate, and distill information for clinicians.

There was a discrepancy between the relative amount of intravenous line consumables that should be used and that being consumed. This was notably evident for consumed (109,400/1,454,440) and required (60,812/592,392) light-protective lines—a difference of 2.75%.

There was reasonable agreement between usage percentages for the low-sorbing line combined with a low-protein binding 0.2-micron filter (consumed: 6000/1,454,440, 0.41%; appropriate: 3407/592,392, 0.58%) and the standard line with a low-protein binding 1.2-micron filter (consumed: 6600/1,454,440, 0.45%; appropriate: 2987/592,392, 0.50%). This may be related to the fact that these are products commonly used for total parental nutrition, either with or without lipids, and that instructions are usually marked very clearly on these products as they are almost exclusively dispensed (and very commonly compounded) by the pharmacy department. It is notable that, in the survey, both the control group (percentage deviation range –22% to 22%) and the test group (percentage deviation range –44% to 44%) showed substantially less deviation for the question on the filtration requirements for total parental nutrition containing lipids than those for the other questions.

Consumption of low-sorbing lines was substantially larger (125,090/1,454,440, 8.60%) than that indicated to be appropriate (15,063/592,392, 2.54%), which may be related to the fact that many facilities in the region use this particular line type for vasoactive infusion administration because the line itself has no lower Y-site, which helps mitigate against inadvertent flushes or push medications being administered into a line that is delivering medications that must be given at a constant and uninterrupted rate.

Figure 1. Tornado distribution plot (percentage deviation from correct selections) for the test group.

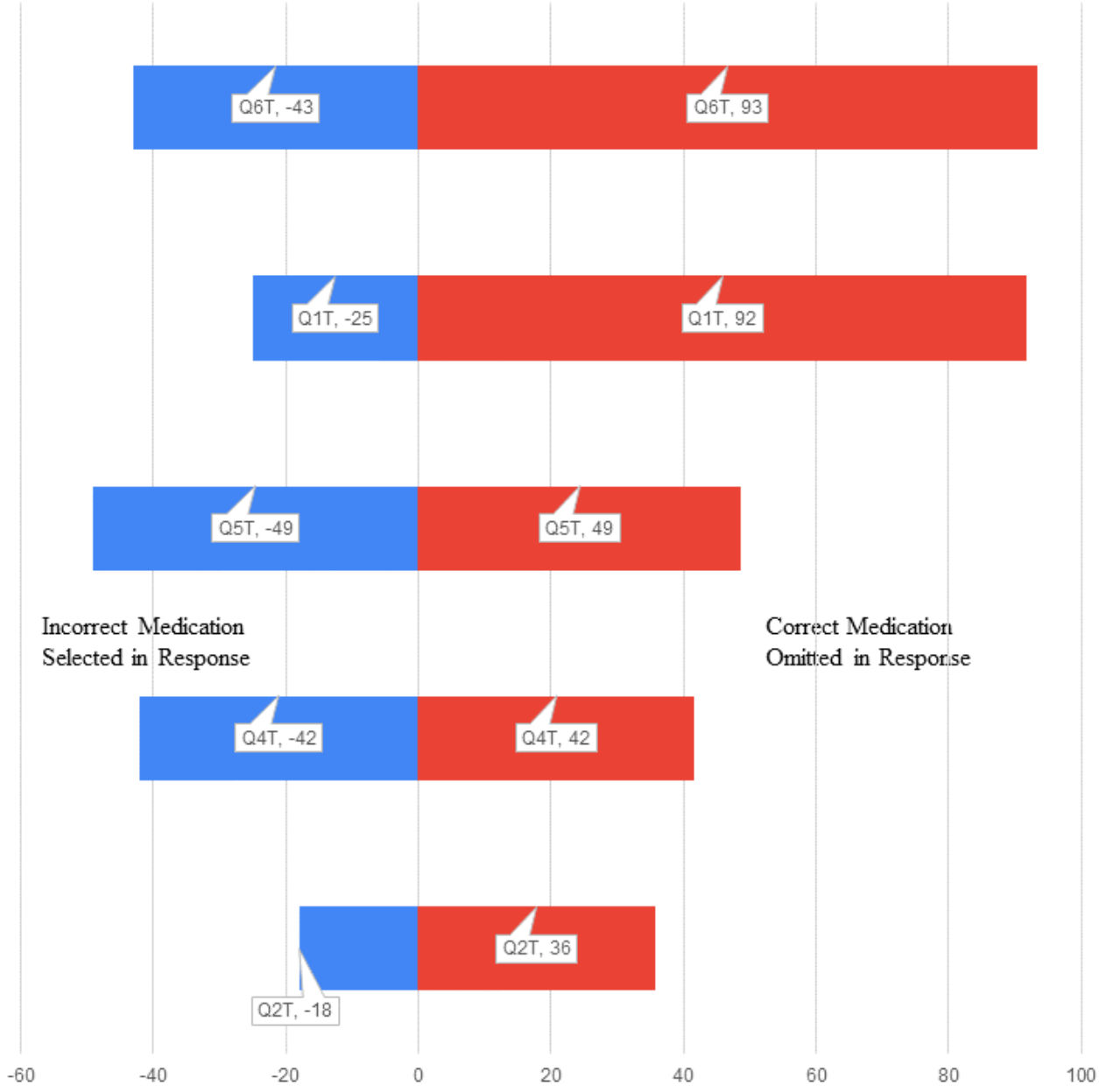


Figure 2. Tornado distribution plot (percentage deviation from correct selections) for the control group.

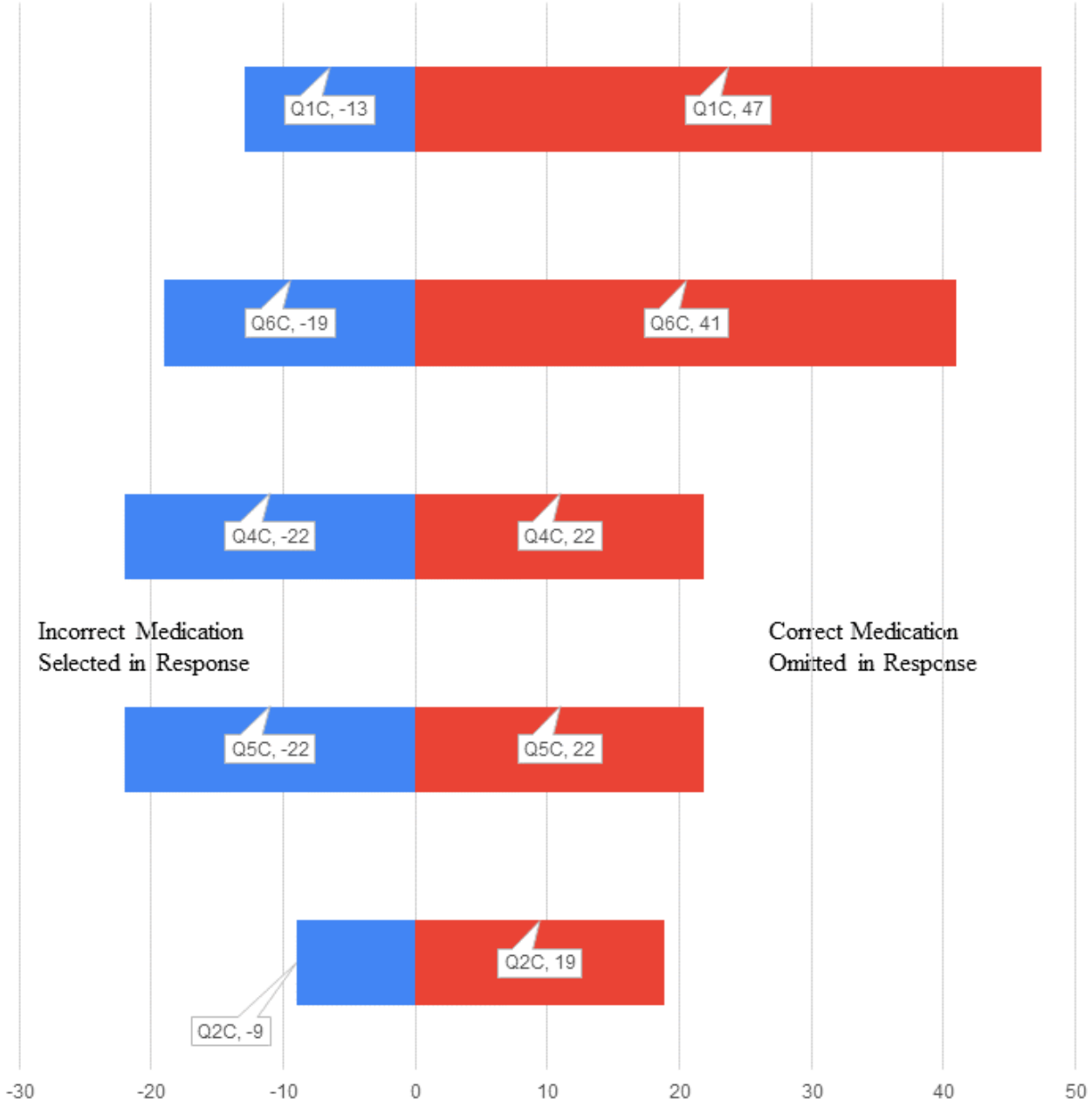
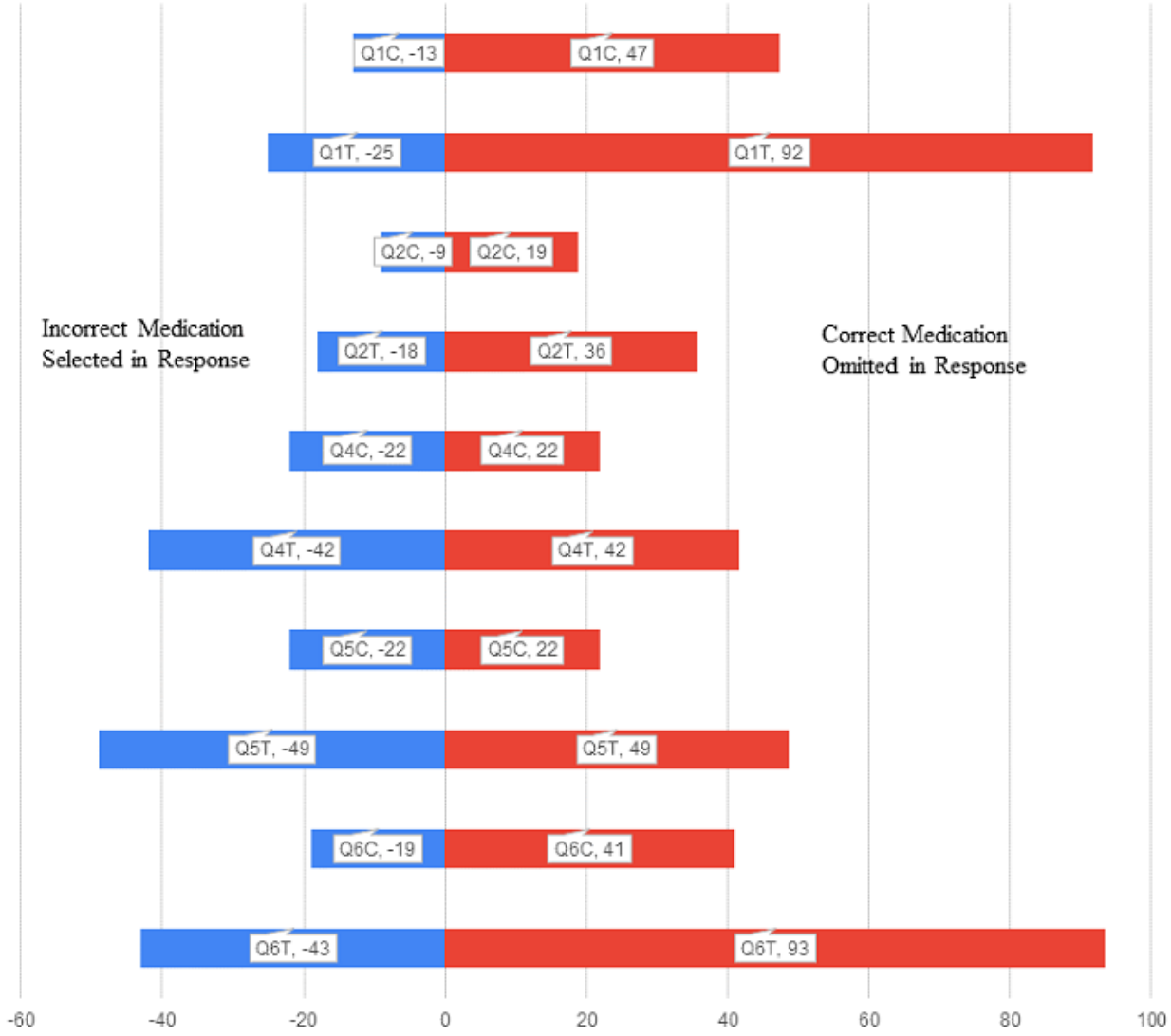


Figure 3. Distribution plots (percentage deviation from correct selections) for control and test groups.



Study Limitations

The study was limited to the Middle East for the main part of the survey, but the control group was composed of clinicians from Europe, the Middle East and Africa. There was certainly a small degree of discussion between some respondents at the in-person survey despite surveyors' requests to complete the survey individually, but this behavior, in fact, imitates nurses' decision-making practices [23].

The test group was predominately composed of nurses who work in intensive care units (all: 44/72, 61.11%; pediatric 14/72, 19.42%; neonatal: 12/72, 16.66%; high-acuity high-dependency: 2/72, 2.81%).

Conclusions

The survey and the review of real-world data and enterprise resource planning data indicated a large degree of clinical variation.

The survey included medications that are in common use throughout critical care, and there was a large difference of opinion among respondents on line type and material required for their administration. This is worrisome, particularly because the medications in the survey are core intensive care unit medications—the risk of incorrect intravenous administration line selection would be expected to increase with unfamiliar medications. The competency pyramid is built on knowledge, skills, and attitude [24]. Competency is difficult to maintain with limited exposure to tasks such as reconstituting and administering uncommonly used medications, and the knowledge environment in which the clinician is operating may also be limited, with no experienced peers or easily accessible information available. In the last two years, we have observed multiple cases of staff working outside of their regular units to meet the needs of expanded critical care units, and crisis conditions that have largely precluded the full supply of central intravenous additive services medications to critical care units.

Furthermore, in critical care, the likelihood of an ideal situation for integrated compounding-administration, with products and information flowing from the central pharmacy to the bedside clinician who receives accurate information from the medication's barcode label, including patient details, drug dose

and volume, and important instructions for administration such as which intravenous administration line is required for safe, effective, and uncorrupted administration, and the product being tracked through connected inventory systems to ensure correct storage of the reconstituted product (particularly those requiring temperature control and protection from light) is unlikely [25]. The Institute for Safe Medication Practices [25] recorded that 28% of respondents to their survey in November 2020 reported "often or always admixing intravenous continuous infusions or titrations, particularly insulin, vasopressors, or lifesaving drug infusions required during emergencies." Much of this reconstitution and mixing takes place outside of the medication room and away from compounding information sources; at the bedside (37%), nursing station desks (28%), and bedside computer workstations (16%) [25].

It is of even greater concern that 53% of the respondents of that survey [25] disagreed or strongly disagreed that their organization requires practitioners who prepare sterile injectable medications and infusions to undergo formal training. Similarly, 49% of respondents disagreed or strongly disagreed that they have been formally trained for the task, and 32% reported no formal training or annual competencies for compounding and reconstitution of intravenous medications [25]. The likelihood of a knowledge gap, not just in terms of dose and dilution but also in terms of administration line requirements for medications, is evident.

The need for a trusted bedside guide for administration line usage and compatibilities is evident. We have known about the ability for handheld and bedside applications to deliver immediate information at the bedside for a considerable time [26]. We suggest that the issue of guidance for administration line selection would be best managed by a handheld device app that could be downloaded to either dedicated facility-owned handheld devices which may have other functions such as barcode reading or alarm routing, or to so-called bring-your-own-device mobile phones or tablets. Any medication and special intravenous administration line guide needs to be accurate, current, and complete. This means that it requires a valid process for both initial and ongoing review. We propose that the best way to manage such a process would be via an initial Delphi panel [27] as this technique is structured around independent work—meetings are kept to a minimum and the participants can be in distant locations and time-zones and still participate. It has also been used to address complex and difficult questions in health care where expert opinion is often the only method of obtaining a cogent outcome, for example, acceptable limits of polypharmacy and types of medication that can be safely prescribed for older adults [28,29]. This could be followed by annual review via the same method. (The initial panel should be tasked with setting this review period.) The findings of this panel could then be incorporated and presented in an easy-to-use guide.

We concentrated on critical care medications, but in the future, we would like to further extend the survey technique to a review of intravenous oncology medications, as this is an area where special administration lines are often required and where loss of efficacy or even debasing of the active molecule has serious consequences for patients and for the facility if cycles of chemotherapy require repeat administration because of incorrect administration [4].

One particular issue with all medication regimens, but one which has a particular resonance with high-value medications and for pediatric oncology, is ensuring a complete dose. Loss of efficacy is a risk, but running infusions to completely empty the intravenous tube of all medication, and thereby, give the complete dose, can also be difficult to manage in a busy ward or outpatient unit, where a single nurse is managing several patients. The choice of administration line can also have consequences here. So-called *short sets* can allow independent intravenous channel rate-control over cytotoxic infusions to run into primary infusions of maintenance or hydration fluids. Administration lines with self-sealing connections that allow the clinician to unlock from a primary bag, lock to the medication to be given, complete the infusion, and run the medication bag dry while avoiding entry of any air into the administration line before switching back to the primary line can help with total delivery, the clinician needs to be aware of them and to know when to use them. Again, a bedside guide that can be consulted prior to medication administration preparation that identifies the material, light protection and filtration requirements, and the most effective administration line would add value.

This formative study was a step toward such a tool. We assayed the extent of the issue of lack of knowledge and information available to nursing staff and compounding pharmacists at the point of care. The survey method would need further development to be able to address pre- and postintervention education, with the addition of nonparametric testing for groups exposed to bedside tools and those who use traditional methods to choosing intravenous administration lines for specific medications.

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Conflicts of Interest

JW is employed in the Medical Affairs Department at Becton, Dickinson and Company. NS is employed in the Medical Affairs Department at Becton, Dickinson and Company.

Multimedia Appendix 1

Questionnaires.
[DOCX File , 36 KB - formative_v6i4e36710_app1.docx]

Multimedia Appendix 2
Questionnaire answers.
[DOCX File , 39 KB - formative_v6i4e36710_app2.docx]

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Original Paper

Design and Evaluation of a Smartphone Medical Guidance App for Outpatients of Large-Scale Medical Institutions: Retrospective Observational Study

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Abstract

Background: The greatest stressor for outpatients is the waiting time before an examination. If the patient is able to use their smartphone to check in with reception, the patient can wait for their examination at any location, and the burden of waiting can be reduced.

Objective: This study aimed to report the system design and postintroductory outcomes of the Tori RinRin (TR2) system that was developed to reduce outpatient burden imposed by wait times before examination.

Methods: The TR2 system was introduced at Tottori University Hospital, a large medical facility that accepts a daily average of 1500 outpatients. The system, which links the hospital's electronic medical record database with patients' mobile devices, has the following functions: (1) GPS-based examination check-in processing and (2) sending appointment notification messages via a cloud notification service. In order to evaluate the usefulness of the TR2 system, we surveyed the utilization rate of the TR2 system among outpatients, implemented a user questionnaire, and polled the average time required for patients to respond to call notifications about their turn.

Results: The 3-month average of TR2 users 9 months after the TR 2 system introduction was 17.9% (14,536/81,066). In an investigation of 363 subjects, the mean examination call message response time using the TR2 system was 31 seconds (median 14 seconds). Among 166 subjects who responded to a user survey, 86.7% (144/166) said that the system helped reduce the burden of waiting time.

Conclusions: The app allowed 17.9% of outpatients at a large medical facility to check in remotely and wait for examinations anywhere. Hence, it is effective in preventing the spread of infection, especially during pandemics such as that of coronavirus disease. The app reported in this study is beneficial for large medical facilities striving to reduce outpatient burden imposed by wait times.

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KEYWORDS

mHealth; outpatient clinics; electronic medical records; COVID-19; EHR

Introduction

For patients undergoing outpatient examination, the wait time from check-in to the start of examination restricts their activity, contributing to mental and physical stress [1-5]. SARS-CoV-2, which causes COVID-19, was first confirmed in 2019 and is spread via droplets through close contact [6-10]. Since COVID-19 is a disease that spreads via droplets, it is important to wear a mask and keep distance among people [11-15]. In

large medical institutions, where many patients have a serious underlying respiratory illness, it is important to prevent in-hospital outbreaks in crowded examination rooms. In recent years, health care apps for smartphones have become widespread in the medical field [16-19]. If patients are able to check-in for their examinations and confirm wait times and queues from their mobile devices, they can avoid crowded spaces as they wait to be seen by a health care provider.

The EasyHos System, designed by Vorakulpipat et al [20], uses patient check-in data stored in hospital information system databases to send notifications to patients' mobile devices regarding their place in the queue for examination. The EasyHos System not only made waiting more convenient for patients but also alleviated work-related burdens on hospital staff. However, it was not introduced at large-scale medical facilities since physicians usually decide the order of examination at such facilities based on the severity of the patient's condition and the arrival of test results, precluding automated notifications of examination start times.

To address this issue, we developed the Tori RinRin (TR2) system, an examination guidance app that can be implemented at large medical facilities. In the TR2 System, a physician can send a notification to an app installed on the patient's mobile phone to call them for examination. This notification is generated while the physician operates the electronic medical record (EMR) screen and reviews information such as the patient's pre-examination test results and check-in queue. This system allows the patient to arrive outside the examination room just before their examination begins, thereby shortening the time spent in the waiting room. The TR2 System is also equipped with a GPS-based examination check-in function that allows patients to check-in for their examination from outside the hospital as long as they are within a 500-meter radius of the hospital. Notifications to patients' mobile devices are sent using a cloud messaging notification function that does not depend on the type of mobile device or operating system.

The inclusion of these features in the TR2 system has enabled its introduction at Tottori University Hospital (TUH), a large medical facility that receives over 1500 outpatients a day. In this study, we aimed to retrospectively assess system design and introduction of the TR2 system to examine the performance of the system's cloud messaging notification function and user registration during the COVID-19 pandemic in order to improve outpatient convenience.

Methods

Experimental Setting

This retrospective study was an analysis of existing, anonymized patient data and materials. According to clinical and epidemiological research guidelines concerning anonymous patient data, ethical review was not required.

TUH, where the TR2 system was developed and introduced, is a medical facility with 40 departments and 697 beds. TUH provides high-level advanced medical care. The TR2 system was developed and named by a research group, which includes the authors of this study who are affiliated with TUH. TUH did not provide a medical guidance application as a countermeasure for outpatient waiting time before the introduction of the TR2 system. The introduction of the TR2 system enabled patients to use an examination guidance app free of charge. The examination guidance app allows users to receive an advance notification message before the start of an examination on their smartphones indicating the expected start time. To promote use of the examination guidance app at TUH, 2 dedicated operators were stationed at the main entrance of the outpatient facility to assist patients in registering for and using the app. For patients who did not have a smartphone owing to financial or other reasons, we rented out an iPod touch with the examination guidance app installed, if desired. There was no change in the waiting order for medical examination regardless of whether the medical examination guide app was used; however, if the patient did not present to the medical examination room when they were notified via the app, the next patient was examined.

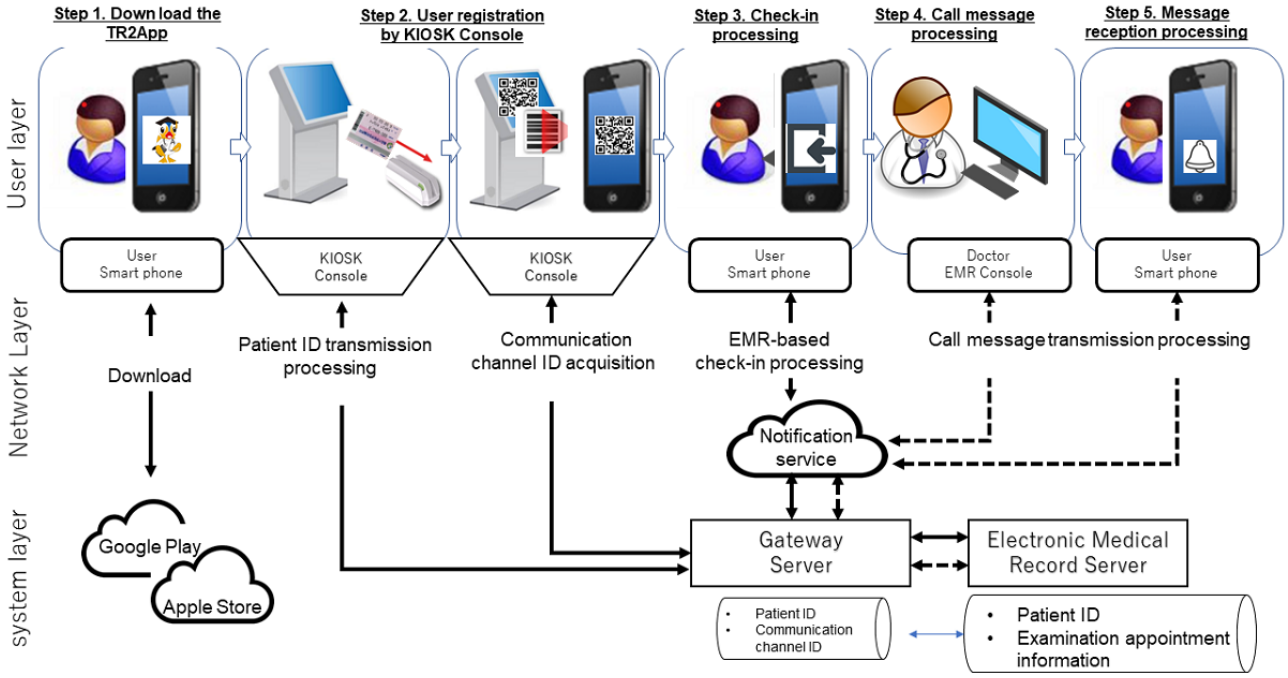
The TR2 system was introduced on a trial basis in 3 clinical departments in July 2019 and started operation in October 2019 for all 40 outpatient facilities.

From July 2020, to prevent nosocomial transmission of COVID-19, TUH has used posters and pamphlets to promote the use of its examination guidance app to help patients maintain distance from others as they wait within the hospital for their examinations.

Outline of the TR2 System

The system processing that occurs from the time of app registration to the time of receiving examination call messages is shown in Figure 1.

Figure 1. Schematic diagram of the Tori RinRin (TR2) system. EMR: electronic medical record.



Step 1: Download the TR2 App

First, outpatients downloaded and installed the examination guidance app (TR2 app) from the internet onto their mobile devices. The TR2 app can be downloaded for free from the Apple Store and Google Play.

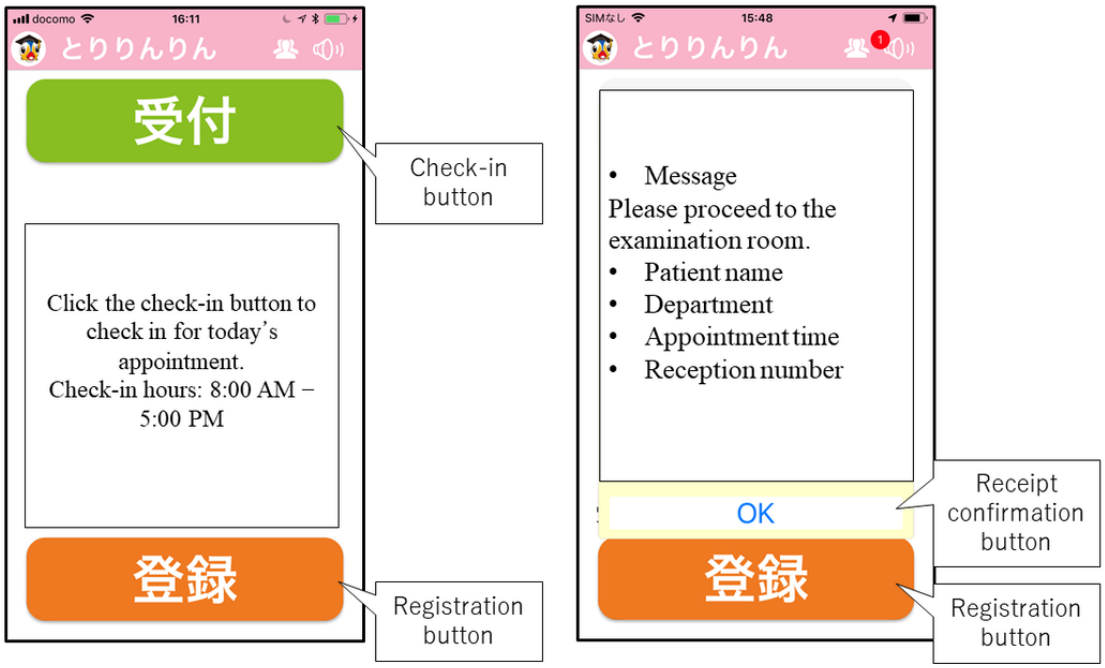
Step 2: Communication Channel ID Acquisition

Outpatients used a barcode reader on a kiosk terminal in the hospital to read the patient ID number on their examination card. kiosk terminals are installed on all floors at which examination check-in is possible. The kiosk terminal sends the patient ID to a gateway server and acquires a communication channel ID. This communication channel ID, issued by Firebase Cloud Messaging (FCM) in the case of Android and by Apple Push Notification service (APNs) in the case of iOS, was used to send a text to the patient's mobile device from their EMR via the internet [21,22]. The patient opened the examination guidance app and read the communication channel ID, which is displayed as a QR code on the kiosk terminal. This series of processes enables the linkage of data between the EMR console and the patient's mobile device.

Step 3: EMR-Based Examination Check-in Using the Examination Guidance App

When outpatients opened the examination guidance app, their location was identified by a GPS function, permitting them to check-in for their examination if they were within a 500-meter radius of TUH (Figure 2). When the outpatient tapped the check-in button on the examination guidance app, a message regarding their examination check-in was sent to their EMR via a gateway server, thereby concluding examination check-in. This operation allowed the physician to confirm that a patient scheduled for an examination that day had arrived at TUH.

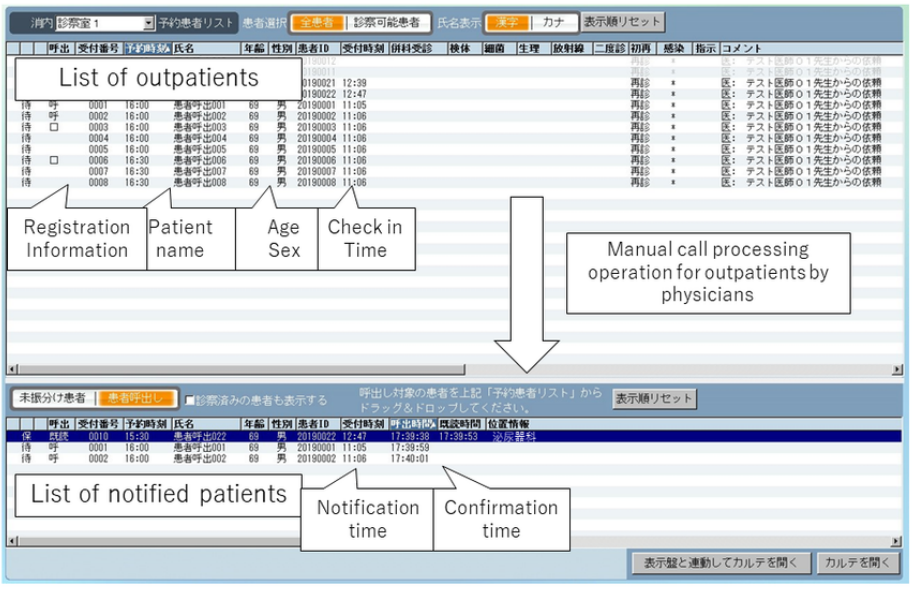
Figure 2. Example screens on the examination guidance app on the outpatient's mobile phone.



Step 4: Transmission of the Examination Call Message From the EMR Console to the Examination Guidance App

The EMR console displays a list of patients scheduled for examination that day; when the physician selected a patient to call from that list, a notification was sent to the patient's smartphone, calling the patient to the examination room (Figure 2). This notification operation is executed approximately 10 minutes before the examination begins. The message is sent via a gateway server as a push notification (Figure 3).

Figure 3. Electronic medical record (EMR)–based notification operation screen used by the physician.



Step 5: Patient Response to the Call Message

Outpatients can receive guidance notifications on their smartphones from doctors before the start of medical examinations. When the patient presses the response button on the call message displayed on their smartphone, the response time is recorded in the "Confirmation time" column of the EMR (Figure 3).

Components Comprising the TR2 System

Table 1 lists the components introduced to run the examination guidance app. The app can be used with both Android and iOS operating systems. To adapt the app to be used by a wide patient age range, the user interface was designed so that all operations can be completed simply by tapping buttons, without the need for flicking or typing. Confirmation operations from examination check-in (Step 3) to the examination call notification (Step 5) can be completed solely by tapping buttons. There were 4 kiosk terminals (1 on each floor) that were operated with a touch panel interface. As the kiosk terminal sent the patient's ID (which is stored in the patient's examination card) to the gateway server, it simultaneously acquired a communication channel ID from the gateway server. The gateway server has a mapping function to associate the patient ID used in the EMR with the communication channel ID and relays text messages to the patient's smartphone via FCM/APNs.

Table 1. Components of the TR2 system.

Name	Use	Source	Hardware: operating system
Examination guidance app	Examination check-in, notification, and guidance	eBase Solutions	Android 8.0/iOS 11 or higher
Kiosk terminal	Data linkage	eBase Solutions	HP ProDesk 400 G6 SF: Windows 10pro
Gateway server	Message transmission, ID mapping	IBM Japan	Windows server 2016 Standard
EMR[a] system	Examination records and patient notification operations	IBM Japan	IBM Power System E950, AIX

[a]EMR: electronic medical record.

Postintroductory Evaluation of the TR2 System

To evaluate the usage of the TR2 system after its introduction, the following parameters were observed: (1) patient response time to the call notification function, (2) the number of registered medical guide apps, and (3) responses to an online questionnaire survey.

Patient Response Time

To evaluate the utility of the app-based messaging service, we investigated the time between notification transmission by the physician to confirmation of the message by the patient. Response time to calls was determined from data recorded in the EMR server database. The target data were collected from 363 people who used the TR2 system for 5 days from February 2, 2020 to February 7, 2020.

Number of Registered Medical Information Apps

From October 1, 2019 to September 31, 2020, we surveyed the number of newly registered patients in the TR2 system on a monthly basis to evaluate app usage. Additionally, from June 2020, as a countermeasure against COVID-19 infection, outpatients were encouraged to use the TR2 system to maintain social distancing. This COVID-19 countermeasure campaign was posted on a poster that recommended the registration and use of the TR2 system at outpatient reception areas of all medical facilities. We compared the utilization rate of the TR2 system in outpatients for the 3 months before and the 3 months after the COVID-19 countermeasure campaign was implemented. The utilization rate was calculated as the cumulative number of outpatients using the TR2 app during the 90-day period divided by the cumulative number of outpatients at TUH during the same period.

Evaluation of Convenience

To evaluate the convenience of the TR2 system, we conducted a questionnaire survey based on a 5-point scale. The question in this survey was "Did the TR2 system help reduce the burden of waiting time?" Respondents to the questionnaire were also able to voluntarily write comments. Respondents were selected by sending an electronic copy of the questionnaire form to patients who used the TR2 system for a period of 5 days from February 2, 2020 to February 7, 2020.

Statistical Analysis

Statistical analyses were performed using R version 3.1.2. Differences in percentages between groups were compared using chi-square tests. *P* values <.05 were considered statistically significant.

Results

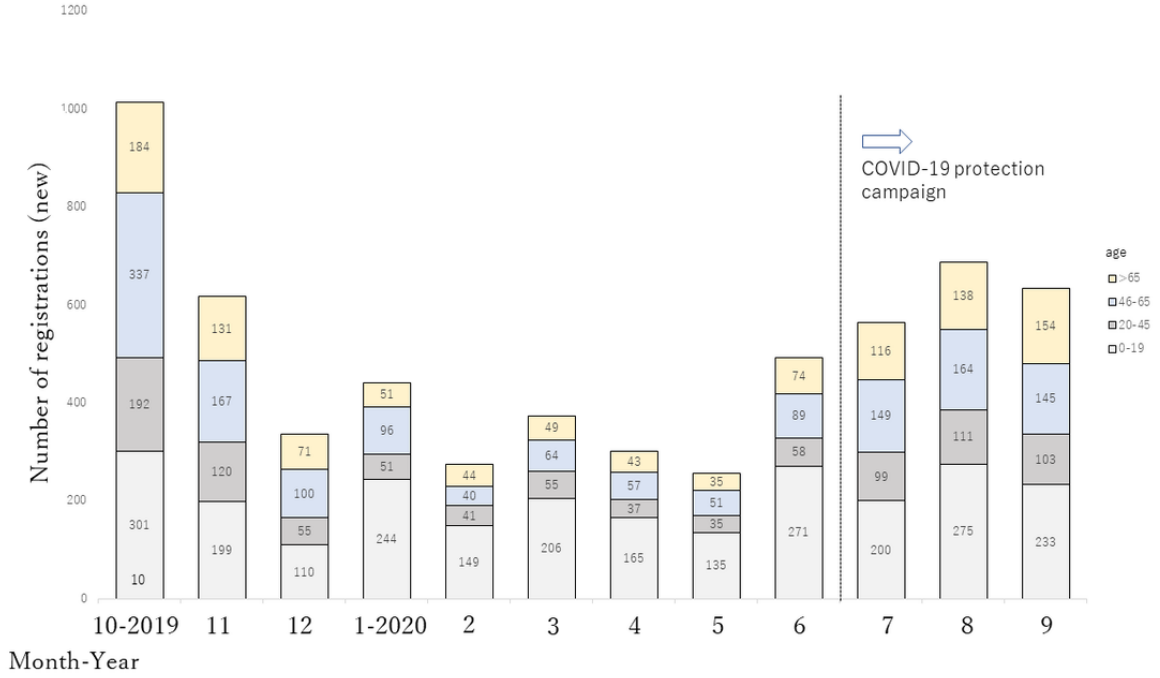
Time From Examination Call Message Transmission to Patient Response

We investigated the time from notification transmission by the physician to confirmation of the message by the patient. This investigation included 363 response times from 363 patients recorded from February 2, 2020 to February 7, 2020. The mean patient response time was 31 seconds, with a median of 14 seconds. Patients took ≥600 seconds to respond to notifications in 19 of 363 cases (5.2%). As a rule, physicians sent notifications 10 minutes before an examination was scheduled to start, and if patients failed to show up to the examination room by the start time, the physician could alter the examination queue.

Changes in the Number of Registered Examination Guidance App Users

A total of 5994 patients registered for the examination guidance app from July 1, 2019 to September 30, 2020 (Figure 4).

Figure 4. Changes in the number of registered examination guidance app users.



From December 2019 to June 2020, the monthly mean number of new registered users was 353 (SD 81). In July 2020, TUH began to promote the use of the examination guidance app to prevent the spread of COVID-19. To assess the effect of promoting the examination guidance app usage as a measure to prevent COVID-19, we compared user registration rates before and after the introduction of the TUH COVID-19 prevention campaign. A comparison of the number of newly registered users for the 3 months before and after the start of the TUH COVID-19 prevention campaign revealed that the number of users increased 1.79-fold after the start of the campaign. Consequently, we found that app usage rate increased significantly from 16.4% (12,444 new registered users of 75,791 total outpatients) prior to campaign introduction to 17.7% (14,536 new registered users of 81,066 total outpatients) after campaign introduction.

Results From the Anonymous Online Surveys of App Users

For the questionnaire survey for users, we decided to send a web-based, 5-point evaluation questionnaire to outpatients using the TR2 app. The number of respondents to the questionnaire was 166 of 363 (45.7%). The 5-point scale for assessing convenience consisted of the following responses: “Strongly agree,” “Agree,” “Neutral,” “Disagree,” and “Strongly disagree.” These responses were given by 82, 66, 15, 1, and 2 patients, respectively. From the results of the 5-point scale, we found that the TR2 system succeeded in its objective of reducing the burden imposed by wait times. Comments from the 41 patients who wrote in the free-response section of the survey were broadly divided into 3 categories (Table 2). From 41 respondents, 17 wrote favorably about the ability to wait for their examination at any location (such as in their cars or the cafeteria) and the ability to check-in for their examinations from outside the hospital. In contrast, the survey also revealed bugs such as notifications not being received by outpatients’ mobile devices.

Table 2. Classification of free-form questionnaire results about the Tori RinRin (TR2) system.

Category	Number of respondents	Responses
Reduction of stress imposed by wait times	17	Being able to wait where I wanted until my examination reduced my stress. Being able to check-in for my examination from outside the hospital was convenient. Being able to avoid crowded spaces while waiting for examinations can help to prevent COVID-19.
Opinions and requests regarding functions	16	I’d like to have an idea of how much longer I have to wait until my examination or how many people are waiting in front of me. They should let us check-in for examinations from more than 500 meters away. I want to know how many people are waiting in front of me so I can avoid COVID-19 exposure in crowded waiting rooms. They should add a page for blood tests and radiological tests. The text should be bigger, and the app should be easy to use.
Bugs in the app	8	I didn’t get an examination call message. The notification sound didn’t stop until I stopped it.

Discussion

Principal Findings

This study assessed the effectiveness of the TR2 system, which was developed to reduce the burden of outpatient waiting time, based on the system's operation and user registration. The study determined patient response time to notifications regarding examination calls, changes in the number of registered users, and users' assessments of the system, all of which revealed the advantages of introducing the system at a large medical facility as well as the associated problems in its implementation.

The examination guidance app's call notification function employs push notifications using cloud messaging services (FCM and APMs). If the patient cannot receive examination call messages via push notifications normally, the outpatient examination queue will be disrupted, resulting in major inconvenience to the physician and patients. Our investigation of patient response times to messages revealed that approximately 5.1% of patients were unable to respond in fewer than 10 minutes; 10 patients reported that their examination notification messages were delayed. Push notifications can convey more information than other forms of notification such as phone calls and can reduce communications costs, which are advantages that have led many companies to adopt push notifications; however, they are highly dependent on individual smart devices. For example, in low power mode in iOS, when the device's battery percentage falls below a certain level, push notifications are delayed [23]. We believe that the cause of 5.1% of delays in response to call messages were because of these smartphone-specific functionalities. One conceivable solution to such problems is to check for delays based on gateway server logs and switch from push notifications to phone calls or text messages when patients do not respond.

Regarding the number of registered examination guidance app users, approximately 12 months after the system was launched, about 6000 patients were registered for the TR2 system.

We learned that the change in the number of users was greatly affected by factors such as the app promotion campaign, COVID-19 pandemic, and outpatient age. Many apps developed to combat COVID-19 use iBeacon and GPS to enable determination of infected patients' contact history and tracking of their actions [14,24-29]. In contrast, while our examination guidance app was not developed with the intention to combat COVID-19, it enables outpatients to wait in the parking lot or anywhere else until their examinations, thereby allowing them to avoid crowded waiting areas, reducing contact among patients and subsequently reducing COVID-19 exposure. As indicated by the results of this study, the number of examination guidance app users increased significantly following the promotion of the app as a COVID-19 countermeasure, suggesting that outpatients had a positive attitude toward using the examination guidance app to prevent the spread of COVID-19. Japan has not yet reported sufficient studies on cases of infection among patients in waiting rooms or on the causes of such infections. We also do not know how effective our examination guidance app is in preventing COVID-19. However, when medical facilities provide examination guidance apps free of charge, patients who are wary of COVID-19 can use their own judgment to avoid crowded spaces and wait elsewhere for their examinations. As revealed in our study, this allows patients to wait where they please and helps reduce their physical and mental stress.

Comparison With Prior Work

Similar examination guidance apps, including the Outpatient Guidance System (OGS) developed by Baek et al [30] and the EasyHos System by Vorakulpipat et al [20], have been previously developed [31]. These systems also send a notification of the day's outpatient schedule (stored in the hospital information system database) to the patient's mobile device. Although the studies that introduced these systems introduced their functions and reported on user registration outcomes and improvements in hospital duties, they did not sufficiently assess how the systems notified patients. Although there are other methods of notifying patients, such as email and phone calls, the rates of patient response to these have not been examined. Therefore, push notifications, which were used in this study, are an effective form of communication for medical facilities, considering the system design and implementation of the TR2 system.

A guidance function that uses iBeacon based on an OGS can determine a patient's location within a hospital. With these functions installed, an examination guidance app can determine the crowding of patients within a hospital (which was not performed in this study) and enable assessment of the app's effects in preventing COVID-19 transmission.

Reported methods for examination guidance other than providing an app, include lending mobile devices to patients. With this method, the initial investment in hardware is extremely expensive. A single mobile device costs approximately US $400, while a management unit costs at least US $20,000. At TUH, where about 1500 outpatients are examined per day, lending out mobile devices would require approximately 1000 devices. Therefore, introducing this system at TUH was estimated to cost about US $420,000. If TUH had developed its own examination app, constructing the system (including the cost to revamp the EMR) would have cost US $120,000. As smartphones have recently exploded in popularity, many of our outpatients already own smart devices. When the initial investment and hardware management costs are also considered, providing an examination call function with an app is advantageous in terms of introduction costs. However, as stated earlier, the causes of defects in the system are difficult to investigate, and operation verification would be required whenever iOS or Android operating systems are updated. Introducing an examination guidance app requires consideration of these merits and demerits as well as consideration of the facility's budget.

Limitations

Clinical features such as sex and underlying disease of TR2 system users were not examined in this study. If the relationship between the clinical characteristics of users and the utilization rate is clarified, it will be useful information for medical institutions targeting specific diseases when considering

introduction of this medical guidance app. By using the EMR of the Gateway server that comprises the TR2 system and the mapping information of the communication channel ID, it is possible to link to the medical care database and analyze the clinical characteristics of each user. In this study, the effects and problems of system introduction on the outpatient clinic have not been completely evaluated. These evaluations will be conducted by polling doctors and outpatient staff using questionnaires.

Conclusion

In this study, we evaluated the introduction and usage record of the medical guidance application TR2 developed to reduce the burden of waiting time for outpatients in large-scale medical institutions. The utilization rate of the app by outpatients 1 year after introduction of the app was about 17.9%. According to the results of the anonymized questionnaire targeting app users, 88% of the users of this system reported a reduction in the burden of waiting time. In addition, by using the TR2 system, outpatients could wait away from crowded places until the start of their medical examinations, allowing the app to be used as an infection control measure in outpatient waiting areas. In the future, in order to prove its effectiveness as an infection control measure, it will be necessary to assess the location of the patient prior to the start of the patient's examination and the congestion of the waiting area outside of the outpatient examination rooms. The results of this study will be a useful index for medical institutions considering the introduction of medical guidance apps.

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Conflicts of Interest

None declared.

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Abbreviations

APNs: Apple Push Notification service
EMR: electronical medical record
FCM: Firebase Cloud Messaging
OGS: Outpatient Guidance System
TR2: Tori RinRin
TUH: Tottori University Hospital

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Original Paper

Developing a Dietary Lifestyle Ontology to Improve the Interoperability of Dietary Data: Proof-of-Concept Study

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Abstract

Background: Dietary habits offer crucial information on one's health and form a considerable part of the patient-generated health data. Dietary data are collected through various channels and formats; thus, interoperability is a significant challenge to reusing this type of data. The vast scope of dietary concepts and the colloquial expression style add difficulty to standardizing the data. The interoperability issues of dietary data can be addressed through Common Data Elements with metadata annotation to some extent. However, making culture-specific dietary habits and questionnaire-based dietary assessment data interoperable still requires substantial efforts.

Objective: The main goal of this study was to address the interoperability challenge of questionnaire-based dietary data from different cultural backgrounds by combining ontological curation and metadata annotation of dietary concepts. Specifically, this study aimed to develop a Dietary Lifestyle Ontology (DILON) and demonstrate the improved interoperability of questionnaire-based dietary data by annotating its main semantics with DILON.

Methods: By analyzing 1158 dietary assessment data elements (367 in Korean and 791 in English), 515 dietary concepts were extracted and used to construct DILON. To demonstrate the utility of DILON in addressing the interoperability challenges of questionnaire-based multicultural dietary data, we developed 10 competency questions that asked to identify data elements sharing the same dietary topics and assessment properties. We instantiated 68 data elements on dietary habits selected from Korean and English questionnaires and annotated them with DILON to answer the competency questions. We translated the competency questions into Semantic Query-Enhanced Web Rule Language and reviewed the query results for accuracy.

Results: DILON was built with 262 concept classes and validated with ontology validation tools. A small overlap (72 concepts) in the concepts extracted from the questionnaires in 2 languages indicates that we need to pay closer attention to representing culture-specific dietary concepts. The Semantic Query-Enhanced Web Rule Language queries reflecting the 10 competency questions yielded correct results.

Conclusions: Ensuring the interoperability of dietary lifestyle data is a demanding task due to its vast scope and variations in expression. This study demonstrated that we could improve the interoperability of dietary data generated in different cultural contexts and expressed in various styles by annotating their core semantics with DILON.

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KEYWORDS

dietary lifestyle data; person-generated health data; ontology; common data element; data interoperability; data standardization; dietary; health informatics

Introduction

Background

Health-related lifestyle data (health lifelog data) provide essential information on one's daily behaviors that directly influence health; thus, such data needs to be used for the management of one's health [1-3]. Health-related lifestyle data are usually captured outside the clinical environment by patients and form a considerable part of the patient-generated health data (PGHD) [4]. Analyzing health-related lifestyle data with clinical, biological, and environmental data may offer additional insights into one's health status [5]. Despite its ever-increasing importance, challenges in data accuracy, data interoperability, and clinical workflow integration have been hindering the utilization of PGHD [6-8].

Capturing health lifelog data in a consistent and interoperable manner is a well-known challenge [9]. Similar to other types of PGHD, data interoperability is a significant challenge to reusing dietary data due to the inconsistent format and the colloquial terms used in describing the data. In addition, dietary data are captured through multiple channels with varying resolutions. One may directly type in the names and amounts of the foods she eats into a food diary app [10,11] or let an artificial intelligence (AI) camera app automatically recognize the type, amount, and nutritional components of the food [10]. Dietary habits are also often assessed using a questionnaire in many clinical or research settings. In this case, respondents need to recall their usual dietary habits for the past week, month, or even year.

The purpose of this study was to build an ontology for dietary behavior to address the interoperability challenge of dietary lifelog data. In particular, this study aimed to construct a dietary lifestyle ontology that incorporates culture-specific dietary concepts and demonstrates its utility in recognizing the data elements designed to assess similar dietary behaviors.

Interoperability Challenges of Dietary Behavior Data

Lack of interoperability is one of the main barriers to using PGHD for patient care [12-14]. PGHD encompasses various health domains and is generated via multiple channels. For example, behavioral health history is collected using health questionnaires, while heart rate, physical activity, and sleep data are automatically captured through wearable sensor devices [15]. Dietary data are collected mainly by direct input from the users, either using a food diary app [16] or a dietary assessment questionnaire [17]. An AI camera automatically captures the type, amount, and nutritional components of the food that one eats, although users still need to confirm the accuracy of the captured information [10]. We may assess eating behavior at each moment of food intake or for a specific period as a health history. Because dietary data are presented in various forms and granularities, standardizing the data is not a trivial task.

Because diet-related lifestyle data are described mainly with nonprofessional terms and a free-text format, standardizing the data becomes more challenging. Dietary questionnaires usually adopt everyday language so that the respondents can easily understand the questions and provide accurate answers. For example, usual protein intake is assessed by asking how often people eat protein-rich food (eg, meat, milk, egg, tofu) in a given period instead of directly asking how many servings of protein they usually have. Therefore, numerous questions can be designed to obtain the same information using different food examples. This approach becomes a barrier to the interoperability of the questionnaire-based data in the nutritional domain unless the food examples are recognized as pointing to the same nutritional components.

Table 1 shows the questions designed to assess the same dietary behavior but with different food examples in different styles. English translations of the two examples from Korean dietary assessment scales are also provided in the table. Systematically identifying and recognizing these assessment items as similar or distinctive is an essential precursor to reusing these data for further analyses.

Table 1. Data elements sharing similar assessment topics.

Questions	Response options	Source	Logical Observation Identifiers Names and Codes (LOINC; version 2.72)
우유나 유제품(치즈, 요플레)을 얼마나 드십니까? [English translation: How often do you have milk or milk product (eg, yogurt, cheese)?]	거의 매일(주6-7일)^가끔(주3-5일)^거의 먹지않는다(주0-2일) [English translation: Almost every day (6-7 times per week), occasionally (3-5 times per week), or rarely (0-2 times per week)]	식습관 평가하기 (대한 영양사 협회) [English translation: Diet checklist (the Korean Dietetic Association)]	N/A[a]
우유나 유제품(요구르트, 치즈) 등을 매일 먹는다. [English translation: I have milk or milk product (eg, yogurt, cheese) every day.]	예^가끔^아니오 [English translation: yes, occasionally, or no]	나의 식생활 평가표 (국가암정보센터) [English translation: My Diet Checklist (National Cancer Information Center)]	N/A
How often do you eat cheese (including on salads or in sandwiches or subs)?	Never or less than one time per month, one time per month, 2-3 times per month, 1-2 times per week, 3-4 times per week, 5-6 times per week, or one or more times per day	Consensus measures for phenotypes and exposures	61441-2
How often do you eat yogurt?	Never or less than one time per month, one time per month, 2-3 times per month, 1-2 times per week, 3-4 times per week, 5-6 times per week, or one or more times per day	Consensus measures for phenotypes and exposures	61457-8
Each time you eat cheese, how much do you usually eat?	less than one slice, one slice, or more than one slice	Consensus measures for Phenotypes and Exposures	61442-0

[a]N/A: not applicable.

Approaches to Standardizing Dietary Behavior Data

Common Data Elements

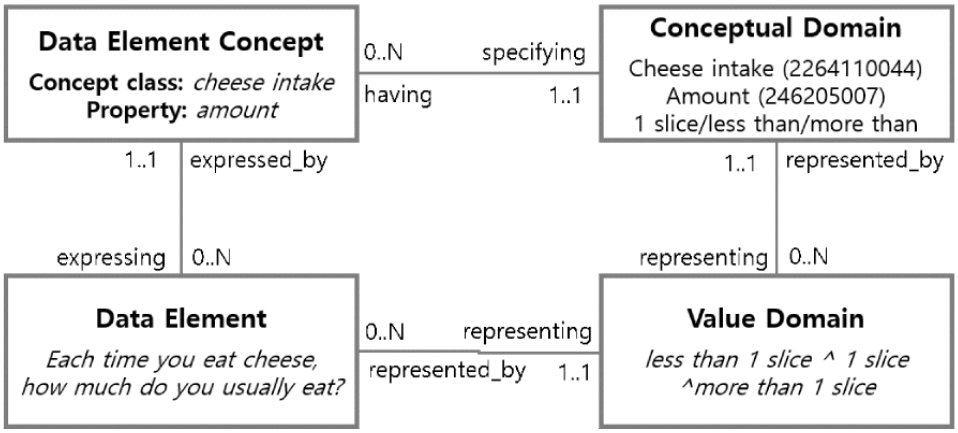
Common Data Element (CDE) is the most popular standardization approach to health-related lifestyle data, especially patient-generated health history data. The National Institutes of Health (NIH) maintains the CDE repository containing various structured data elements that health researchers should consider adopting to produce interoperable data [18]. The CDE repository provides detailed information on a data element, including definition, the development context, and standardized concept mapping with Logical Observation Identifiers Names and Codes if available [18]. The well-organized and reusable CDEs certainly help us address the interoperability challenges of questionnaire-generated data to some extent. However, treating an entire data element as a single concept makes a data element distinctive if it contains a slight variation in the wording of a question or a response option, as shown in Table 1.

Metadata Annotation

The International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 11179 metadata registry (MDR) standard offers a means of attaching more detailed semantic information to data elements [19]. MDR standard-based metadata annotation requires specifying concept layers and representation layers of a data element (Figure 1). Data element concepts are divided into object classes and properties in a concept layer. The data element concepts and the response options (ie, value domain) are coded with standardized terminologies [19]. The concept layer of a data element enables us to identify the data elements that share similar assessment topics and permissible values, which thus can be analyzed together. However, existing standardized biomedical terminology systems provide limited dietary lifestyle concepts (and other health-related lifestyle concepts); therefore, it is hard to achieve complete vocabulary encoding of the concepts identified in the conceptual domain annotation.

Systematized Nomenclature of Medicine (SNOMED) is a comprehensive health terminology containing many health-related lifestyle concepts [20]. Even if appropriate concept codes are available in SNOMED [20], identifying similar or related questions through the conceptual structure of SNOMED is cumbersome because SNOMED is a large and complex system encompassing the broad scope of a health domain. The concepts relevant to dietary lifestyle are indeed scattered across the conceptual structure of SNOMED. In this regard, metadata annotation with the MDR standard alone is still limited in achieving interoperability of dietary lifestyle data, even though it enables capturing more detailed semantic information of a data element with standardized terminology encoding.

Figure 1. The International Organization for Standardization/International Electrotechnical Commission 11179 metadata model (Systematized Nomenclature of Medicine concept ID is included in parentheses).



Ontologies for Food and Dietary Behavior

Multiple ontologies have been developed to serve various food and nutrition domains. A few examples include tracking the food production process [21], representing nutrient-related isotopic information [22], incorporating metabolomics of nutrients [23], systematically organizing culture-specific food names [24], recommending food for global travelers [25], and representing food additives for food safety [26]. Finally, FoodOn is a comprehensive food ontology that aims to be "a farm to fork ontology," encompassing the concepts from food production to the food names in a restaurant menu [27].

Several studies reported adopting a food ontology to support various health management tasks. For example, food recommendation systems that targeted patients with specific chronic medical conditions were built based on food ontologies [28,29]. Applications that monitor one's general behavioral health and provide personalized healthy lifestyle choices were developed based on an ontology covering a dietary domain [30,31]. These studies indicated that ontologies had been actively used to represent dietary concepts in health domains. However, the ontologies used in these efforts primarily focused on describing food names, nutritional components, and the food production process. The existing ontologies have not sufficiently covered the concepts of diet-related lifestyle.

Food Is a Cultural Concept

As a dietary lifestyle, we are primarily concerned about the types, amount, and time of food intake. A dietary lifestyle depends highly on one's culture. Food names, cooking methods, and food preservation methods vary across different regions and populations. Therefore, the scope and the number of concepts of dietary behavior are inherently vast, and developing a single standardized vocabulary system that encompasses all dietary concepts in the world is a daunting task.

FoodOn is a highly sophisticated and comprehensive food ontology covering food sources, categories, products, and manufacturing concepts [27,32]. However, it misses many culture-specific dietary concepts. For example, FoodOn lacks iconic food or common dietary behaviors frequently used to assess Korean people's eating habits. Typical unhealthy dietary patterns in Korea include eating convenience store food, late-night delivery food, and too much hot and spicy instant noodle soups (ramen). Examples of salty food are Jeot-gal and Jang-a-chi, crudely translated in English as salted fish and pickled vegetables. Various seasoned vegetables (namul-muchim) and kimchi are typically considered healthy food in Korean culture. These typical Korean foods and dietary patterns are not included in the food ontology developed in Western countries, including the most comprehensive one like FoodOn. A few culture-specific diet ontologies exist, but their primary developmental goals were to demonstrate modeling domain knowledge with an ontology [33] or organizing specific food names and nutritional components [24]. Therefore, they were not extensible to incorporate dietary lifestyle concepts from different cultural contexts.

Purpose

The primary purpose of this study was to develop a dietary ontology with an extensible concept structure to support the interoperability of dietary lifestyle data from different cultural contexts. This study also demonstrated the utility of this ontology by addressing the interoperability issues presented in a set of ontology competency questions prepared for this study.

Methods

Developing Competency Questions

To guide the ontology development and evaluation process, we first prepared a set of ontology competency questions. The primary purpose of developing a dietary lifestyle ontology in this study is to support the interoperability of questionnaire-generated dietary behavior data by explicitly capturing the main concepts and relationships of a data element. Therefore, we designed the competency questions reflecting the use cases of systematically identifying data elements assessing similar dietary behaviors based on assessment topics or measurement types (Textbox 1).

Textbox 1. Competency questions.

CQ1. Identify the questions by the assessment domain.

- **CQ1.1** questions on protein intakes.
- **CQ1.2** questions on carbohydrate intakes.
- **CQ1.3** questions on unhealthy eating behaviors.

CQ2. Identify the questions by assessment properties.

- **CQ2.1** assessing frequencies.
- **CQ2.2** assessing general degrees.
- **CQ2.3** assessing applicability (ie, true or false).

CQ3. Identify the questions that specify an observation period.

- **CQ3.1** assessing the behavior of the past month.
- **CQ3.2** assessing the behavior of the past 6 months.

CQ4. Identify the questions that share the same assessment domain and property.

- **CQ4.1** questions on the frequency of high-calorie food intake.
- **CQ4.2** questions on the applicability of unhealthy eating behavior.

Collecting Dietary Terms and Concepts From Existing Questionnaires

Diet-related data elements were retrieved from the NIH's CDE repository with “eating,” “diet,” and “nutrition” as search keywords. Korean dietary assessment questionnaires were retrieved from a web search using similar search keywords. These searches yielded 367 unique Korean data elements and 791 unique English ones. Note that the data elements were treated as distinctive unless expressed in precisely the same words and styles, even if they carry the same information. For example, the examples presented in Table 1 were treated as distinctive data elements.

For this study, 2 nursing students and 1 medical informatics student reviewed and curated the questions following the ISO/IEC 11179 MDR standard [19]. This metadata curation includes identifying essential concepts such as extracting data element concepts from the questions and dividing the data element concepts into an object class and properties. The object class and properties were decomposed into atomic dietary concepts when necessary. This concept extraction process yielded 515 unique dietary concepts (224 from Korean data elements, 363 from English data elements, and 72 overlapping Korean and English data elements). The concepts extracted from the questions and the permissible values were the main ingredients for building the dietary lifestyle ontology.

Reviewing Existing Food and Nutrition Ontologies

We reviewed the FoodOn [27] ontology to benchmark its high-level conceptual structure. Major concept branches (or axes), concept categorization schemes, and higher-level class labels were examined and borrowed to construct the backbone structure of the dietary lifestyle ontology. The food product and food transformation process classes of FoodOn provided valuable insights into categorizing food names and food handling methods.

Ontology Building

The authors reviewed the extracted terms and grouped them into broad categories benchmarking the existing ontologies. The broad categories were food items, food preparation or handling, eating behaviors, and descriptors. These top-level categories were further divided into subcategories representing more specific dietary concepts.

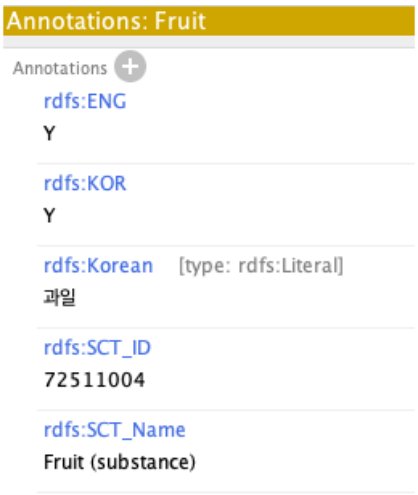
The scope of the dietary domain is vast, spanning from specific food names to physical and mental health status related to food intake. In particular, incorporating the names of all the existing food in the world in this ontology is a demanding and maybe unnecessary task. Therefore, the concept branch that includes food names is structured to facilitate the future addition of food names. The food item class focuses on representing broad types of food, and specific food names were added as instances.

We first built a draft ontology that included every concept we extracted from the text source (ie, 367 Korean data elements and 791 English data elements). We then pruned the ontology by removing the concepts that are too peculiar (eg, salty snack) or already well reflected in other related concepts. For example, we removed “eating out” and kept “restaurant food,” “delivery food,” and “convenience store food.” We also added new concepts to make the concept classes more complete. For example, “appetizer” and “chopstick” were added to the meal course and the utensil classes, respectively, although our text source did not include those concepts.

We built the dietary lifestyle ontology considering the structural component of the ontology quality evaluation and requirement (OQuaRE) [34]. A few examples of the structural elements of OQuaRE include cohesiveness, consistency, lack of redundancy, lack of cyclic structure, and good domain coverage [34]. The concept classes were labeled in English, even those extracted from a Korean questionnaire. All concepts took a singular noun form, and the first character of a concept label was capitalized.

Each concept was annotated with a Korean translation of the concept, language of the concept source (ie, Korean questionnaire or English questionnaire), and SNOMED CT (SNOMED Clinical Terms) concept codes when available. We used the September 1, 2021, version of the US edition SNOMED CT (Figure 2).

Figure 2. Annotation of a concept.



Ontology Evaluation

We evaluated the dietary lifestyle ontology built in this study for concept coverage, structural quality, and utility.

Concept Coverage

We evaluated the concept coverage of the dietary lifestyle ontology with the concepts extracted from the dietary habit questions not used for the ontology building. We pulled 374 concepts from 134 Korean data elements and 92 concepts from 50 English data elements using the same process described in the "Collecting dietary terms and concepts from existing questionnaires" of the methods section. We then examined the extent to which the dietary lifestyle ontology covered this newly prepared set of concepts.

Structural Quality

We evaluated the structural quality of the dietary lifestyle ontology using the ontology Debugger plug-in of Protégé [35] and OntOlogy Pitfall Scanner! (OOPS!) [36]. The Debugger plug-in of Protégé examines the consistency and the coherency of an ontology. If an ontology contains a class defined with two conflicting conditions (ie, unsatisfiable), the ontology is incoherent [35]. At the same time, an unsatisfiable class cannot have an instance that fits the class definition; thus, the ontology is inconsistent [35]. OOPS! is a web-based application that evaluates the quality of an ontology against common errors of ontology authoring based on state-of-the-art ontology authoring principles [37].

Utility

We evaluated the utility of the dietary lifestyle ontology by finding answers to the competency questions (CQs) presented previously. To answer the CQs, we randomly selected 68 dietary assessment data elements that we had analyzed to build this ontology and instantiated them under the data element class. The data element class has two subclasses of question and value set. We instantiated the questions under the question class and their permissible values under the value set class. The question instances took an abbreviated form for simplicity. The complete data element information, such as a full question sentence and the associated permissible value set, was captured as an annotation for better legibility. Figure 3 shows how a data element instance, "how often eat deep-fried foods away from home or take out," is annotated and defined with object properties for the utility testing.

Table 2 presents the object properties constructed to capture a data element's semantics and bind its value set to its question.

We developed query rules with the Semantic Query-Enhanced Web Rule Language (SQWRL) rules to retrieve the data element instances that satisfy the conditions of the CQs. The authors reviewed the query results for accuracy.

Figure 3. An example of the instantiated data elements.

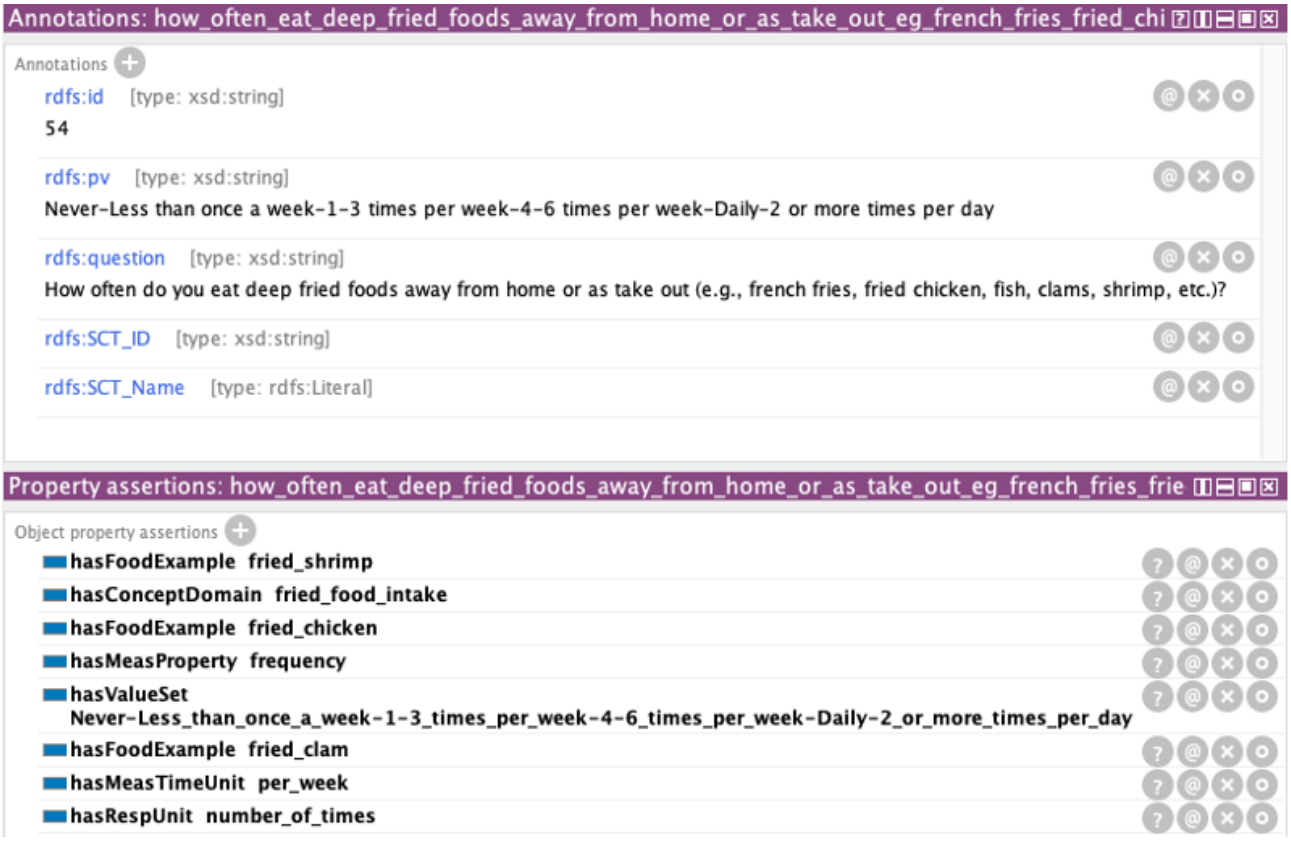


Table 2. The object properties.

Object property name	Purpose	Example
hasConceptDomain	The core topic area of a data element	Fast food intake, dairy food intake, eating speed, etc
hasMeasProperty	The property of the topic area	Frequency, amount, etc
hasFoodExample	Food examples used to explain the core topic area	Yogurt, macaroni, cheese, fruit juice, etc
hasMeasTimeUnit	Unit of assessment duration	Per day, per month, per week
hasObsPeriod	Observation period that a data element represents	Past 3 months, past week, past 6 months, etc
hasRespUnit	Response unit	Number of days, number of times, calories, etc
hasValueSet	A set of permissible values	Less than one cup, one cup (8 ounces), more than one cup

Results

The Dietary Lifestyle Ontology

The Dietary Lifestyle Ontology (DILON) was built with 262 concept classes, 513 instances, and 7 object properties. The final version of the ontology contained 224 concepts from Korean questionnaires, 363 concepts from English questionnaires, and 233 added concepts. Only 72 concepts appeared in both the Korean questionnaires and the English questionnaires. Figure 4 shows the top-level hierarchy and the key metrics of this ontology. The concept hierarchy rendered in Korean is offered with an English translation of each class label.

Figure 4. The top-level hierarchy and key metrics of the dietary lifestyle ontology.

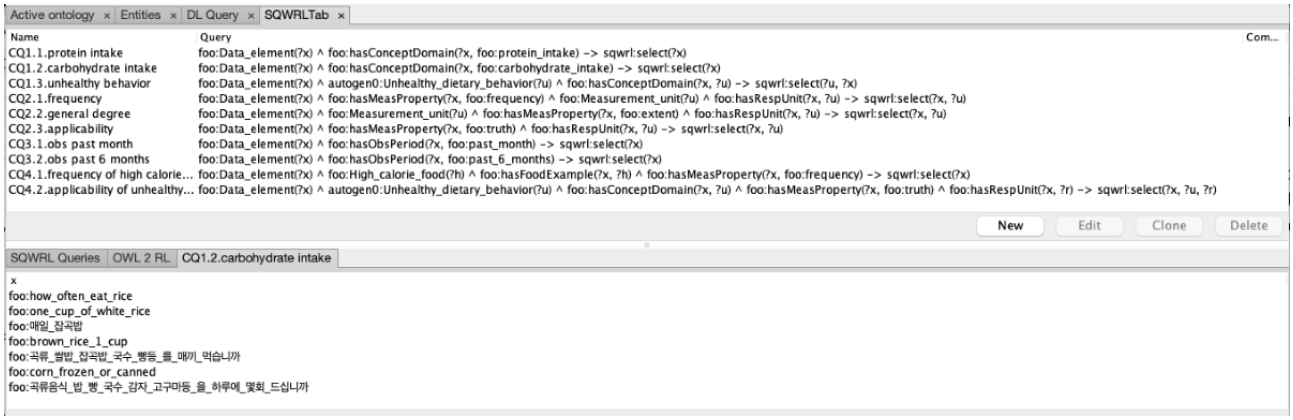
Ontology Evaluation Results

The test of concept coverage showed that DILON covered most of the dietary concepts from the text source prepared for the ontology evaluation. Only 19 concepts from Korean questions and 6 from English questions were not covered in DILON. A few examples of the concepts missing in DILON were green dietary life, food combination, retching, and teaspoon.

The Debugger plug-in for Protégé confirmed that DILON has a consistent and coherent structure. OOPS! suspected that some equivalent concepts were defined as distinctive in DILON. A few examples of the concept pairs that OOPS! suspected as equivalents were regurgitation and vomiting, frying and sauteing, grain and cereal, shellfish and mollusk, and thirst and hunger. Because these concept pairs are not equivalent, we concluded that OOPS! did not find any substantial pitfalls in DILON. DILON is available in the National Center for Biomedical Ontology BioPortal [38].

The SQWRL [39] implementation of the competency questions is presented in Figure 5. The SQWRL queries correctly identified the data elements that meet the conditions specified in the CQs. The SQWRL query results demonstrated that it is possible to systematically identify the data elements that share similar assessment topics, measurement methods, and response types when the main concepts of the data elements are annotated with DILON. The full results and SQWRL queries are presented in the supplementary file.

Figure 5. CQ evaluation using SQWRL. CQ: competency question; SQWRL: Semantic Query-Enhanced Web Rule Language.



Discussion

Principal Findings

This study demonstrated improving the interoperability of questionnaire-generated dietary lifestyle data using the proposed ontology DILON. Dietary concepts and their relationships in DILON are useful for resolving the challenges introduced when treating an entire diet-related data element as a single concept. Explicitly capturing the core semantics of a data element with the concepts and the object properties of DILON enabled us to identify the data elements that carry similar information. It is an important step toward achieving interoperability of questionnaire-generated data that can have many variations of expression for the same information.

Eating food is a cultural concept. Thus, diet-related concepts such as food names and dietary patterns vary by culture. We observed clear distinctions in food examples between Korean questionnaires and English questionnaires. FoodOn is an extensive and highly comprehensive system. Although FoodOn contains the Cultural Food Product class, this class includes only twelve food examples as subclasses. The Prepared Food Product class of FoodOn contains a long list of cooked dish names. Some of those cooked dish names are generic (eg, leafy vegetable, potato soup, sandwich), and some have a specific cultural origin (eg, brochette, chow mein, tataki). The Prepared Food Product class probably does not intend to be a complete list of culture-specific food names; thus, most typical food names from specific cultures are missing. Consistent and unambiguous representation of various food names and their nutritional information is crucial for analyzing and interpreting dietary behavior data. Of note, only 54% of the dietary concepts in DILON were mapped to SNOMED CT.

Developing a single comprehensive dietary ontology covering all food and dietary behavior concepts is a daunting task. Instead, a more feasible approach is creating a smaller yet extensible ontology representing the dietary concepts required for a specific task or a given cultural context. In addition, separating the portions common to any cultural contexts from those culture-specific would make an ontology easily extensible and later integrable with other specialized food ontologies when the need arises. For that reason, in DILON, dietary concepts common to any cultural context were created as classes with a relatively simple hierarchy, and food names were included as instances. DILON does not intend to be a comprehensive culinary taxonomy. Therefore, complex hierarchical information among food types is omitted in DILON to keep the concept structure manageable.

Many apps offer efficient ways to capture dietary intake patterns and produce additional information such as nutritional components and calorie intake. Nonetheless, questionnaire-based assessment is still helpful for capturing general patterns of dietary behavior and diet-related health history. The dietary ontology like DILON may also facilitate the integration of app-generated data and questionnaire-generated data.

Limitations

This study has several limitations. The first is using the relatively limited text sources to identify dietary lifestyle concepts. DILON was built with the terms and concepts collected from existing food ontologies and a limited number of dietary assessment questionnaires. Therefore, the current version of DILON is a small system with relatively limited content coverage, and continuous augmentation is warranted. The second is methodological scalability. DILON was developed through a manual process. Thus, the methods adopted in this study may not be scalable. We need to establish an algorithmic strategy to facilitate continuous update and augmentation of DILON. The third limitation is the scope of the utility testing. The utility testing of DILON depended on the competency questions that reflect a narrow spectrum of interoperability challenges. Therefore, the utility of DILON in addressing interoperability challenges of dietary data needs to be demonstrated through a real data integration use case in a future study.

Conclusions

Dietary lifestyle data offer crucial information on one's health, but the interoperability challenges are a significant barrier to reusing the data. The vast scope of dietary concepts, the colloquial style of expression, and the various cultural contexts reflected in dietary lifestyle data make standardizing the data a demanding task. This study showed that we could improve the interoperability of the dietary lifestyle data generated from questionnaires in different cultural contexts by annotating essential semantic information of dietary data elements with the dietary lifestyle ontology DILON.

Acknowledgments

HK designed the study, built and validated the ontology, and wrote the manuscript. JJ prepared and analyzed dietary concepts, built the ontology, and edited the manuscript. JC prepared and analyzed dietary concepts, evaluated the ontology, and edited the manuscript. We thank Yoobin Kim, Jina Lee, and Nayoung Kim for helping with corpora preparation. This study was supported by the New Faculty Startup Fund from Seoul National University.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semantic Query-Enhanced Web Rule Language result table.
[DOCX File , 32 KB - formative_v6i4e34962_app1.docx]

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Abbreviations

AI: artificial intelligence
CDE: Common Data Element
CQ: competency question
DILON: Dietary Lifestyle Ontology
IEC: International Electrotechnical Commission
ISO: International Organization for Standardization
MDR: metadata registry
NIH: National Institutes of Health
OOPS!: OntOlogy Pitfall Scanner!
OQuaRE: Ontology Quality Evaluation and Requirement
PGHD: patient-generated health data
SNOMED: Systematized Nomenclature of Medicine
SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms
SQWRL: Semantic Query-Enhanced Web Rule Language

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Original Paper

Blended Treatment for Alcohol Use Disorder (Blend-A): Explorative Mixed Methods Pilot and Feasibility Study

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Abstract

Background: In Denmark, approximately 150,000 people have alcohol use disorder (AUD). However, only approximately 10% seek AUD treatment, preferably outside conventional health care settings and opening hours. The AUD treatment area experiences low adherence to treatment, as well as high numbers of no-show and premature dropouts.

Objective: The purpose of the Blend-A (Blended Treatment for Alcohol Use Disorder) feasibility and pilot study was to describe the process of translating and adapting the Dutch treatment protocol into Danish and Danish culture with a high amount of user involvement and to report how patients and therapists perceived the adapted version, when trying it out.

Methods: The settings were 3 Danish public municipal outpatient alcohol clinics. Study participants were patients and therapists from the 3 settings. Data consisted of survey data from the System Usability Scale, individual patient interviews, and therapist group interviews. Statistical analyses were conducted using the Stata software and Excel. Qualitative analysis was conducted using a theoretical thematic analysis.

Results: The usability of the treatment platform was rated above average. The patients chose to use the blended treatment format because it ensured anonymity and had a flexible design. Platform use formed the basis of face-to-face sessions. The use of the self-determined platform resulted in a more thorough process. Patient involvement qualified development of a feasible system. Managerial support for time use was essential. Guidance from an experienced peer was useful.

Conclusions: This study indicates that, during the processes of translating, adapting, and implementing blended, guided, internet-based, and face-to-face AUD treatment, it is relevant to focus on patient involvement, managerial support, and guidance from experienced peers. Owing to the discrete and flexible design of the blended offer, it appears that it may reach patient groups who would not otherwise have sought treatment. Therefore, blended treatment may increase access to treatment and contribute to reaching people affected by excessive alcohol use, who would not otherwise have sought treatment. In addition, it seems that the blended offer may enhance the participants' perceived satisfaction and the effect of the treatment course. Thus, it appears that Blend-A may be able to contribute to existing treatment offers. Such findings highlight the need to determine the actual effect of the Blend-A offer; therefore, an effectiveness study with a controlled design is warranted.

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KEYWORDS

alcohol use disorder; blended treatment; usability; patient perceptions; therapist perspectives; mobile phone

Introduction

Background

The long-term consequences of alcohol consumption include the risk of developing somatic diseases such as liver cirrhosis, cancer, and cardiovascular disease [1]. Furthermore, untreated alcohol use disorder (AUD) is associated with employment problems, economic burden, high rates of domestic violence, and reduced quality of life [2].

In Denmark, there is general agreement as to what constitutes high-quality treatment of AUD. National and international clinical guidelines recommend evidence-based psychological treatments such as cognitive behavioral therapy (CBT) and motivational interviewing (MI) [3]. Overall, treatment for AUD is easily accessible in Denmark and is free of cost to the patients, in addition to the possibility of patients staying anonymous during the treatment course [4].

The gap between the number of individuals with AUD and those receiving treatment is large [5,6], and those who seek treatment do so when their alcohol dependence is advanced [7]. Among people with persistent AUD, approximately one-fourth do not seek treatment even though they could benefit from it [8]. The reasons for the treatment gap and treatment delay are considered to be that treatment seeking is attached to stigma [9,10], but barriers to treatment seeking also include practical issues, lack of knowledge about treatment, and simply not wishing to stop drinking [11]. Many individuals who seek professional help to curb their alcohol problems have been reported to prefer to receive treatment outside conventional treatment settings and opening hours [12].

Internet-based treatment may be one way to minimize barriers to treatment seeking and increase access to evidence-based treatment for mental health and addictive disorders [13-15]. The potential benefits of internet-based psychological treatment modules include ease of access, cost efficiency, and ability to reach a wide range of users [16]. In particular, guided internet-based treatments have attracted interest during the last decade. Guided internet-based treatment involves a certain level of contact with a therapist, typically via asynchronous chat, text messages, or emails and may function as an important and effective treatment strategy [17,18]. Qualitative studies show that feedback and personal support are perceived positively by patients and keep them motivated [19,20]. Thus, although unguided treatment in some cases may also demonstrate good effect [21], guided internet-based treatment is overall the most promising [22].

Access to personal feedback and to a therapist are features associated with larger effects in a meta-regression of internet-based alcohol interventions [23], and a correlation has been found between personal support in internet-based interventions and positive clinical outcomes and compliance with treatment [24,25]. Departing from this observation, adding internet-based modules to face-to-face treatment [26] or combining face-to-face treatment with internet-based therapy into one integrated and blended treatment protocol has also attracted interest [27-30]. In the blended treatment approach, part of the face-to-face treatment is replaced by internet-based components, while the traditional face-to-face relationship between the therapist and patient is retained. The face-to-face element is considered to ensure that patients benefit from a supportive therapeutic relationship, which is likely to increase their motivation to complete treatment [31,32]. Internet-based elements may provide flexibility, allowing patients access to the treatment modules at the time of their choosing. The increased personal responsibility that comes with such flexibility is also reported to give patients a sense of autonomy and empowerment [33]. Furthermore, through the internet-based platform, therapists can provide feedback to patients and help them stay on track with treatment [31,34].

Pilot studies have found that offering personal support and guidance during web-based addiction treatment in a blended fashion is associated with higher completion levels, increased clinical outcomes, and cost-effectiveness [24,28,35]. Thus, blended treatment may provide a delivery format capable of reaching out to people not inclined to show up for treatment as well as keeping clients motivated during the treatment. In Denmark, however, neither therapist-guided internet-based treatment nor blended treatment for AUD is implemented in the daily clinical routine.

Blended Treatment at Jellinek

The Dutch addiction treatment clinic, Jellinek, is one of the largest treatment institutions in the Netherlands. Since 2011, Jellinek has been offering blended treatment in routine addiction treatment, and currently, 50% of the patients seek AUD treatment (N=800 per year). Jellinek developed a platform for AUD treatment together with a provider of treatment platforms for internet-based CBT. The platform treatment manual combines face-to-face and internet-based therapy into one integrated protocol [27-29]. The content of the blended protocol is similar to the face-to-face AUD treatment offer, based on evidence-based manuals for MI and CBT [3,36]; the elements are quite similar to the CBT modules in the manual used in project Combine [37]. The blended treatment consisted of a fixed set of sessions, with weekly alternating face-to-face sessions and sessions on the web (approximately 50%:50%) with web-based feedback from the therapist. Sessions on the web were delivered through a secure internet-based treatment platform.

The Jellinek blended treatment approach has not yet been investigated in effectiveness trials, but continuing quality monitoring indicates that treatment compliance is improved when combining face-to-face sessions and internet-based modules with therapist feedback. Dropout rates are lower; patient satisfaction is high; and patients are generally more actively involved in their treatment, spending more time on homework assignments compared with regular face-to-face treatment. Concerning expenditures, Jellinek saw no higher

costs per patient compared with regular face-to-face treatment. Furthermore, Jellinek clinics experience increased treatment fidelity to the treatment protocol because of the increased structure in treatment planning and integration of internet-based modules. Thus, although not properly evaluated, the Jellinek blended treatment approach seems to be meaningful, feasible, and promising.

The Blend-A Study

After a study visit to the Netherlands, we decided to implement and evaluate the treatment approach used at the Jellinek clinics because (1) our impression of the blended treatment protocol was good, (2) the content covered recommendations in Denmark, and (3) both the management and staff at the Jellinek clinics described it as possible to implement in an outpatient treatment structure that is rather similar to the Danish treatment structure. As the Dutch treatment protocol was already digitalized and implemented in the Netherlands, it seemed out of proportion to start from scratch and develop a new treatment protocol to be implemented in Denmark.

As Denmark is *naïve* in making use of internet-based tools in the treatment of AUD, Blend-A (Blended Treatment for Alcohol Use Disorder)—the Blend-A study was developed as an opportunity to evaluate the blended, guided, internet-based, and face-to-face treatment of AUD in Danish settings on a large scale. However, as a predecessor to the Blend-A study, a feasibility study was needed to minimize the need for further adjustments of the treatment platform and work schemes in a large-scale study.

The Blend-A feasibility and pilot study was therefore initiated to develop the Danish version of the Jellinek treatment platform and translate the treatment protocol from Dutch into Danish language and culture; thus, the content of the 2 programs was quite similar. Furthermore, it was initiated to carry out preliminary tests, early phase implementation, and evaluation in 3 AUD treatment clinics. As the research literature typically neither includes a description of the practical process of translating and adapting interventions nor how therapists and patients experience the use of such new internet-based tools, we also decided to collect a series of data in the process, thus making it possible to report our experiences.

Aim

The aim of this study was to describe the (1) process of developing and adapting the platform and content, (2) therapist and patient experiences of the platform and content during development, (3) implementation of the Blend-A pilot platform, and (4) pilot testing of the platform with new patients and subsequently, to examine the (1) usability of the platform, (2) patient perceptions of a blended treatment course involving the platform, and (3) therapist's perspectives on blended treatment involving the platform.

Methods

Design

The design of the Blend-A feasibility and pilot study was explorative and performed as a mixed methods study [38] based on data obtained from observations, structured questionnaires, semistructured individual patient interviews, and unstructured therapist group interviews.

Settings

The Blend-A feasibility and pilot study was conducted in collaboration with three public outpatient alcohol clinics in Southern Denmark: Haderslev, Kolding, and Svendborg municipalities. These clinics are comparable with all publicly funded clinics in Denmark. The treatment was in an outpatient setting, and the staff consisted of a multidisciplinary team of nurses, social workers, and psychiatrists. Therapists are trained in MI and CBT, receive supervision on a regular basis, and follow clinical guidelines. During a normal face-to-face treatment course, patients are initially offered detoxification, if needed. During the acute phase of treatment, they are offered MI and pharmacological treatment, if needed. When withdrawal symptoms have been treated, the patients undergo an assessment interview and are offered individual CBT. Normally, therapy sessions take place every other week and last for approximately 1 hour. The patients underwent status sessions every 3 months, and the treatment course was evaluated. A standard treatment course is planned to last for approximately 3 months but is typically prolonged, if needed [39].

Participants

From the 3 clinics, 7 therapists participated in the Blend-A feasibility and pilot study, constantly with 2 from each clinic. In the development and adaptation phase of the Blend-A pilot platform, 3 patients were invited to participate with the therapists. The 3 patients were in the midst of their treatment course, enabling them to contribute to their experiences of what to expect from a treatment protocol. When the Blend-A pilot platform was developed, a series of new, consecutive patients (a total of 20-30 patients were aimed for) from the 3 clinics were invited to participate in the Blend-A pilot study to try the platform during their individual therapy course; 22 of the invited patients agreed to help in the testing and answer the System Usability Scale (SUS) [40]. At the end of the study, 18% (4/22) of these patients were invited and agreed to participate in an individual qualitative interview about their experience of using the pilot platform. At the end of the feasibility and pilot study, the 7 therapists involved in the development, adjustment, and testing were interviewed in group settings about their experiences.

Platform Development

The development phase was inspired by participatory design [41] and was conducted in an agile process involving therapists and patients in several development and test iterations. This process lasted for 5 months.

The Blend-A Pilot Platform and Content

An overview and content description of the platform modules are provided in Table 1. The modules and submodules were organized in a fixed structure. The platform was set up to allow therapists to gradually add sessions on the web to the patient's individual platform. The sessions on the web contained text and videos with information as well as assignments. According to the treatment protocol, patients received feedback on the web

from their therapists on assignments. The platform allows the sharing of information and homework assignments with their significant others. It was estimated that future patients would use the treatment protocol for 3 months and relapse prevention for 6 months. On completion of treatment, future patients will have access to the web-based treatment platform to reread information and look up exercises.

Table 1. Blend-A (Blended Treatment for Alcohol Use Disorder) pilot platform modules.

Module number and title and submodule title	Submodule content description
1. Welcome	
Welcome to Blend-A	• Explanation of the Blend-A treatment protocol • Explanation of the Blend-A research project
Onward to a new start	• Introduction to being onward to a new start and experience cravings
Support from your social network	• Introduction to needs for support from social network • Task where it can be mapped
Test your knowledge on alcohol	• Test of knowledge on alcohol
Questions and contact	• Contact information
2. Alcohol treatment	
Preparation to change	• Explanation of disadvantages when using alcohol and advantages of change • Task with the purpose of highlighting the disadvantages of using alcohol and the advantages of quitting drinking • Explanation of alcohol registration
Goals and techniques for self-control	• Explanation of a change plan for alcohol use (goal setting) • Explanation of the SMART[a] criteria • Tips for making a change plan • Explanation of techniques for self-control concerning alcohol use • Task where techniques can be described
List of alcohol use risk situations	• Explanation of risk situations for alcohol use and instruction to questionnaire • Questionnaire where overview >80 risk situations for temptation and self-confidence can be filled out • On the basis of the questionnaire, top 5 risk situations are filled out
Function analysis and emergency plan	• Explanation of function analysis for alcohol use • Task: fill out the function analysis • Explanation of how an emergency plan can be helpful to prevent relapse or limit the harm • Task: description of emergency plans

Tackling craving	• Description of craving
	• Task: which situations trigger craving, how is craving experienced, and who can craving be explained to
	• Explanation of tasks for 4 different ways to tackle cravings:
	  • Diverting yourself by doing something else
	  • Surf with your emotions
	  • Think differently
	  • Talk to your family and friends about it

Restructuring	• Restructuring of thoughts

Turning alcohol offers down	• Explanation of how turning down alcohol offers is a skill that can be learnt through role-play
	• Task: description of 3 risk situations and examples of saying no
	• Task: description of a situation where an offer needs to be turned down
	• Task:
	  • Role-play—rehearsing turning alcohol offers down
	  • Access to diary “evaluation of turning alcohol offers down”

Evaluation	• Evaluation of turning alcohol offers down
Midterm evaluation	• Deciding optional skills

Module number and title and submodule title	Submodule content description
3. Optional skills	• Social skills—small talk • Social skills—tackling criticism • Social skills—giving criticism • Tackling feeling sad and depressed • Tackling stress • Solving problems effectively • Tackling relapse
4. Relapse prevention (maintenance)	
Month 1	• Alcohol status • Quality of life
Month 2	• Alcohol status • Quality of life—your assessment
Month 3	• Alcohol status • Quality of life—your assessment • Support
Month 4	• Alcohol status • Quality of life—your assessment • Support—your assessment
Month 5	• Alcohol status • Quality of life—your assessment • Support—your assessment • Motivation
Month 6	• Alcohol status • Quality of life—your assessment • Support—your assessment • Motivation—your assessment • Evaluation of the maintenance phase

[a]SMART: Specific, Measurable, Achievable, Realistic, and Timely.

Data and Data Collection

For patients who agreed to pilot-test the Blend-A pilot platform, data on platform use were retrieved from the platform provider. To assess how the usability developed over time during the pilot study, questionnaire data were retrieved at baseline and 5 follow-ups, with 2 weeks between each measurement. Questionnaire data were collected using a validated Danish version [42] of the questionnaire SUS [40]. The SUS questionnaire consists of 10 questions about a given system's usability, availability, and coherence. The questionnaire results are presented in Table 2. The 10 questions were answered on a Likert scale from 1 (strongly disagree) to 5 (strongly agree). These 10 responses were used to calculate an SUS score between 0 and 100. Questionnaire data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) [43], hosted at the Odense Patient data Explorative Network. Questionnaire links and reminders were sent via REDCap every other week to the participants' private email addresses at baseline and 5 follow-ups, to be filled out on the web using their computer, tablet, or smartphone.

A total of 2 anthropologists and 1 sociologist observed all workshops and training sessions that were performed with patients and therapists throughout the development phase and the implementation and pilot testing of the Blend-A pilot platform and took comprehensive field notes. An anthropologist also conducted qualitative interviews with patients and therapists during the pilot phase.

Table 2. System Usability Scale (SUS; Digital Equipment Corporation, 1986).

Items	SUS scores				
	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Qualitative data on patient perceptions were collected from 4 individual, semistructured interviews. When the Blend-A pilot platform was implemented in the 3 clinics for half a year and the questionnaire data were collected, patients were invited to participate in the qualitative interviews. The researchers asked the therapists at 2 clinics to invite patients who were willing to use the Blend-A pilot platform and who had answered at least some of the SUS questionnaires. The interviews consisted of open conversations about patients' experiences with the Blend-A pilot study, supported by an interview guide. Textbox 1 presents the interview guide. The 4 interviews lasted for 14, 19, 24, and 28 minutes, respectively, and were audio recorded and transcribed.

Textbox 1. Interview guide for semistructured individual patient interviews.

Interview questions

- How long have you received blended internet-based and face-to-face treatment?
- How often have you used the platform?
- Why did you use the platform as often or seldom as you did?
- How was it to use the platform?
  - to log on
  - to read the text
  - to solve the assignments
  - to receive feedback
- Would you have liked to interact with your therapist via videoconferencing?
- Why did you choose to receive internet-based treatment?
- How was it to receive internet-based treatment, compared with face-to-face treatment?
- What impact has the blended setup had for your interactions with your therapist?
- What impact had the blended setup had on your treatment course?
- Do you have any ideas for alterations?
- Do you have anything to add or ask about?

Additional qualitative data on therapist perspectives were collected from 4 unstructured group interviews conducted with the 7 therapists from the 3 clinics during the pilot study. The group interviews were conducted by an anthropologist and a sociologist. An interview guide updated before each interview inspired the interviews. Textbox 2 presents the interview guide. The group interviews were conducted as part of the implementation process and lasted for approximately 2 hours each. One group interview was audio recorded and transcribed, and field notes were taken from the 3 others.

Textbox 2. Interview guide for therapist group interviews.

Interview questions

- The Blend-A pilot platform
  - Which modules have you used?
  - Describe your experience of using the platform.
  - Describe the patients' reactions to using the platform.
  - How do you experience starting a patient up in the program?
  - Is it your impression that the patients feel well informed?
  - How is it to give feedback on the platform?
  - How do you structure your working week concerning Blend-A?
  - Are there functions in the program, which provide new insights in relation to face-to-face sessions?
  - Are there insights you do not get when using the Blend-A pilot platform for treatment?
  - Have you experienced situations where videoconferencing would have been beneficial?
- Training
  - To you who have replaced a therapist: does peer-to-peer training work?
- Workflow description
  - How often do you use it?
  - Are there workflows we have not described?
  - Are there workflows that counteract each other?
  - Have you experienced the need of actions outside the platform; for example, mails or calls?
- Supervision and clinical conference
  - In your team, how do you consult about the contact to patients using the Blend-A pilot platform?
  - Do you have the need for further sparring concerning using the Blend-A pilot platform in your workday?
- Patient recruitment
  - How many patients have you recruited?
  - How do you recruit?
  - What challenges have you found while recruiting for the Blend-A pilot?
  - Which reasons do patients provide for choosing to use the Blend-A pilot platform compared with face-to-face sessions?
  - Which reasons do patients provide for choosing not to use the Blend-A pilot platform?
- Defects
  - What defects have you experienced?
  - What defects have the patients expressed?

Analyses

Analysis of the rather little structured data from the SUS questionnaires was conducted using the Stata software and Excel.

A qualitative analysis of interviews with patients and therapists was conducted using a theoretical thematic analysis approach [44]. Thematic analysis is a widely used method for identifying and describing themes within data without being bound to any pre-existing theoretical framework. A theme was defined as a meaningful emergence relative to the research question. In the present pilot study, thematic analysis was used as an essentialist or realist method to describe participants' experiences in the development, implementation, and usability of a blended treatment course involving the Blend-A pilot platform. The analysis consisted of six phases: (1) reading and rereading studies while noting the initial ideas, (2) coding interesting features systematically in the *Results* section, (3) collating codes into potential themes, (4) checking whether the themes work in relation to the coded extracts and entire data set, (5) performing ongoing analysis to refine the specifics of each theme and to

generate names for each theme, and (6) performing final analysis of selected extracts relating the analysis to the research question.

Observational data from field notes were used to describe the development process and assess the engagement and concern expressed by both therapists and patients. Similar to the process of analyzing the qualitative interview data, the notes were read, reread, and combined into overall themes and subthemes. In the reporting of the findings from the notes, information stemming from the qualitative interviews of patients and therapists was added to the observational data when they added information about the development process and how the usability and function of the platform was experienced by the parties.

Qualitative analyses were conducted by JR and KT, originally trained as a sociologist and an anthropologist with approximately 10 years of experience each. ASN, with approximately 30 years of experience in qualitative research, supervised the analyses.

Ethics Approval

The pilot study was notified to the Danish Data Protection Agency (file number 18/1994). The study was conducted in accordance with ethical standards; however, as it is based on questionnaires and interviews, it is not notifiable to the Regional Committees on Health Research Ethics for Southern Denmark. After receiving oral and written information about the project, participants signed consent forms for participation.

Results

The Process of Developing and Adjusting Platform and Content

The Blend-A pilot platform is accessible on the web via any given web browser. As mentioned earlier, the platform consisted of 4 modules with submodules, which started with therapy information, followed by multiple exercises and homework assignments, training in optional skills after patients' individual needs, and relapse prevention.

The Dutch content was maintained overall, as it described MI and CBT-based modules, consistent with standard face-to-face treatment in Danish alcohol treatment clinics. The translation process in which the Dutch platform content was translated into Danish went through five phases: (1) translation of overall concepts and treatment flow was conducted in a full-day workshop together with the platform provider, 3 patients, 6 therapists, 2 consultants, and 2 researchers, of which 1 was a sociologist and 2 were anthropologists; (2) the platform provider made the first rough translation from Dutch to Danish, translating all text, text on buttons, and image texts and providing Danish subtitles on Dutch videos; (3) therapists, researchers, and consultants revised and edited the translation draft, focusing on linguistic, cultural, and therapy-related translations; therapy-related translation was the least time-consuming part, as the included AUD clinics already offered CBT, whereas the linguistic and cultural translation was more time consuming and involved patients, therapists, consultants, and researchers; (4) the content was implemented in a test version of the platform and tested by 6 therapists and 3 patients during a half-day workshop, in particular, during the workshop, the text fields were thoroughly considered and made easy to understand, and in this process, participating patients' feedback was of particular importance; at the workshop, both therapists and patients went through all elements and discussed the feasibility and acceptability of both the content and layout, and based on this feedback, the content and platform were revised; and (5) the content was then implemented in the production-ready platform, which was named the Blend-A pilot platform.

Therapist and Patient Experiences of Platform and Content During Development

Patients and therapists who participated in the development and adjustment phases quickly grasped the platform. Both groups provided useful information on the usability of the platform, particularly in spotting passages or larger text blocks, which might be a barrier for future use. The possibilities for flexibilities on how to combine modules were stressed. Both patients and therapists found that videos and graphics were often preferred to text to reduce cognitive load. The videos in the pilot version of Blend-A were Dutch, with the Dutch material subtitled in Danish, and both therapists and patients found that although it might work in a pilot version, it was not optimal. The participating patients became so engaged that in the development process, they kept trying the platform outside the workshop and returned to their therapist with additional information on what they found useful. The therapists found it helpful for future use that they had had the opportunity to work through the content and platform together with patients during the development and adjustment phases, as it allowed them to grasp what engaged the patients the most.

Implementation of the Blend-A Pilot Platform

During the process of implementing the pilot version, the therapists were trained on how to provide written feedback, patients were recruited, and the Blend-A platform came into operation. The Blend-A pilot platform came into operation in February 2018, and the pilot test was run for 6 months. The therapists involved in the development and translation process described earlier were also the main therapists offering treatment to the new patients via the Blend-A pilot platform. Therapist training before the pilot test consisted of 2 sessions, with 2 hours of training each in the use of the platform and a fortnight of practice in between. A Dutch psychologist experienced in blended treatment participated in preparing the training and offered support to therapists. The therapists were encouraged to offer a blend of face-to-face sessions and internet-based modules that they, together with the patients, found the most helpful and attractive. Thus, no firm structure describing a fixed number of face-to-face sessions before offering the patients the opportunity to continue the treatment course by means of internet-based modules was prescribed. Rather, therapists were encouraged to discuss this with their patients and decide on the optimal blend.

Pilot Testing of the Platform With New Patients

We planned to pilot test the Blend-A pilot platform with 20-30 new patients. Patients were recruited by means of regular

advertisements in local newspapers, Facebook posts, and face-to-face approaches among eligible patients receiving treatment at the 3 clinics. A total of 41 patients completed the Blend-A pilot platform. There was a difference between how far during the treatment program the patients came in the 3 pilot municipalities. In 1 municipality, approximately half of the patients finished the program, and the rest stopped during module 2. In the 2 other municipalities, only one-tenth finished the program, and the rest stopped during and after module 2, respectively. All 41 patients were invited to participate in the evaluation, and 22 agreed to fill out the questionnaires. During the pilot phase and upon request from the therapists, a workflow description for the blended treatment course was developed and regularly updated to provide therapists with details on how to involve a patient in the blended treatment offer. An example workflow is presented in Table 3.

The quantitative and, in particular, qualitative data analyses led to the following findings regarding usability, patient perceptions, and therapist perspectives on the Blend-A pilot platform.

Table 3. Example of workflow description.

Patient	Therapist
Contacts the clinic for treatment of AUD[a].	Offers the patient detoxification, MI[b], and assessment.
Decides to change habits and work focused.	Offers the patient a treatment course; informs the patient orally about Blend-A and that it is optional to participate, but it requires that the patient has a computer or a tablet; and hands out written information on Blend-A to the patient.
Reads the information sheet at home and decides on participation in Blend-A.	At the first treatment session (flexibility according to resources): asks the patient about participation in Blend-A.
Declines to participate in Blend-A.	Offers patient regular treatment course.
Agrees to participate in Blend-A and signs consent form.	Photocopies the signed consent form and gives the copy to the patient and scans the original form and uploads it to the secure Blend-A Sharepoint.
Receives from and agrees with therapist	Introduces the patient to Blend-A, adds the patient on the platform (administration module can be used by therapists and administrative workers), sends an invitation to the platform to the patient, informs the patient that emails from the platform provider may end up in spam filter, urges patient to store password in a safe place that the patient can remember, agrees with patient on number of sessions internet-based and face-to-face, and informs the patient that it is a possibility to bring a PC to the face-to-face sessions to be introduced to the platform.
Accepts invitation to the platform.	Assigns patient to therapist, assigns treatment modules to the patient, offers to solve some of the first assignments together with the patient, and decides on homework assignments together with the patient.
Uses the platform.	For the rest of the treatment course: receives an email when the patient has solved an assignment, reserves a time slot every week for written feedback on solved assignments (more time consuming in the beginning), and sends reminders to the patient if the assignments are not solved (brief, motivating approach).
Attends treatment session face-to-face.	Completes treatment session with the patient entailing content from the platform.
—[c]	Besides direct patient-therapist interaction: compiles mutual guideline for written feedback, undergoes professional sparring, and participates in treatment conferences.

[a]AUD: alcohol use disorder.

[b]MI: motivational interviewing.

[c]Patient has no task during this step.

Usability of the Blend-A Pilot Platform

The 22 patients who agreed to participate in the evaluation consisted of 15 (68%) men and 7 (32%) women. Of the 22 patients, 16 (73%) answered one or more SUS questionnaires. A patient was excluded because of a large amount of missing information in the questionnaire. Of the 22 patients, the remaining 15 patients (94%) consisted of 9 (60%) men and 6 (40%) women. Their mean age of the participants was 47 (SD 12) years; the youngest aged 28 years and the oldest aged 73 years.

At baseline, the mean SUS score for the patients (15/22, 68%) was 71 (range 43-85). At the first follow-up, 2 weeks after initiating treatment on the Blend-A pilot platform, the mean SUS score for the patients (10/22, 45%) was 74 (range 53-93). At the second follow-up, the mean SUS score for the patients (3/22, 14%) was 67 (range 58-73). At the third follow-up, the mean SUS score for the patients (3/22, 14%) was 69 (range 63-75). At the fourth follow-up, the mean SUS score for the patients (3/22, 14%) was 78 (range 73-80). At the fifth follow-up, the mean SUS score for the patients (3/22, 14%) was 78 (range 75-85).

Patient Perceptions of a Blended Treatment Course Involving the Blend-A Pilot Platform

A total of 4 patients who were still enrolled in the treatment agreed to participate in a qualitative interview concerning their experiences with the Blend-A pilot platform. At the time of the conclusion of the pilot study and for the final qualitative interviews, the interviewed patients had been using the Blend-A

pilot platform between 3 and 5 months. The interviewed patients used the platform to varying degrees from daily to weekly, typically more frequently at the beginning of the treatment course.

Interaction Between Internet-Based and Face-to-Face Treatment

The patients had learned about the possibility of participating in the blended treatment through newspaper advertisements and chose to use Blend-A, particularly because of the blended setup of the treatment course. The platform functioned as a basis for face-to-face sessions with the therapist. Here, a participant explained as follows:

> *It has been such a good departure point for a talk [...] where she then interprets some things, probably based on my answers [...] so that is kind of like the foundation of it, I think [...] it has worked on me [...] now we have had something to depart from [...] something concrete.* [Participant 3, female]

It was important for the patients that they could stay at home, read the texts calmly, and solve assignments on the platform. They found that reading the texts started a cognitive process and that performing the assignments touched them emotionally. Being able to use the platform when they had the time to do so had given them breaks, enabling them to think about their answers. Being able to use the platform when they felt motivated had given them the experience of a higher gain from the treatment course, enabling them to apply the therapy to their rehabilitation process, in addition to feeling in control. A participant explained as follows:

> *I think it is good, this interaction [...] it is very good, and then it is, eh, then I can work with it alone in my head at home in peace and quiet, and then I can come up here [at the clinic] and get a briefing or get a, well what is it called, a pat on the back, that may be able to support me a little to work through some of the stuff again.* [Participant 2, female]

As such, patients felt that the interaction between the use of the platform and face-to-face sessions had a positive impact on their treatment course.

Flexibility

The patients felt that an optimal blend for them was using the platform twice or more per week, together with face-to-face consultations once or twice a month. A patient stated that this cadence was adequate to secure enough substance during the treatment course.

A patient explained that the flexibility in the blended solution was the main reason they enrolled in the treatment. They elaborated on the difference between going to treatment sessions more often and receiving a blended treatment offer with the internet-based platform and fewer face-to-face sessions:

> *Here, you can do some things at home so you don't have to spend time on it, there is also a job that needs to be done [...] there are multiple work schedules that, like, has to fit into each other too [...] it is nicest that you can go to and from it and do it when you have the time, or, and when the desire is there [...] it is not something that you have hanging over your head.* [Participant 1, male]

Because of their work situation, this patient would not have been able to participate in regular treatment with more frequent face-to-face sessions.

Anonymity

In addition, the patients liked the possibility of a more anonymous treatment course. A patient explained that it was transgressive to sit in the waiting room, that they felt so wrong, and that it was unpleasant.

Another participant gave anonymity as one of the reasons for choosing the blended treatment course:

> *It is probably also because it is something that I can sit at home and do, it is a little bit more anonymous, eh, so that was probably why.* [Participant 1, male]

Another participant preferred the discretion of not attending the clinic more than necessary, as they had the wish not to be recognized as one attending treatment, which could cause feelings of not being able to manage on their own:

> *I thought that I was drinking too much, and I couldn't, I couldn't really succeed in minimizing it and, eh, then, then I saw this offer and an anonymous offer even, and I don't have to tell anyone so, eh, and I feel...So I thought this is it, now you have to get started with this [...] I could have enrolled treatment in a group with others, and I didn't feel much like that [...] I liked the anonymous [...] I want to hide myself a little bit and, eh, I don't want to be seen around by people.* [Participant 2, female]

However, 2 of them had experienced a shift toward not having the need to remain anonymous.

Usability

The patients also emphasized the importance of presenting treatment material on the platform relevant to the patient groups most likely to use Blend-A. It mattered to them that the material was in their native language and targeted to their particular patient group. The patients found it helpful that blended care involved homework assignments, including reading and specific tasks, and that it was possible to go back and repeat the reading and tasks if they felt that they needed a brush up. None of the patients described having shared the content of the platform with their significant others.

For the patients, the platform was simple with regard to the text, examples, assignments, and feedback from therapists. They were satisfied with the platform setup and the reading friendliness of the texts. They found that the platform was easily accessible to use, for example, during the log-on and submission of solved assignments.

However, they emphasized the importance of a range of factors that (1) the platform is technically stable, so it can be used when the needs and wishes are there; (2) it can be seen at first glance that assignments have already been performed; (3) it is easy to return to the assignments and revise; (4) the content is

numerically indexed so that feedback can be tracked on the assignments performed; (5) the structure was set up logically; (6) too many questionnaires should be avoided in the modules; and (7) it should be fast to monitor alcohol use, because it is frequently performed. Ideally, the frequency of monitoring should automatically be based on individual needs.

Therapist Perspectives on Blended Treatment Involving the Blend-A Pilot Platform

The 7 therapists participated in 4 group interviews conducted during the implementation of the Blend-A pilot platform and at the conclusion of the pilot study.

Implementation

The therapists emphasized the following factors to be important for training and for future use of the platform: (1) sufficient time for training, that is, reserving one whole day for a training workshop emphasizing case-based training; (2) availability of the therapeutic material in a printed version beforehand, allowing focus on the technical part of the workshop; (3) getting to know the platform properly; that is, working through the platform, pretending to be patients, to understand the program thoroughly from the patients' views; and (4) in particular, the therapists liked having an experienced peer from the Netherlands describing their experiences with using the platform and giving advice; for example, on how to give written feedback to patients via the platform as this was new to the Danish therapists.

Particularly in the early phase of the implementation of the platform, therapists emphasized the importance of having a workflow description easily available. It was important for them that the document entailed pictures describing various workflows. Moreover, they found it important to have manageable guidelines for maintaining records of the blended treatment courses.

Therapists found that the blended-care approach could easily be integrated into community-based treatment offers for AUD. Providing feedback on patients' internet-based homework was not considered a problem. On the contrary, the therapists felt that they had more time to reflect and focus compared with giving feedback in a direct face-to-face conversation. In the early days of the pilot phase, therapists allocated 40 minutes a week per patient for written feedback. Later, when they had gotten used to giving feedback in writing, approximately 20 minutes per patient every week was found to be sufficient. In the beginning, the therapists found themselves ever so often logging on to the platform, looking at the assignments handed in, and providing feedback. However, it was their experience that when they gathered it in a dedicated time slot, they gave the patients time to reflect before the new homework was assigned. One of the therapists elaborated as follows:

> *I am treating a woman over the platform, she's like 80 years old or something, and she is very industrious and reflective and not one of those who replies in short, but writes a lot, eh, and she stays at home so she has the time to do the assignments, but she, even though she is thorough, she does it quickly, so it is actually me who deliberately has chosen to stall it regarding giving the feedback and say now I will give feedback for three assignments today, and then she can look at that for a few days and then I wait for another couple of days before I give more feedback and then I stall it regarding uploading more so it is me who [...] delays it [...] I think she should have time to reflect in the meantime and not only when she is in front of the screen.* [Therapist 1, female]

The therapists emphasized managerial support for time use as essential. In addition, they felt that it was important to spend time on (1) educating a dedicated superuser who can allocate time to be the focal point of sparring and information about the use of the platform for treatment, particularly with technical aspects; (2) sparring with colleagues, for example, on how to conduct good blended AUD treatment and provide good feedback; (3) mutual sparring of technical issues when using the platform; and (4) clinical conferences with supervision of blended treatment courses.

Usability

The therapists also made several comments on the practicality of the platform. In particular, they suggested not to assign a series of assignments and submodules to the patient simultaneously, but rather to assign them one at a time. They found that the reward for completing a module was important to the patients, and if completing the modules was too time consuming, some patients lost enthusiasm. For those who had not answered the given assignments, therapists sent brief motivating reminders. One of the therapists explained as follows:

> *We try on Mondays, I give feedback on Wednesdays, so I try to send out like a reminder, and you call it a little shove, I call it something else for them, also to just say that like, you can right there orientate and say, hey where are you, are you a place where you think you need to be discharged.* [Therapist 2, female]

Thus, the therapists also recommended dividing modules into smaller versions with fewer assignments, which may potentially induce a feeling of more assignment completions and progress for the patients.

Furthermore, the possibility of flexibly combining modules was important. Thus, the therapists recommended allowing assignments to be skipped or new assignments to be released quickly, thereby avoiding waiting times between relevant assignments. They also found that it was important to provide feedback quickly after each module was completed.

Patient Recruitment

Concerning the procedure of recruiting patients and motivating them to enroll in a blended treatment course, the therapists emphasized the importance of giving interested patients an opportunity to contact the clinic via email, and not just by telephone or in person, as was the case in the pilot phase. One of the therapists elaborated on their experience of what the patients used the platform for:

> *Well, it is to stop their alcohol use or at least decrease it [and if this solution had not been a possibility] then they wouldn't have had any where to turn to, and this is what they say, it is a good way to do it, it is to be*

> *able to be totally anonymous if you are, say, a known person in town.* [Therapist 5, female]

It was their experience that this might make recruitment easier because the contact might feel more anonymous for the patients.

The therapists also experienced how the assignments on the platform were used for extended reflection and served as a foundation for the treatment sessions at the clinic. Here, one of the therapists explained how this may especially be the case for those who feel challenged by sharing in speech:

> *When he works, it is very clear that things emerge from his assignment-solving that I could not have guessed from our conversations of something, there are some areas for him that he needs to maybe talk about and work more with, and it became very clear, and then I could bring it into our conversations, which made sense for him, so for him it was actually a big help to have something elaborated that he just, which just is but he couldn't get out into the open on his own, so it is just such a good experience actually, eh, so I think that those patients who don't say much in the sessions and who think that it might be interesting to solve assignments, it might be an extra bonus in some way.* [Therapist 4, female]

As different target groups have different needs and wishes for their treatment courses, the therapists suggested offering patients different blends in the future:

1. Anonymous treatment: all initial contacts were handled by email or telephone, and the therapist could only contact the patient by email or by the feedback and message options in the platform. Information about the patient was registered anonymously, and the only information the therapist had about the patient was the patient's information in the email or in the program.
2. Platform use combined with face-to-face treatment: the patient was treated via telephone or email and was invited to a face-to-face interview. The patient was registered with personal information; that is, their social security number, in the electronic patient record before using the platform. After a month of using the program, there was a follow-up either by telephone or face-to-face conversation.
3. Platform use combined with face-to-face and pharmacological treatment: this blend is similar to face-to-face treatment combined with platform use but with the addition of a clinical treatment consisting of supportive medication. During this treatment form, the patient is followed up more closely every second or third week.

In addition, they emphasized the importance of having a pamphlet to hand out to the patients, describing the blended offer.

Discussion

Principal Findings

The purpose of this pilot study was to describe the process of translating and adapting a Dutch treatment protocol on treatment, consisting of blended face-to-face treatment sessions and internet-based modules, into the Danish language and culture. In addition, we report how patients and therapists perceived the adapted version when trying it out. In particular, we focused on experiences from the process of adaptation and pilot testing, which could inform future projects.

Even though the Netherlands and Denmark are much alike, we do have different languages and cultures, as well as slightly differently organized treatment systems. Thus, translating, culturally adjusting, and implementing effective and necessary treatment offers across borders is not straightforward. In this process, it is important to include both therapists and patients to facilitate the development of a treatment program in which they can identify themselves; thus, they choose to complete the program [45,46].

In this study, the development and translation process was inspired by participatory design [41] and was conducted in an agile process involving therapists and patients in several development and test iterations. Such collaboration with end users may more likely result in adaptations considering stakeholder views [41], ensuring the use of the platform and treatment content. Further involvement of patients in the early development phase as well as the later test phases might have helped us to better qualify assessments, videos, and length of the modules, thereby mitigating the need for further refinement of the platform. This is in line with recent qualitative studies concerning web-based alcohol treatment, which emphasized that incorporating patient feedback into the delivery may enable improvement of a treatment offer [45], and that stakeholder feedback can be used to bolster acceptability, appropriateness, and adoption of alcohol internet-based CBT, thus contributing to implementation success [47]. In this study, both patients and therapists were highly engaged in the process and added valuable, in particular pragmatic, information that led to adjustments of both the content and layout of the platform.

We found managerial endorsement and support crucial for the therapists' dedication of time to the pilot phase, enabling them to recruit patients and provide feedback to the process. Throughout the development process, the 7 therapists each spent 2 hours per week on an average for the project. During the pilot phase, the number of therapists per site (constantly 2 from each clinic) was sufficient to secure a high level of co-ownership in the development of the Blend-A pilot platform. Overall, the therapists participating in this study were very positive toward and engaged in the development and testing of the Blend-A platform. They found that giving feedback to patients in writing, in contrast to the immediate feedback that they were used to giving in face-to-face sessions, led to time to reflect and consider the feedback better. Our findings thus support previous findings on therapists' experience in delivering guidance via the internet [48]. Previous studies of therapists' experiences with internet-based CBT have, however, found that therapists may also find it more difficult to *read* patients over the internet [48-50]. Such considerations give support to the praxis of blended therapy, where the patients and therapists have a number of initial face-to-face sessions and then continue working internet-based if it suits the patients' needs. This study adds to this suggestion.

Reasons for Seeking Blended Treatment

The pilot study revealed 2 prominent reasons why patients chose to participate in the blended treatment.

The first reason was that the patients were attracted to the blended treatment setup, as it meant that they had to attend the clinic physically less often and at the same time took responsibility for their own treatment. This is in line with findings from other studies on web-based treatments [20,31,51]. In studies on barriers to treatment seeking, factors such as lack of transport and time to attend a treatment course have been found to be structural obstacles to seeking treatment [11,51].

The second reason for seeking a partly internet-based treatment offer was that the patients were attracted to the more anonymous option in the treatment offer owing to the imbedded discretion. We also found that therapists had experienced that allowing for contacting the clinic anonymously by email made patient recruitment easier. During the study, an additional number of patients who did not participate in the Blend-A pilot study were chosen to receive completely anonymous treatment via the Blend-A pilot platform, without face-to-face sessions, to ensure complete anonymity. One of the leading obstacles to seeking treatment is reported to be stigma; for example, because patients feel ashamed to be associated with the clinic and worry about what others might think [9,11,51,52]. This points to the relevance of offering an anonymous version of internet-based alcohol treatment as it might reach a group of non–treatment seekers not otherwise reached, for example, owing to stigma, as also suggested elsewhere [53].

Platform Use

We found a difference between how far during the treatment program the patients came in the 3 pilot municipalities. In one municipality, approximately half of the patients finished the program, and the rest stopped during module 2. In the 2 other municipalities, only one-tenth finished the program, and the rest stopped during and after module 2, respectively. According to a study on attrition in internet-based treatment of problem drinkers, the challenge of internet-based alcohol treatment programs is no longer their effectiveness but keeping participants involved until the end of the treatment program. In comparison, they found attrition rates of 55% and 65% [54], which seems to be the norm within internet-based alcohol intervention studies [55-57]. It is important to use a significant amount of graphics and videos in the native tongue to reduce the cognitive load. In addition to having an individualized and flexible platform with small modules, it can potentially induce feelings of more assignment completions and progress.

Among the patients, we found a baseline mean SUS score of 71. According to previous research, a system's usability can be assumed to be above average if the SUS score is ≥68 or higher [58]. We also found a patient-perceived positive impact of the blended treatment course owing to the interaction between platform use and face-to-face sessions, as the former could serve as a basis for the latter. This is in line with findings from other studies on web-based treatments, where it was found that blended therapy might be able to improve treatment usefulness, as it was possible to use input from the platform to prepare for face-to-face sessions [31,34]. However, in the study on blended depression treatment, it was emphasized that face-to-face sessions are crucial to motivate patients and facilitate the guidance of the web-based content [31]. Furthermore, we found a patient-experienced higher gain in the blended treatment, probably stemming from the ability to match treatment needs and the available time to platform use. This finding is concurrent with studies on web-based treatments, where the convenience of always having access to the platform was seen as an enhancer of self-management by enabling the patients to perform the assignments at their own pace [31,51]. In addition, we found rewarding elements in the possibilities of thinking assignments through and revisiting materials on the platform. This finding adds to the findings from previous studies on web-based treatments, where patients have found it easier to express themselves in writing, compared with face-to-face [48,59] or valued being able to download the material to use it after the treatment [45].

We found therapist-experienced importance of reserving a time slot for providing feedback, ensuring both therapist and patient time to work on assignments and feedback. This finding is in agreement with another study [60], which found that therapist feedback expressed a desire to tailor the nature and amount of support to patients. Finally, we found that it was important for the therapists to draw upon the experience of peers during training. Therefore, experiences from the pilot study will be used to inform and train new therapists in the future Danish national rollout of Blend-A.

Optimal Blend

Patients and therapists participating in the pilot study chose to use the Blend-A pilot platform to varying degrees. Other studies have discussed what might be an optimal blend [27,31]; for example, a study on blended depression treatment [31] found that patients preferred 50% to 60% of the sessions on the web, whereas therapists preferred 75% of the sessions to be face-to-face. The same study also emphasized tailoring treatment to individual patient needs by adjusting the amount and ratio of the web-based modules to patients' problems, skills, and characteristics. Supporting this, several studies on patient feedback suggest that it may be beneficial to tailor therapist support according to patient needs [32,48,49,61,62]. This might point to the importance of offering different blends targeting the needs of different patient groups, as this might make treatment accessible to an increased number of patients. Hence, the therapists in the present pilot study suggested offering 3-different blends: anonymous treatment, blended treatment, and blended treatment combined with pharmacology.

Strengths and Limitations

This study is a small feasibility and pilot study and therefore has a series of limitations. First, it was based on a few therapist and patient reports. Although it may be considered a strength that we used a validated questionnaire to assess usability, it is a severe limitation that only 3 patients answered the questionnaire at follow-ups 2 to 5. Therefore, whether the patients' assessment of the usability of the platform develops over time should be interpreted with caution. In future upscaling, we will rely as much as possible on register data and on more

routes for collecting patient data, that is telephone calls and the use of e-Boks (the Danish system for digital communication with the authorities) [63]. Moreover, some usability models are considered problematic, as theory to speculate about the relationship between measures may be lacking [64]. Instead, Drew et al [65] suggested using SUS scores for comparison between, for example, iterations or conjunction with formative usability testing methods to provide a holistic view of real and perceived user experience.

Second, the researchers and consultants who were responsible for the development, adjustment, and implementation of the Blend-A platform worked together and may have been interpreted as being a team by the therapists and patients. Thus, although we do not believe this to be the case, we cannot rule out that this may have led the therapists to be less critical toward the process of development and implementation. It is, however, a strength that 4 group interviews were conducted with therapists, refining their perspectives during the pilot study.

Third, only 4 patients participated in qualitative interviews regarding their experiences with the translated and adapted versions of the platform. We cannot rule out the possibility that those who participated in the qualitative interviews were more positive toward the use of internet-based modules in a treatment course.

Finally, it may be considered a limitation that transcripts and codes of the qualitative interviews were not stakeholder-checked [66] by letting participants provide feedback [67]. However, it is a strength that 3 independent raters were involved in the coding process, as this may enhance the credibility of the analysis [68,69] and increase reliability and internal validity [70].

Conclusions

Our study indicates that during the processes of translating, developing, and implementing blended, guided, internet-based, and face-to-face AUD treatment, it is relevant to focus on patient involvement, managerial support, and guidance from experienced peers. Owing to the discrete and flexible design of the blended treatment offer, it appears that patient groups who would not otherwise have sought treatment can be reached. Blended treatment may thus increase access to treatment and contribute to reaching people affected by excessive alcohol use, who would not otherwise have sought treatment. Our initial findings indicate that the blended treatment may enhance participants' perceived satisfaction and the effect of the treatment course. However, we still need to determine the actual effect of Blend-A; therefore, an effectiveness study is currently being performed to evaluate the effect, compliance, and cost-effectiveness of implementing the blended treatment program [63].

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Conflicts of Interest

None declared.

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Abbreviations

AUD: alcohol use disorder
Blend-A: Blended Treatment for Alcohol Use Disorder
CBT: cognitive behavioral therapy

MI: motivational interviewing
REDCap: Research Electronic Data Capture
SUS: System Usability Scale

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Original Paper

Objective Measurement of Hyperactivity Using Mobile Sensing and Machine Learning: Pilot Study

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Abstract

Background: Although hyperactivity is a core symptom of attention-deficit/hyperactivity disorder (ADHD), there are no objective measures that are widely used in clinical settings.

Objective: We describe the development of a smartwatch app to measure hyperactivity in school-age children. The LemurDx prototype is a software system for smartwatches that uses wearable sensor technology and machine learning to measure hyperactivity. The goal is to differentiate children with ADHD combined presentation (a combination of inattentive and hyperactive/impulsive presentations) or predominantly hyperactive/impulsive presentation from children with typical levels of activity.

Methods: In this pilot study, we recruited 30 children, aged 6 to 11 years, to wear a smartwatch with the LemurDx app for 2 days. Parents also provided activity labels for 30-minute intervals to help train the algorithm. Half of the participants had ADHD combined presentation or predominantly hyperactive/impulsive presentation (n=15), and half were in the healthy control group (n=15).

Results: The results indicated high usability scores and an overall diagnostic accuracy of 0.89 (sensitivity=0.93; specificity=0.86) when the motion sensor output was paired with the activity labels.

Conclusions: State-of-the-art sensors and machine learning may provide a promising avenue for the objective measurement of hyperactivity.

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KEYWORDS

assessment; machine learning; hyperactivity; attention-deficit/hyperactivity disorder; ADHD; wearables

Introduction

Attention-Deficit/Hyperactivity Disorder and the Need for Objective Measurement of Hyperactivity

ADHD is the most common neurodevelopmental disorder of early childhood, affecting over 5% of American children [1]. There are 3 presentations of ADHD: (1) predominantly inattentive presentation, (2) predominantly hyperactive/impulsive presentation, and (3) combined presentation. In school-age children, ADHD predominantly hyperactive/impulsive presentation and combined presentation make up 55% of all ADHD cases [2]. Although there are objective assessment tools such as the Conners Continuous

Performance Test 3rd Edition (Conners CPT 3) to measure inattention (the core symptom of the predominantly inattentive presentation of ADHD), there are no comparable objective assessment tools to measure hyperactivity (the core symptom of ADHD predominantly hyperactive/impulsive presentation). Instead, the current standard measurement for hyperactivity consists of subjective reports via questionnaires from parents and teachers, such as the Vanderbilt Assessment Scales. Reliance on subjective questionnaires to measure hyperactivity is a significant public health concern as it causes misdiagnosis including overdiagnosis and underdiagnosis [3-5]. Overdiagnosis can lead to unnecessary treatment, while underdiagnosis can lead to delayed treatment [6,7].

Sensor Technology and Machine Learning

Advances in sensor technology and machine learning provide opportunities to develop new methods of diagnoses with enhanced objectivity and precision. Wearable technologies (eg, smartwatches) with state-of-the-art sensors are practical, cost-effective solutions for providing objective measures of hyperactivity in children. The wide array of sensors (eg, accelerometer) embedded in wearable technology offer new opportunities to develop objective and accurate measures of hyperactivity. Although actigraphy has been around for decades and extensively used in research settings, its use has largely been confined to sleep studies [8]. Actigraphy has been used in a limited number of studies on children with ADHD, typically to measure sleep duration [9-11], rather than quantify daytime levels of hyperactivity to aid in diagnosis.

Multilevel Classification to Determine the Context of Symptoms

Context is critical in correctly diagnosing hyperactivity. For example, symptoms of ADHD include “often leaves seat in classroom or in other situations in which remaining seated is expected” and “often runs about or climbs excessively in situations in which it is inappropriate” [1]. While running and climbing in the playground do not contribute to a diagnosis of ADHD, running and climbing in a classroom does. Machine learning can be applied to sensor data to establish the context in which hyperactivity is present. Context is a combination of activity and situation. To assess context, we have developed a multilevel classification approach that first classifies the wearer’s activity, then contextualizes the level of motion, and finally evaluates activity level based on that context. The method analyzes hand motion to detect various activities; it collects the relationship between the wearer’s condition, activity, and magnitude of motion through accelerometer, time, and location data. Although it is not possible to have a class for every activity a user might perform (eg, fidgeting or other nonpurposeful motion), LemurDx classifies activities into common categories as a first layer of classification that is sufficient to condition algorithm parameters.

This Study

We describe the development of a smartwatch app to measure hyperactivity in school-age children. The LemurDx prototype is a software system for smartwatches that uses built-in sensors and machine learning to measure hyperactivity, with the goal of differentiating children with ADHD combined presentation or predominantly hyperactive/impulsive presentation from children with typical levels of activity. In this pilot study, we used LemurDx and supervised machine learning models paired with activity data from 30 children to develop initial classification algorithms. We report on usability scores from the LemurDx prototype and accuracy results from the initial algorithms.

Methods

Overview

This pilot study tested the feasibility of collecting, storing, and analyzing motion, as well as contextual (ie, GPS, heart rate, Bluetooth) data, from children aged 6 to 11 years who wore an Apple smartwatch with the LemurDx app for 2 days. The data from the days when the participants with ADHD were unmedicated combined with contextual data extracted from the smartwatch sensors, as well as activity labels were included in the final analyses.

Ethics Approval

The project was approved by the Institutional Review Board (19040006) at the University of Pittsburgh.

Participants

Participants were recruited via a web-based research registry called Pitt + Me, through the University of Pittsburgh’s Clinical and Translational Science Institute program. The research staff subsequently contacted interested participants via phone to complete the eligibility screening. The sample consisted of 30 children aged 6 to 11 years (ADHD combined presentation or hyperactive presentation=15; non-ADHD=15) and their families. Inclusion criteria for the ADHD sample included a formal diagnosis of ADHD combined presentation or hyperactive presentation, which was confirmed using the ADHD module of the Kiddie Schedule for Affective Disorders and Schizophrenia Present and Lifetime Version (K-SADS-PL) diagnostic interview and a score of ≥10 on the hyperactivity items of the Vanderbilt Assessment Scale–Parent report (VAS-P). Exclusion criteria included serious child psychopathology requiring alternative treatment (eg, bipolar disorder, major depressive disorder, psychosis, autism spectrum disorder).

Measures

VAS-P Report

VAS-P [12] is a 47-item survey that scores instances of behavior based on frequency of occurrence. Scoring is broken down into the following subtypes: inattentive, hyperactive/impulsive, or combined types. For the purposes of the study, only the 5 hyperactive subtype questions were asked in order to determine the level of the child’s hyperactive behavior. Symptoms are rated on a Likert scale from 0 to 3.

K-SADS-PL Diagnostic Interview

The K-SADS-PL [13] is a semistructured diagnostic interview designed to assess current and past episodes of psychopathology in children and adolescents according to Diagnostic and

Statistical Manual criteria. Probes and objective criteria are provided to rate individual symptoms. For the purposes of the study, the research staff only asked about the items related to the ADHD diagnostic criteria located in the ADHD supplement.

Post-Study System Usability Questionnaire

The Post-Study System Usability Questionnaire (PSSUQ) [14] is a 19-item survey that assesses 3 factors: system usefulness, information quality, and interface quality. The survey uses a 7-point Likert scale in which participants indicate the degree to which they agree or disagree with each item. Lower scores indicate higher levels of agreement, while higher scores indicate lower levels of agreement.

Activity Labels

Parents also provided activity labels to help train the algorithm. The activities were logged at a 30-minute resolution. For each 30-minute increment of time, from 6 Am to midnight, the parent had a drop-down menu of 5 activity classifications that best summarized the child's activities over the course of the 30-minute block. The activity categories were as follows: sleeping (eg, napping, sleeping); sitting/quiet activity (eg, watching TV, reading a book, using the internet, etc); everyday/household activity (eg, taking a walk, cleaning room, going shopping, playing an instrument, etc); exercise (eg, playing a sport, running, playing in the playground); and not wearing the watch. The activity labels created an additional level of qualification to the motion data collected. The purpose was to be able to later use the deidentified activity labels data to parallel the sensor data, to check the fidelity of the sensor data, and qualify outliers found in the sensor data.

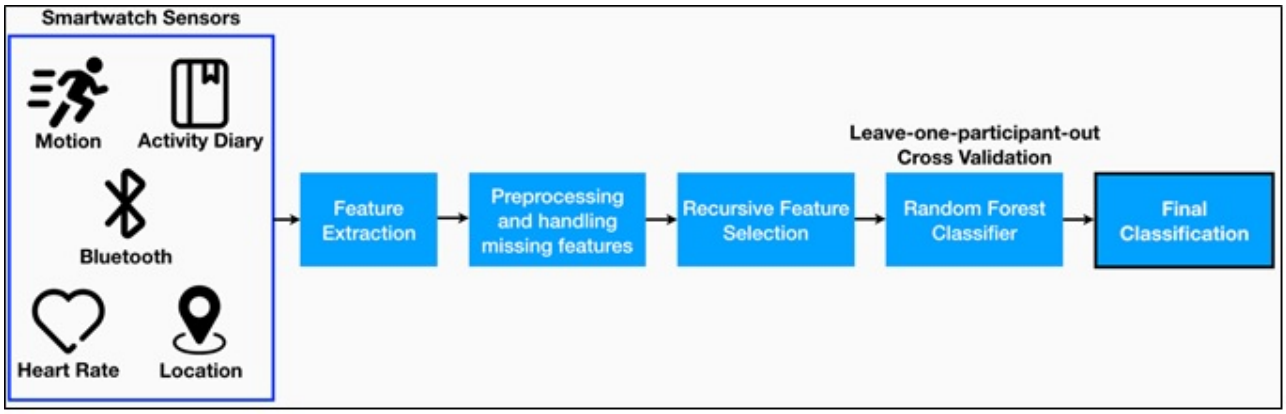
Procedure

After obtaining informed consent from the parent and assent from the child, the participants wore an Apple smartwatch with the LemurDx app running on it for 2 days. One arm of the study (n=15) consisted of children diagnosed with ADHD predominantly hyperactive/impulsive presentation or combined presentation, confirmed using the K-SADS-PL. The children wore the smartwatch for at least 1 day when they did not take their medication (eg, Saturday, Sunday, medication holidays), given that properly titrated stimulant medication reduces hyperactivity. The control arm (n=15) included children without an ADHD diagnosis, confirmed using the K-SADS-PL. The parents also provided activity labels via an automated remote assessment.

Data Processing and Analyses

The data processing and analysis pipeline consisted of three main steps: (1) feature extraction to calculate a set of motion and behavioral features over different time periods, (2) feature selection to identify a set of useful features and reduce the dimensionality, and (3) modeling the final set of features (Figure 1) to identify children with ADHD using a supervised machine learning approach.

Figure 1. LemurDx classification pipeline.



Feature Extraction

We computed 3 sets of features from the motion data collected on the watch. The first set included information about the shape of the motion curves over time and included features such as skewness and kurtosis. These features allowed us to identify the *type* of motion the children were making. The second set of features included statistical summaries of the motion data and included features such as mean, variance, median, magnitude, and hour quantiles of the observed motion. These features tend to capture both the *amount* of and the *changes* in motion. The third set of features included the cumulative motion recorded by the watch. This feature captured the total amount of motion exhibited over a time window. We calculated all 3 sets of features for 3 axes of the acceleration data and over 3 time windows, that is 1, 5, and 10 minutes. Apart from calculating these features over the course of the whole day, we also divided the features into times of the day when the children were performing specific activities as recorded in the activity labels. We used features from 3 activity classes: sitting/quiet, exercise, and everyday/household activity. Next, we handled the missing features due to missing sensor data. We occasionally missed sensor data due to technical issues with the app or watch, or compliance and human factors issues (eg, the family forgot to charge the watch). We imputed all the missing features with a value of –1.

Feature Selection

We used the randomized logistic regression (RLR) method to select an optimal set of features before classifying the data. RLR randomly subsamples the data and calculates feature importance based on their performance in a classification task, using logistic

regression [15]. This approach usually leads to a stable and reproducible set of selected features. We selected the top 20 features outputted from RLR implementation of scikit-learn.

Modeling

We used Python's scikit-learn library (Python Software Foundation) for the model building and for all analyses. We tried 3 types of learning algorithms: random forests, support vector machines (SVMs), and logistic regression. We chose these algorithms for their ability to generalize, capture inherent nonlinearity in the data (using specific kernels in case of SVMs), and their ability to model noisy data. Our analyses showed that random forests (with 2000 decision stumps or estimators) gave the best performance. Analyses were performed with leave-one-participant-out cross-validation to ensure that the models did not overfit. This approach builds a separate model for each participant in the validation phase and ensures that no participant's data are shared between training and testing.

Results

Participant Demographics

Key demographic variables and hyperactivity scores are summarized in Table 1.

Table 1. Participant demographics.

Characteristics	All participants (N=30)	
	ADHD[a] (n=15), n (%)	Non-ADHD (n=15), n (%)
Age (year), mean (SD)	9.6 (1.6)	10.1 (1.8)
Gender, n (%)		
Female	6 (40)	9 (60)
Male	8 (53)	6 (40)
Other	1 (6.7)	0 (0)
Race, n (%)		
White	11 (73.3)	14 (93.3)
Black or African American	1 (6.7)	1 (6.7)
More than one race	1 (6.7)	0 (0)
Chose not to answer	2 (13.3)	0 (0)
VAS-P[b] hyperactivity scores, mean (SD)	11.5 (2.2)	1.9 (1.7)

[a]ADHD: attention-deficit/hyperactivity disorder.

[b]VAS-P: Vanderbilt Assessment Scale-Parent report.

Usability

Sensor data from the LemurDx app were successfully collected for 28 of the 30 child participants. A total of 2 participants accidentally turned off location recording in the settings of the watch. For 3 other participants, the watch failed to record heart rate. Also, 5 participants (3 in the ADHD group and 2 in the control group) had trouble recording additional sensor data. We theorized that this failure was due to a loose fit of the watch on the children's small wrists. The overall PSSUQ usability scores were high (mean 1.81, SD 0.93) as were all the other subscale scores including usefulness (mean 1.81, SD 1.13), information quality (mean 1.75, SD 0.89), and interface quality (mean 1.92, SD 1.16). There were 3 common themes among the qualitative survey results: challenges with the app's interface, low battery life, and participants who enjoyed using the app. Fewer than 20% of the participants had some trouble with the watch's interface. Qualitative feedback is summarized in Table 2.

Table 2. Smartwatch app usability survey qualitative feedback.

Theme	Example quotes	Frequency, n (%)
Challenges with the interface	• "It would be helpful if it showed something on the face of the watch to let you know that the app was running in the background." • "There was really very little we saw of the study app. Just that we turned it on, saw how long it was running for and turned it off. It's hard to say how satisfied we were with its functions."	5 (17)
Low battery life	• "We struggled with the battery running out before we were finished recording a full day's data, despite the battery being at 100% at 7.30 AM." • "Phone ran out of battery on first day- hope that did not affect things- we can redo it if needed."	4 (13)
Enjoyed the app	• "It was fun to participate." • "Study is well organized and was easy to follow instructions."	3 (10)

Accuracy

The top 20 motion features extracted from motion sensor data are summarized in Table 3.

Alone, the model was no better than chance at differentiating between ADHD and non-ADHD children (accuracy=0.46; X^2_1=0.14, P=.70). When the motion sensor data was paired with the contextual sensors (ie, GPS, heart rate, Bluetooth), the model performance improved significantly (accuracy=0.71) and could differentiate between ADHD and non-ADHD children at better than chance level (X^2_1=5.25, P=.02). Model performance was best when the sensor data was paired with the activity labels (accuracy=0.89) and could reliably differentiate between ADHD and non-ADHD children (X^2_1=17.37, P<.001). Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for each model are summarized in Table 4. Finally, our analyses showed (Figure 2) that the magnitude of motion when the child was expected to "sit quietly" was the biggest differentiator between ADHD and non-ADHD children, consistent with a clinical profile of hyperactivity.

Table 3. Top 20 features extracted from motion sensors.

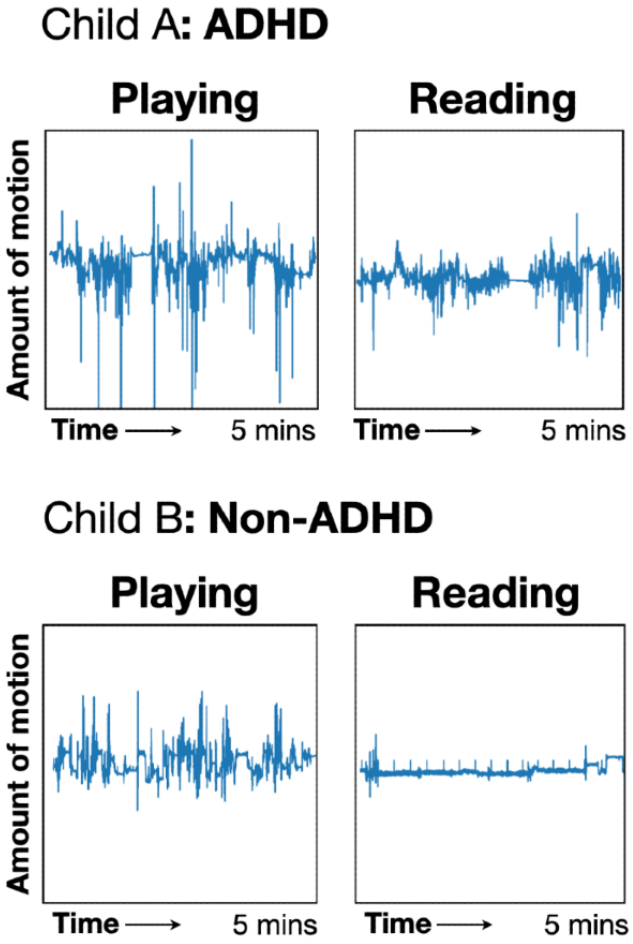
Number	Motion feature	Axis	Time interval
1	Cumulative variance	X-axis	10 minutes
2	Cumulative mean	X-axis	1 minute
3	Cumulative mean	X-axis	5 minutes
4	Cumulative mean	Y-axis	10 minutes
5	Cumulative variance	Z-axis	1 minute
6	Cumulative mean	All 3 axes	10 minutes
7	Cumulative variance	All 3 axes	5 minutes
8	Mean motion	X-axis	10 minutes
9	Variance	X-axis	10 minutes
10	Variance	X-axis	1 minute
11	Mean	Y-axis	10 minutes
12	Variance	Y-axis	10 minutes
13	Mean	Y-axis	1 minute
14	Variance	Y-axis	1 minute
15	Mean	Y-axis	5 minutes
16	Variance	Y-axis	5 minutes
17	Variance	Z-axis	10 minutes
18	Mean	Z-axis	1 minute
19	Variance	Z-axis	1 minute
20	Mean	Z-axis	5 minutes

Table 4. LemurDx accuracy, sensitivity, specificity, positive productive value (PPV), and negative productive value (NPV).

Model	Accuracy	Sensitivity	Specificity	PPV	NPV
Motion sensors plus activity labels	0.89	0.93	0.86	0.87	0.92
Motion sensors plus contextual sensors[a]	0.71	0.79	0.64	0.69	0.75
Motion sensors alone	0.46	0.50	0.43	0.47	0.46

[a]Contextual sensors included GPS, heart rate, and Bluetooth.

Figure 2. Motion spectrograms (x-axis: time; y-axis: motion) for 5-minute periods. A: The top panels are for a child with attention-deficit/hyperactivity disorder (ADHD). B: The bottom panels are for a child from the control group. In the first panel (playing), the child with ADHD moved 24.7 % more than the child in the control group. In the second panel (reading), the child with ADHD moved 41.2 % more than the child in the control group. ADHD: attention-deficit/hyperactivity disorder.



Discussion

Principal Findings

This study examined the LemurDx smartwatch app prototype among a sample of 30 children. Usability scores were high, pointing to the potential clinical utility of this approach to provide an objective measure of hyperactivity. However, qualitative feedback pointed to some issues with the interface and battery life, indicating that further development is needed in these areas. Despite these limitations, the app performed well enough to collect usable sensor data from 93% of the sample and successfully classify children with high accuracy.

As expected based on past actigraphy studies, motion data alone were a poor classifier of hyperactivity. Using motion sensors alone, model performance was no better than chance level at differentiating children with ADHD (hyperactive or combined presentations) from the ones in the healthy control group. Accuracy improved significantly when contextual information and activity labels were added to the models. These results suggest that contextual information is important when using sensor motion data to make inferences about the presence of hyperactivity.

These promising results point to the value of further research on contextualizing motion data for clinical purposes. Using the range of sensors provided in modern smartwatches could allow us to further refine the machine learning algorithms. These results would likely yield increases in accuracy based on variables specific to each child. The LemurDx app also has the potential to provide an objective measure of response to stimulant medication, thereby providing clinicians with objective

data based on which medication titration decisions could be made. Overall, the data from this study support the further refinement of the LemurDx app and algorithms in order to provide an objective measure of hyperactivity to supplement the subjective parent and teacher questionnaires.

Limitations

A limitation of this study was the absence of children with borderline levels of hyperactivity. Only children who met the specific cutoff numbers on the Vanderbilt's hyperactivity screen were recruited. Children had to score an 8 or above to meet the ADHD condition, while a score of 5 or below was needed for the control condition. Recruiting children who scored an 8 or higher but still met the control condition would help with diversifying the data. Another limitation of this pilot study was the small sample size, as only 30 families were included in the study sample, with usable motion data from 28 children. The sample size, however, was sufficient for this preliminary pilot work. A larger sample in the future will allow for stronger indicators of context, better visualization tools for clinicians, and more precise machine learning models.

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Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
K-SADS-PL: Kiddie Schedule for Affective Disorders and Schizophrenia Present and Lifetime Version
PSSUQ: Post-Study System Usability Questionnaire
RLR: randomized logistic regression
SVM: support vector machine
VAS-P: Vanderbilt Assessment Scale-Parent report

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Original Paper

Workplace Reintegration Facilitator Training Program for Mental Health Literacy and Workplace Attitudes of Public Safety Personnel: Pre-Post Pilot Cohort Study

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Abstract

Background: Public safety personnel (PSP) impacted by operational stress injuries can find themselves needing both time off work and support reintegrating back into the workforce. Work reintegration programs have been introduced in PSP organizations to support those who aim to return to work. One such peer-led workplace reintegration program (RP) was created in 2009 by members of the Edmonton Police Service (EPS). The primary goal of the EPSRP is to assist PSP in returning to work as soon as possible following a critical incident, illness, or injury while diminishing the potential for long-term psychological injury. The EPSRP is delivered by peers through 3 interrelated components: (1) the Reintegration Program Facilitator Training (RPFT) Program; (2) a short-term Critical Incident RP; and (3) a long-term RP. There is a dire need for research that incorporates strong study designs to the determine long-term effectiveness of the program on increasing workplace reintegration, improving mental health knowledge, and creating culture change within PSP organizations. Simultaneously, the efficacy, effectiveness, and fidelity of the RPFT in providing the tools, mental health knowledge, and skills the RP peer facilitators will need for the RP must be evaluated.

Objective: The purpose of this quasi-experimental pre-post pilot cohort study is to evaluate the effectiveness of the EPSRPFT course on influencing mental health knowledge and attitudes of RPFT attendees who will be future RP peer facilitators.

Methods: This pre-post cohort study collected data via 2 questionnaires from RPFT participants (N=60) which included the Mental Health Knowledge Survey (MAKS) and the Open Minds Survey of Workplace Attitudes (OMSWA). Descriptive, parametric (sample *t* tests), and nonparametric (Wilcoxon signed rank tests) statistics were used to compare the pre- and post-RPFT results and to analyze results by gender and profession.

Results: Statistically significant changes were observed in pre-post questionnaire scores in the domains of mental health attitudes and knowledge.

Conclusions: Although results are explorative, the RPFT may facilitate positive changes in workplace mental health attitudes and knowledge among PSP. It is hoped these findings will contribute to a broader evidence base that can inform changes to the program, practices, and policies, and inform decision-making regarding the EPSRP.

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KEYWORDS

public safety personnel; mental health; return to work; reintegration; first responders

Introduction

Background

Public safety personnel (PSP; eg, correctional workers, dispatchers, firefighters, paramedics, police officers) are at an elevated risk of experiencing occupational stress injuries (OSIs) [1]. OSIs which are more common among PSP are work-related psychological distress, mental illness, and work place injuries that result from exposure to events and tasks that can be unpredictable, traumatic, and high risk [2]. A recent study surveying 5813 PSP in Canada found that 36.7% of municipal police, 34.1% of firefighters, 50.2% of Royal Canadian Mounted Police (RCMP), and 49.1% of paramedical staff screened positive for a mental health condition, such as posttraumatic stress disorder (PTSD), depression, anxiety, or substance abuse [3]. These prevalence rates are similar to those in other nations where there are elevated rates of mental health conditions and suicidality among their PSP when compared to the civilian public [4-8]. In an Australian study, 1 in 3 emergency services personnel were reported to experience high or very high psychological distress [7]. In the United States, it is estimated that 30% of first responders develop mental health conditions compared with 20% in the general population [8].

High rates of OSIs can lead to elevated levels of work absenteeism, which risks compromising the level of service that PSP organizations can provide in their communities and increasing the burden on health care and workers' compensation. OSIs interfere with daily functioning in social, work, or family activities and can leave PSP in need of time off work or unable to return to work in the short- or long-term [9]. These conditions have the potential to impact an individual's quality of life and can result in decreased community integration, increased social isolation, and greater difficulty forming and maintaining meaningful relationships [10,11]. OSIs such as PTSD can lead to issues with self-care, health, and sleep, all of which can negatively affect success in productive roles such as employment [12]. Productivity-related occupational performance issues attributed to OSIs can cause difficulty with returning to and maintaining work [12].

Facilitating return to work among PSP who have experienced posttraumatic stress injuries and OSIs is a primary concern for PSP, their families, and their organizations. Workplace reintegration interventions offered in clinical health or workers' compensation settings to address posttraumatic stress injuries and OSIs can be effective in reducing psychological distress and improving daily function. They may have a limited ability, however, to help PSP constructively engage with real-world occupational stressors given that they are offered outside of the PSP service environment [13]. As a result, peer-support interventions and programs offered as an adjunct to clinical evidence-based interventions have become more common within military and PSP organizations.

Peer-support relationships—supportive relationships between people who have a common lived experience—may both enable PSP to take a first step toward recovery and assist individuals throughout the rehabilitation process [14]. Research has illustrated that many PSP feel more comfortable and are more likely to share psychological health challenges with their peers than with a health care professional [15,16]. Commonly shared PSP peer experiences may relate to their career paths and roles as well as mental health challenges or illnesses [14].

Peer-support programs can differ in their area of focus, delivery format and context, and aims. Some programs are associated with critical-incident stress debriefing, critical-incident stress management, peer support, psychological first aid, and trauma risk management [17]. Such programs are delivered in community, clinical, and workplace contexts in both group and one-to-one formats which can contribute to increased accessibility for PSP [14]. Peer-support programs may also be introduced prior to, during, or upon conclusion of clinical interventions and a person's return to work, and may be the first step a person takes toward recovery. They may also bridge care gaps when geography or organizational security requirements are barriers to care (eg, while clinicians are unable to access PSP environments that require specialized training, certification, and security clearance). In these circumstances, peers can support the therapeutic process within PSP-specific environments, provide a more nuanced understanding of specific occupational stressors and triggers, and help to support or develop creative occupational-specific coping strategies.

Evidence-based literature to support peer-support initiatives among PSP is scarce but emerging. A small body of literature demonstrates promise for peer-support programs in effectively reducing symptoms of psychological distress and increasing self-efficacy and empowerment in civilian and veteran populations with various mental health diagnoses [18,19]. A recent scoping review focused on collating evidence on the use of early interventions for trauma in workers in organizations such as police, fire and rescue, ambulance, and health professionals where traumatic events are routinely experienced due to the nature of the work. With respect to peer-based or peer-led interventions, the reviewers noted that interventions inclusive of peer-group debriefings led to significant reductions in trauma-related absenteeism, and 25 out of 34 studies that delivered an early intervention in a group format found that peer support had facilitated recovery or made for a better experience [20]. A 2015 Finnish survey found that a majority of police officers endorse peer support as a preferred method of learning about stress, health, and posttraumatic treatment [16]. The current literature does not provide information on the functional implications and workplace reintegration outcomes of peer-support programs, which may include workplace presenteeism, work satisfaction, postinjury job demands, perceived organizational justice, perceived work-life balance, and interpersonal workplace relationships as well as the type, intensity, and frequency of the postinjury work (eg, full or part time, modified duties, change in role). Moreover, while some research exists regarding peer-support programs, there is little research evaluating the efficacy and effectiveness of the training

that PSP peer-support facilitators receive prior to engaging as leaders in peer-led initiatives.

In 2009, the Edmonton Police Service (EPS) developed a peer-led work reintegration program (RP) that engages police officers in a step-by-step occupation-specific process in actual policing contexts. The primary goal of the EPSRP is to enable officers to return to work as soon as possible, while diminishing the potential for long-term psychological injury [13]. It accomplishes this by engaging the officer in a step-by-step process that addresses the unique stressors that an officer may experience. The pace, scope, depth, and goals of the program are guided by the individual officer with support from the officer's clinical team. The EPSRP, which includes relationship building, reintroduction to equipment, skill building, exposure therapy, and street exposures [13], is delivered by peers through 3 interrelated components: (1) a RP Facilitator Training Program (RPFT), (2) a short-term Critical Incident RP, and (3) a long-term RP [13]. The short-term Critical Incident RP is offered to support PSP following critical incidents, such as officer-involved shootings. Goals of the long-term RP are to assist officers who have been off work for an extended period of time to return to the normalcy of work settings by providing support and training that are outside the scope of what they have received from their health care provider (ie, psychologist, clinician, or occupational therapist). This study focuses on the first component, the RPFT, and will be outlined in depth in the Methods section.

Since the RP's inception, 185 EPS officers and 200 plus Alberta Health Services (AHS) emergency services and RCMP K Division staff in Alberta, Canada, have participated in the RP. In the province of Ontario, the Ottawa Police Service and RCMP O Division are actively using the RP with participants while the London Police Service, Ontario Provincial Police, and the Niagara Police Service are in the process of implementing the RP [21]. Evidence regarding the effectiveness of the EPSRP is evolving. Findings from a 2018 internal study by the EPS indicated a 70% reduction in days lost following introduction of the program [13]. A further analysis conducted by the AHS comparing 2 cohorts of emergency services employees demonstrated promising numbers, with 50% more work-days lost in the cohort without the RP compared to the cohort with access to it [21]. Interest in the EPSRP has been stimulated among various PSP groups as a result of positive anecdotal reports. A qualitative analysis of the RPFT was published in 2021, concluding that while the EPSRP holds promise, it is essential that evidence-based research be used to guide RPFT and RP spread and sustainability [22]. PSP organizations in other Canadian provinces, New Zealand, and the United Kingdom are also at various stages of exploring or implementing the EPSRP.

Although PSP organizations are beginning to integrate peer-supported workplace reintegration programs into their mental health strategies, caution must be used. Despite emerging research, a body of scientific literature supporting the efficacy, safety, and effectiveness of peer-lead workplace RPs is lacking, making conclusive decisions about their implementation and use difficult [23]. High-quality RP effectiveness studies that incorporate stronger study designs, rigor, validity, and reliability are needed. Determination of their long-term effects are also required, together with an assessment of potential risk of harm to the participants and facilitators [23]. Research of peer-supported RPs, as well as the facilitator training programs within the Canadian, provincial, and municipal contexts, are needed to ensure that this approach is safe and beneficial for PSP [23,24].

Objective

The purpose of this quasi-experimental, pre-post, pilot cohort study is to measure changes in the mental health knowledge and attitudes of PSP attendees of the RPFT based on self-reported outcome measures. This study is unique in that it aims to be the first externally peer-reviewed quantitative research regarding this RP that incorporates an a priori study design and includes considerations of rigor, validity, and reliability. The results of this study may assist with the further development, fidelity, and implementation of the RPFT, with the goal of strengthening the RP and initiating further research to meet the aforementioned need for addressing questions regarding efficacy, effectiveness, and safety.

Methods

Study Design

This pre-post, quantitative, quasi-experimental, pilot cohort study was part of a larger mixed methods pilot project which employed a convergent parallel design [25,26]. Concurrent collection of quantitative and qualitative data and triangulation occurred once all data were collected.

Ethical Approval

This study received ethical approval from the University of Alberta Research Ethics Board (study approval #Pro00089517) and was supported by the EPS.

Reintegration Program Facilitator Training

The 5-day RPFT course was developed and implemented to prepare PSP peers to deliver the EPSRP to colleagues who sought to reintegrate back into work following an OSI and to increase the spread of the RP across PSP organizations. EPS offers the RPFT program multiple times per year for PSP who are interested in becoming RP facilitators or who are implementing an RP within their organizations. The training includes both psychoeducational and experiential components. Examples of psychoeducational topics include the physiological effects of trauma, basic neuroanatomy and physiology, mental health disorders, specific counseling exercises, and interpersonal skills, such as active listening. Experiential components include hands-on graded activities, such as firearms exposures on the firing range for police, mock interrogations for border patrol personnel, donning of equipment for firefighters, and specific scenarios in an ambulance for paramedics. Participants were required to attend and engage in the 40-hour training prior to being designated a RP peer facilitator within their respective PSP organizations.

Recruitment and Sampling

Participants (N=60) included Alberta-based PSP (eg, RCMP, police, emergency medical services, fire, sheriffs) and clinicians (psychologists and occupational therapists) working with PSPs who attended the RPFT. The participants voluntarily signed up to attend the 5-day RPFT course and had attained approval to participate from their employer. All RPFT attendees were invited to participate in this research study. Upon registering in the RPFT, attendees were asked by the reintegration coordinator if they were interested in participating in the study. Those interested were enrolled and, prior to commencing the RPFT, provided written and verbal consent.

Outcome Measures

Questionnaires that were administered pre- and posttraining captured descriptive data (eg, age, gender, role), along with information about participant knowledge, skills and attitudes, mental health literacy (Mental Health Knowledge Survey [MAKS]) [27], work reintegration, mental health stigma, and workplace attitude (Open Minds Survey of Workplace Attitudes [OMSWA]) [28].

The MAKS was developed from the theoretical underpinning that stigma comprises 3 constructs: knowledge (ignorance), attitudes (prejudice), and behavior (discrimination) [27]. The MAKS is a 12-item self-report questionnaire designed to measure mental health literacy and stigma [27]. Items are rated on a 5-point Likert scale measuring level of agreement ranging from 1 (strongly disagree) to 5 (strongly agree). Psychometric data support the internal consistency and test-retest reliability of the measure, and the measure appears sensitive to changes in participant responses based on interventions [27,29]. The OMSWA is a 23-item self-report questionnaire designed to measure mental health stigma and workplace attitudes. Items such as “I would be upset if a coworker with a mental illness always sat next to me at work” are rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) [28]. There does exist psychometric data to support the internal consistency of this outcome measure, and it is commonly used by the Mental Health Commission of Canada [29].

A pre-post mental health knowledge questionnaire developed specifically for the EPSRPFT was also trialed based on the RPFT curriculum goals and objectives (Multimedia Appendix 1). This questionnaire employed a 5-point Likert scale ranging from 1 (not at all true) to 5 (very true) for 2 sections: (1) Understanding of Concepts, “I have an excellent understanding of ….” and (2) Skills, “I have excellent skills to ….” A third section required the respondent to rate their level of agreement from 1 (strongly disagree) to 5 (strongly agree) regarding statements related to workplace mental health knowledge, stigma, and attitudes.

Data Collection

After providing written and verbal consent, and prior to commencing the RPFT, participants were provided a participant number by the lead researcher (CJ) along with a blank envelope containing the precourse surveys. This allowed for participants to be reassured both that their employers were unaware of who participated in the study and their responses and that the study was being conducted externally by independent researchers. Participants were asked to complete the outcome measures and immediately return the envelope to the research team. This process was also completed at the conclusion of the RPFT. Data were then manually entered into SPSS software (IBM Corp) by the research team for analysis.

Data Analysis

Demographics of the sample were calculated for each of the measures as were total scores for each dependent variable pre- and post-RPFT. Quantitative data were analyzed using SPSS software with sample *t* tests and Wilcoxon signed rank tests. Two-level multilevel modeling analyses were conducted for each repeated measure analysis in the study. Time, as a fixed variable, was coded into 2 time points: (1) baseline and (2) postintervention. Each model included 1 of the dependent variables (ie, MAKS and OMSWA) at each time point (level 1) nested within participants (level 2). Baseline differences in scores among individuals were accounted for by including both a fixed and random intercept in the model. Each final model included the fixed effect of time as the primary predictor variable. All models were computed using the maximum likelihood estimation. All hypothesis testing was conducted using 1-tailed tests at an α level of .05. Cohen *d* effect sizes were computed for all models by standardizing each outcome measure and rerunning the resulting *z* scores in each model. All models were bootstrapped to generate robust probability values and corresponding CIs. A sample of n=30 or higher was required for a power of 0.8, and an attrition rate of 20% was predicted.

Results

The demographics of the PSP sample are displayed in Table 1. The sample was largely composed of men (n=44), which is common in PSP professions. PSP in policing professions, including municipal policing (n=14) and RCMP (n=12), were the most common among the sample. Of the participants, 32 reported already having an established RP within their home organization.

Statistically significant changes in preintervention to postintervention scores were noted for the overall sample with the MAKS (preintervention: mean 48.70, SD 3.688; postintervention: mean 50.70, SD 3.452; t_{50}= –3.373; *P*=.001) and are displayed in Table 2. The OMSWA also showed statistically significant preintervention (mean 38.01, SD 9.830) and postintervention (mean 33.18, SD 7.362; t_{49}=3.692; *P*=.001) changes. This would indicate that among the entire PSP sample, mental health knowledge, literacy, and workplace attitudes toward mental health increased while mental health stigma decreased. The sample was further broken down to analyze the significance of changes on the MAKS and OMSWA by gender and profession (Tables 3 to 6).

The scores of participants who identified as women and completed both pre- and postoutcome measures (n=15) were compared on the pre- and post-MAKS using the Wilcoxon signed rank test (Table 3). Women’s participant scores for posttraining (meaning 20.07, SD 1.32) were lower than those for pretraining (mean 20.93, SD 1.02). The Wilcoxon signed

ranks test indicated that the median posttraining ranks on the MAKS were not statistically significantly lower than the pretraining ranks on the MAKS (z= –1.67; P=.95).

The women's scores were compared on the OMSWA pre– and post–work reintegration training. The women's scores posttraining (mean 31.3, SD 1.75) were lower than those pretraining (mean 36.4, SD 2.68). However, the Wilcoxon signed rank test indicated that the median posttraining ranks on the OMSWA were not statistically significantly lower than the pretraining ranks on the OMSWA (z= –1.50; P=.13).

The scores of those participants who identified as men and completed both pre- and postoutcome measures (n=35) were compared on the MAKS before and after use of the paired sample t test (Table 4). The men's scores posttraining (mean 21.17, SD 0.82) were lower than those pretraining (mean 23.57, SD 0.82). This improvement was statistically significant (t_{34}= 4.09; P<.001). The men's scores were compared on the OMSWA pre– and post–work reintegration training. Men's participant scores posttraining (mean 34.37, SD 1.24) were lower than those pretraining (mean 41.06, SD 1.69). This improvement was statistically significant (t_{35}=3.11; P=.004).

Municipal police (n=14) were the most likely to demonstrate a change in the pre-post OMSWA (z=–1.97; P=.049), demonstrating improvements in workplace attitudes after the RPFT (Table 5). The RCMP (n=12) showed the most statistically significant changes on the MAKS (z=–2.37; P=.02; median score pretraining 28; median score post training 17.5), which demonstrated an increase in mental health knowledge (Table 6). All other pre-post comparisons of the MAKS and OMSWA for specific PSP professions were nonsignificant.

Table 1. Demographic characteristics of the participants (N=60).

Profession	Statistic, n (%)
Municipal police	14 (23)
Men	11 (18)
Women	3 (5)
RCMP[a]	12 (20)
Men	12 (20)
Women	0 (0)
EMS[b]**/paramedical**	9 (15)
Men	4 (7)
Women	5 (8)
Sheriff or peace officer	9 (15)
Men	7 (12)
Women	2 (3)
Firefighter	6 (10)
Men	4 (7)
Women	2 (3)
Other	7 (12)
Men	5 (8)
Women	2 (3)
Clinician	3 (5)
Men	1 (2)
Women	2 (3)
Total	60 (100)
Men	44 (73)
Women	16 (27)

[a]RCMP: Royal Canadian Mounted Police.

[b]EMS: emergeny medical services.

Table 2. Overall outcome measure scores.

Outcome measure	Statistic (N=57)		
	Mean score (SD)	*t* value	*P* value
OMSWA[a]			
Pre	38.01 (9.83)	N/A[b]	N/A
Post	33.18 (7.362)	3.692	.001
MAKS[c]			
Pre	48.7 (3.688)	N/A	N/A
Post	50.7 (3.452)	–3.373	.001

[a]OMSWA: Open Minds Survey of Workplace Attitudes.

[b]N/A: not applicable.

[c]MAKS: Mental Health Knowledge Survey.

Table 3. Pre-post outcome measure scores by gender: women.

Outcome measure	Statistic (N=15)		
	Mean score (SD)	*t* value	*P* value
OMSWA[a]			
Pre	36.4 (2.68)	N/A[b]	N/A
Post	31.33 (1.75)	–1.50	.13
MAKS[c]			
Pre	20.93 (1.02)	N/A	N/A
Post	20.93 (1.32)	–1.67	0.95

[a]OMSWA: Open Minds Survey of Workplace Attitudes.

[b]N/A: not applicable.

[c]MAKS: Mental Health Knowledge Survey.

Table 4. Pre-post outcome measure scores by gender: men.

Outcome measure	Statistic (N=35)		
	Mean score (SD)	*t* value	*P* value
OMSWA[a]			
Pre	41.06 (1.69)	N/A[b]	N/A
Post	34.37 (1.24)	3.11	.004
MAKS[c]			
Pre	23.57 (0.82)	N/A	N/A
Post	21.17 (0.82)	4.90	<.001

[a]OMSWA: Open Minds Survey of Workplace Attitudes.

[b]N/A: not applicable.

[c]MAKS: Mental Health Knowledge Survey.

Table 5. Pre-post outcome measure scores for municipal police.

Outcome measure	Statistic (N=12)		
	Mean score (SD)	*t* value	*P* value
OMSWA[a]			
Pre	40.00 (11.19)	N/A[b]	N/A
Post	35.00 (7.90)	–1.97	.049
MAKS[c]			
Pre	23.21 (5.29)	N/A	N/A
Post	21.85 (4.05)	–1.33	.18

[a]OMSWA: Open Minds Survey of Workplace Attitudes.

[b]N/A: not applicable.

[c]MAKS: Mental Health Knowledge Survey.

Table 6. Pre-post outcome measure scores for Royal Canadian Mounted Police (RCMP).

Outcome measure	Statistic (N=10)		
	Mean score (SD)	*t* value	*P* value
OMSWA[a]			
Pre	38.50 (10.91)	N/A[b]	N/A
Post	33.63 (6.37)	–1.54	.12
MAKS[c]			
Pre	27.18 (6.78)	N/A	N/A
Post	20.25 (6.96)	–2.37	.02

[a]OMSWA: Open Minds Survey of Workplace Attitudes.

[b]N/A: not applicable.

[c]MAKS: Mental Health Knowledge Survey.

Discussion

The purpose of this quasi-experimental, pre-post, pilot cohort study was to evaluate the effectiveness of the EPSRPFT course on influencing mental health knowledge and attitudes of RPFT attendees. The statistical results of the outcome measures, notably the MAKS, OMSWA, and EPSRPFT-specific questionnaire, indicated that the 5-day, 40-hour course likely facilitated increased knowledge of mental health and improved workplace attitudes amongst the participants. The amount of change of the overall scores was statistically significant. Improving mental health knowledge may facilitate a positive impact on stigma, facilitate help seeking, and contribute to a greater proportion of PSP with mental illness engaging in medical treatment [27-30]. It should be noted, however, that knowledge alone is not enough for behavioral change and that additional intrinsic and extrinsic factors, such as cultural awareness, life experiences, the environment, and the responses of others, will also affect whether this knowledge and awareness may influence behavioral change [31,32]. If the EPSRPFT was successful at influencing and facilitating positive change in the level of mental health knowledge, awareness, and skills while improving workplace attitudes in 5 days, this may carry over into the PSP workplace culture and organizations.

Change in scores pre-post training suggests potential gender, profession, organization, and individual differences. Data analysis found that men were more likely to see a larger pre-post change in scores as were municipal police and RCMP. It is hypothesized that the smaller number of women and the smaller subsamples being analyzed for differences between professions might have reduced the sensitivity of the statistical analysis within this study. Gender differences, however, may be important; despite being speculative, the current literature demonstrates that in general, women have greater mental health knowledge or comfort expressing that knowledge to others than do men [33,34]. The lack of change in scores, therefore, does not necessarily indicate that the RPFT program is not meeting its objectives. Rather, it may be indicative that some PSP professions, organizations, and individual PSP had more baseline mental health knowledge upon entering the RPFT and, therefore, did not have as much threshold for change.

Participants appeared to be enrolled in the RPFT for differing reasons. Notably, 53% (32/60) of the sample were from PSP organizations that had already established RPs. It is possible that some of the other participants were enrolled in the RPFT for their own personal growth and learning and did not intend to participate as RP facilitators posttraining. As previously stated, improving mental health knowledge and attitudes can

positively influence workplace culture. That being said, it may also be beneficial to reserve the RPFT for those intending to become RP facilitators, with separate learning opportunities available for those participating in the RPFT for other reasons. It is also possible that some of these participants had plans to return to their respective organizations to initiate an RP where one did not previously exist. It may be advantageous to provide information and guidance to this group on how to take steps to implement such a program.

The results of this study should be interpreted with caution, as there were a number of limitations. The data collected in this study were from a single RPFT course specific to a workplace RP without a control group. The specificity of the program and sample limits the generalizability and comparison of the findings. It should also be noted that, although unlikely within the short time period of 5 days, it is possible the observed changes in the PSP attendees mental health knowledge and attitudes could be attributed to other unknown confounding variables aside from the RPFT. A further limitation relates to barriers to open discussion among participants that may arise due to ranks and roles associated with the hierarchical nature of PSP organizations. Stigma surrounding issues regarding mental health, reintegration, PSP culture (norms of hegemonic masculinity, authoritarianism, and emotional control), and organizational culture and policies may also hinder PSP's confidence in verbally sharing ideas and answering questions. Regarding the sample size, the subsamples had a low number of participants, which might have reduced the sensitivity of the statistical analysis for a given PSP and gender. This is a constant challenge within PSP organizations that can and has been mitigated but is unlikely to be eliminated within the research of this population. As with any study with self-report measures, there are a myriad of issues with self-reporting regarding memory and social desirability biases in reporting. Furthermore, the RPFT-specific questionnaire has yet to be validated. Validation of the questionnaire, which will require more studies with additional participants, may be an asset to the RP in its evaluation as a measure of its effectiveness. Finally, although this study would have benefited from a follow-up 3 and 6 months post-RPFT, the COVID-19 pandemic prevented this from being possible. Despite these limitations and barriers, the overall RP program is experiencing international spread without peer-reviewed research supporting it. It is important to have a pragmatic approach in capturing the RP, as it is currently being deployed in real time to generate preliminary research that uses an evidence-based approach that can be applied within the given context.

More research is needed to evaluate the effectiveness, efficacy, and safety of peer-led workplace RPs and their associated facilitator training programs. As emphasized in the Blue Paper and other research on PSP peer-support initiatives, research conducted by external stakeholders could lead to the evidence-based validation of programs such as the peer-led EPSRP and RPFT program for PSP [23,24,35]. Study of organizational and cultural impact, cost-benefit, implementation drivers and processes, and knowledge mobilization strategies is also warranted. Specifically, studies which employ larger samples would allow for more sensitivity to detecting change in pre-post scores. It is critical that future studies look at the long-term impact of the RPFT and whether mental health competencies, knowledge, and attitudes are maintained over time. As this research expands, other populations at elevated risk of OSIs, such as military, veteran, and health care professionals, could also be included to examine the overall impact of peer-supported workplace reintegration initiatives. Favorable research findings would potentially pave the way for more widespread program adoption and integration that ensures risk management strategies and the maintenance of program fidelity [24]. Use of effective implementation science approaches would best facilitate sustainable spread and scale, enabling more PSP with OSIs to be supported in targeting recovery and return to work. Additionally, the pre-post EPSRPFT questionnaire would benefit from further validation studies to establish parametric data. It may be appropriate to use in future evaluations of other courses related to mental health knowledge and training.

The EPSRP is designed to assist PSP in workplace reintegration after a critical incident or long-term absence from the workplace due to mental or physical health conditions. Evidence-based, curriculum-driven training within programs such as EPSRP may increase return-to-work success among PSP. This pilot study demonstrated preliminary evidence that a 5-day RPFT may contribute to improved mental health knowledge and workplace mental health attitudes among PSP. These newly minted RP facilitators will take this information, perspective, and knowledge from the RPFT into their workplace where they will aim to assist their peers with reintegrating back into the PSP work environment. As a foundational objective evaluation of the RPFT conducted by arms-length researchers, the study responds to the imperative detailed both in the Blue Paper [23] and other publications regarding PSP peer-support programs. It is hoped these findings will contribute to a broader evidence base that can inform changes to the program, practices, and policies, and inform decision-making regarding the EPSRP.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Reintegration Program Facilitator Training (RPFT) Specific Questionnaire.
[DOCX File , 16 KB - formative_v6i4e34394_app1.docx]

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Abbreviations

AHS: Alberta Health Services
EPS: Edmonton Police Service
MAKS: Mental Health Knowledge Survey
OMSWA: Open Minds Survey of Workplace Attitudes
OSI: occupational stress injuries
PSP: Public Safety Personnel
PTSD: posttraumatic stress disorder
RP: reintegration program
RPFT: Reintegration Program Facilitator Training

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Original Paper

The Quality of Internet Websites for People Experiencing Psychosis: Pilot Expert Assessment

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Abstract

Background: Clinicians need to be able to assess the quality of the available information to aid clinical decision-making. The internet has become an important source of health information for consumers and their families.

Objective: This study aimed to rate the quality of websites with psychosis-related information (to provide clinicians with a basis for recommending material to guide clinical decision-making with consumers and their families), using a validated instrument as well as a purpose-developed checklist, and consider improvement in quality over a 4-year period.

Methods: Two measures of website quality were used: the DISCERN scale and the Psychosis Website Quality Checklist (PWQC). Terms related to psychosis, including “psychotic,” “psychosis,” “schizophrenia,” “delusion,” and “hallucination,” were entered into Google, and the first 25 results were analyzed. In total, 6 raters with varying health professional backgrounds were used to evaluate the websites across two time points: January-March 2014 and January-March 2018.

Results: Of the 25 websites rated, only the 6 highest ranked websites achieved a DISCERN score, indicating that they were of “good” quality (51-62 out of a possible 75), while the mean score of the websites (mean 43.96, SD 12.08) indicated an overall “fair” quality. The PWQC revealed that websites scored highly on “availability and usability” (mean 16.82, SD 3.96) but poorly on “credibility” (mean 20.99, SD 6.68), “currency” (mean 5.16, SD 2.62), and “breadth and accuracy” (mean 77.87, SD 23.20). Most sites lacked information about early intervention, recreational drug use and suicide risk, with little change in content over time. Stating an editorial or review process on the website (found in 56% of websites) was significantly associated with a higher quality score on both scales (the DISCERN scale, P=.002; the PWQC, P=.006).

Conclusions: The information on the internet available for clinicians to recommend to people affected by psychosis tended to be of “fair” quality. While higher-quality websites exist, it is generally not easy way to assess this on face value. Evidence of an editorial or review process was one indicator of website quality. While sites generally provided basic clinical information, most lacked material addressing weighing up risks and benefits of medication and alternatives, the role of coercive treatment and other more contentious issues. Insufficient emphasis is placed on detailed information on early intervention and importance of lifestyle modifications or how families and friends can contribute. These are likely to be the very answers that consumers and carers are seeking and this gap contributes to unmet needs among this group. We suggest that clinicians should be aware of what is available and where there are gaps.

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KEYWORDS

psychosis; schizophrenia; DISCERN; quality; websites; mental health; Australia; health information; patients; consumers; accessibility; patient empowerment; reliability; eHealth; electronic health; website

Introduction

Accessing information related to one's illness and treatment enables consumers to discuss their health and treatments more confidently with their doctors [1], is central to the patient-centered health care delivery [2] and improves clinical outcomes [3]. It also offers an opportunity to seek information privately and at one's own pace. This is particularly important in relation to psychotic disorders given the bewildering and anxiety-provoking nature of the symptoms themselves for the consumer, and their families or carers. Additionally, the impact of stigma, misinformation, and low levels of mental health literacy can impact have on outcomes of care [4,5].

Several mental illnesses, including schizophrenia, schizoaffective disorder, bipolar disorder, and some physical illnesses, can present with psychosis [6]. This is characterized by disrupted cognitive processes, delusions, hallucinations, and changes to speech and behavior patterns, which are bewildering for those who experience psychosis and their families. People experiencing psychosis, especially those with schizophrenia, often have pronounced fear and anxiety related to social engagement, and the internet offers a safe space to obtain mental health information without having to interact with others [7] and averts any possibility of feeling devalued.

The last decade has seen the internet become increasingly central to the dissemination of health care information. This technological transition has accelerated with the COVID-19 pandemic [8], where "accessing basic requirements like health and education" is increasingly achieved through web-based portals. While there is no conclusive evidence that the COVID-19 pandemic has increased the prevalence of severe psychiatric disorders such as psychosis, the associated distress, enforced social isolation, and related uncertainties may exacerbate symptoms [9]. Additionally, the pandemic has led to a decrease in face-to-face appointments with mental health professionals for those experiencing mental illness, leading to increased reliance on technology; for example, using the internet for both therapy sessions and informal information and support [9]. In one study, approximately 30% of patients with a psychotic disorder reported using the internet "a lot" during the pandemic; this rate was comparable to that of internet use by individuals with other severe mental illnesses [10].

The increasing reliance on the internet as a source of mental health information highlights the importance of clinicians being aware of what information is available on the internet. Even prior to the pandemic, approximately half of Australia's 15 million internet users reported using internet to search for health-related information [11-13]. In mental health services, over 50% of people with a previous diagnosis of mental illness and access to the internet have used the internet to find diagnosis-related information [14,15]. Research has also shown that patients with schizophrenia differ from those with other mental illnesses in their internet search behavior, including the times of the day they use the internet and the search terms used [16]. In a recent study of people hospitalized for schizophrenia [17], over 75% of them had used the internet to search mental health–related content in the previous 6 months and individuals "appear to be using the Internet for obtaining information about their early symptoms and experiences prior to their first contact with psychiatric care."

The apparent frequency and wide-ranging use of the internet by people with psychosis has associated drawbacks, primarily related to the lack of regulation of web-based content. Multiple studies of web-based mental health search behavior among people with psychosis have found that patients express a desire for their mental health clinician to provide a recommended list of reputable websites rather than needing to navigate the plethora of available information unguided [18,19]. Kirschenbaum et al [17] called for more understanding by clinicians of what consumers are looking for when conducting internet searches, and that this increased understanding should help clinicians tailor web-based resources to improve care pathways and reduce the duration of untreated psychosis. Further research has highlighted a need for clear guidance for clinicians aid them in recommending reputable web-based resources to those with severe mental illnesses [20]. As it has been noted that the development of web-based mental health resources and treatments is far outpacing their evaluation [21], mental health professionals would benefit from guidance on what resources to recommend. Hence, it is important that clinicians have some confidence in the quality of information being accessed, and whether it is targeted to the consumers' needs [22].

Despite the central role that the internet now plays in the delivery of health information and services, clinical services generally do not have formal approaches for using the internet for health information in collaboration with consumers and their support network. Clinicians have limited guidance and time to evaluate the plethora of websites available but are aware that poor-quality information can produce unnecessary worry, increase inappropriate consultations, or lead to use of ineffective treatments [13]. Inconsistencies in the quality and clarity of information on the internet make it difficult for clinicians to help guide patients to the best information available. For example, a meta-analysis [23] revealed that 42% of mental health websites are either owned by, or receive funding from, pharmaceutical companies, and that these websites are significantly more likely to be biased toward recommending medication, and not all websites disclose such funding. It has been noted that aiding clinicians to identify reputable websites has been suggested as an important enhancement to patient care [20]. The challenge for health care professionals is to know how to appraise the trustworthiness of psychosis-related website services to enable them to adequately inform consumers, their families, carers, and the general community [24].

This paper focuses on the clinician's perspective, with the aim of providing clinicians with a process to aid them in identifying

appropriate and reputable websites that may be recommended to people experiencing psychosis and their network with information. This study aimed to (1) identify which websites with psychosis-related content surfaced when common diagnostic terms for psychosis are entered into a popular search engine and (2) rate the quality of these websites using a validated instrument (the DISCERN scale) and a purpose-developed checklist of content defined specifically for psychosis. It is anticipated that these results may be useful for clinicians to guide them in recommending high-quality websites to consumers and families experiencing psychotic disorders.

Methods

Measures of Website Quality

This paper uses an operational definition of website "quality" in accordance with the criteria employed by two website quality rating scales: the DISCERN scale [25] and the Psychosis Website Quality Checklist (PWQC) as described below. While the DISCERN scale is the most widely used instrument for evaluating health information websites for any health problem, it does not evaluate specific disorders. The PWQC was used to account for this.

The DISCERN Scale

The DISCERN tool [25] was developed to "enable patients and information providers to judge the quality of written information about treatment choices." The tool is freely available in conjunction with a web-based handbook [26] to evaluate internet-based health information. It rates website reliability, treatment options, and the quality of information with 16 items using a 5-point Likert scale across two subscales: Reliability (Is the publication reliable?) and Quality (How good is the quality of information on treatment choices?). The overall DISCERN scale is obtained by summing the first 15 items of the scale (range 15-75). While the DISCERN tool is useful for rendering the results of this study comparable to that of other studies evaluating web-based health information, it is not designed for evaluating the quality of specific disorders or treatment content.

The PWQC

A disorder-specific website quality checklist was based on the Bipolar Website Quality Checklist (BWQC) devised by Barnes et al [27]. The BWQC has high interrater reliability and a strong correlation with the DISCERN instrument. Five general BWQC subscales were replicated verbatim for the PWQC (see Multimedia Appendix 1):

- Credibility (7 items): is the website reputable, does it have clear quality markers?
- Currency (2 items): is the currency of the website clear?
- Objectivity (6 items): is the website clear about its aims, sponsorship, etc?
- Availability and Usability (4 items): is the website easy to navigate?
- Design and Aesthetics (2 items): are text and images presented in a clear way?

The sixth subscale was adapted from bipolar disorder–specific to schizophrenia-specific content. The Brief Psychiatric Rating Scale [28] and information derived from the Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines for Treatment of Schizophrenia and Related Disorders [29] were used as the basis for developing the 29-item disorder-specific subscale measuring Breadth and Accuracy of the diagnostic and treatment-related information on psychosis.

The individual PWQC items were on a 5-point Likert scale with defined anchor points (1=no, 3=partially, and 5=yes) with a total score ranging 50-250. A PWQC User Guide detailed descriptors of each item and was provided to all raters to enhance interrater reliability (see Multimedia Appendix 1).

General Website Characteristics

The general website characteristics assessed included reporting the presence of an editorial board, ownership type, and scope of information provided [27,30]. Websites were allocated by 2 authors (KW, CMH) to an organizational type: professional (not-for-profit sites associated with a government or professional body with demonstrated health professional involvement [31]), commercial (associated with a privately owned company, professional individual, or drug company for profit), or consumer (referred to as peer-to-peer online support group, forum, virtual community, social network, bulletin board, web-based discussion forum, or live chat room). Consumer organization websites have been evidenced in previous research to support consumers to feel more active as participants in their health care decisions, improve empowerment, and reduce societal loneliness [32].

Website Selection

The search terms "psychotic," "psychosis," "schizophrenia," "delusion," and "hallucination" were entered as a string into the search box for search engine Google. These were selected based on diagnostic terms used by psychiatrists in accordance with the Diagnostic and Statistical Manual of Mental Disorders, fifth edition [33]. Google was selected as the most highly used search engine, with over between 87%-89% of the search market share in the study period. The searches were carried out on a browser where cache, cookies, and browser history were cleared. In line with previous research, the inclusion criterion was that the website fell within the first 25 sites listed by the search engine [34]. Websites were excluded if they were either of the following: a personal blog, news or a media article, not in English, or a paid listing or advertisement. The websites were assessed at 2 time points (January-March 2014 and January-March 2018) by three raters. All identified websites were evaluated using both DISCERN and PWQC instruments. When sites were checked before the second set of assessors in 2018, only one (consumer) site no longer existed and was excluded (see Multimedia Appendix 2 for flowchart and Multimedia Appendix 3 for Results of the Google search of psychosis-related terms).

Raters

In total, 5 raters evaluated the websites. There were initially 3 raters, but owing to interest expressed by further raters, we repeated the exercise 4 years later. One author (KW) rated at

both time points to provide some evaluation of whether the websites returned by the search engine were similar at each time point. However, the second rating was carried out without reference to the previous rating. Raters at each time point included individuals with specialist mental health knowledge and general medical knowledge to ensure that a range of experience and expertise was captured. Thus, raters included a consultant psychiatrist (both time points), and either a clinical nurse consultant or psychiatry registrar and a final year medical student. The aim was to have raters with a capacity to appraise accuracy and quality of the clinical information but with different levels of expertise. All raters read the PWQC manual (see Multimedia Appendix 1) and the DISCERN handbook and evaluated the websites independently of each other. Consumers were not included as the evaluations of content required an ability to critically appraise the clinical information.

Statistical Analyses

Statistical analysis was conducted using SPSS (version 24; IBM Corp). Each rater's DISCERN and PWQC scores for each website were calculated as a mean score. For the primary analysis, the Pearson product-moment correlation coefficient was calculated to examine associations between DISCERN and PWQC total scores, and the interrater reliability for each scale was examined using intraclass correlation coefficients and calculated using the 2-way mixed model with consistency type. Two-tailed paired *t* tests were used to determine changes in mean scores on the DISCERN and PWQC instrument between time 1 (2014) and time 2 (2018). One-way analyses of variance were used to compare scores on the DISCERN and PWQC instruments by website ownership type (professional, commercial, or consumer organization).

Results

Websites Retrieved

Of the 25 websites described in Multimedia Appendix 3, a total of 9 were rated as commercial organizations (links to pharmaceutical companies or seeking referrals to private services or facilities), 11 as professional organizations (mainly aimed to provide information, often backed by a university or health service rather than relying on advertising or charitable grants), and 5 as consumer organizations. Consumer blogs by people who had lost a close family member or friend to mental illness were not included as they were not intended to provide information about the disorders.

A quality marker was associated with 10 of 25 (40%) websites and membership to a code of conduct with 12 (48%) websites, while 14 (56%) websites had an editorial or review process in place and 21 (84%) websites noted sources of information provided or gave references. There were no significant changes in DISCERN or PWQC scores between the 2 data collection time points. Therefore, data were combined for the remainder of the analyses.

Overview of the DISCERN Ratings

The mean DISCERN score was 43.96 (SD 12.08) (in Multimedia Appendix 4), which DISCERN scoring criteria categorize as being of "fair" quality (total score 39-50). The range of scores was 32-57, with the 8 lowest-ranking websites being of "poor" quality (total score 27-38) and 6 highest-ranking websites meeting the criteria for "good" quality (total score 51-62). No websites were rated as "excellent." The mean overall rating (DISCERN item 16) was 2.91 (SD 1.11) of a possible total of 5: the two highest websites received a mean rating of 4.

The intraclass correlation coefficients indicate moderate interrater reliability for Reliability subscale and Overall rating, and good interrater reliability for the Quality subscale and the Total DISCERN score. For each scale, the CIs were wide, suggesting that the true interrater reliability for the Reliability subscale and overall rating was "poor" to "good," and that of the Quality subscale was "moderate" to "excellent," and the DISCERN total score was "moderate" to "good." This reflects variability in the different raters' appraisal of each website, suggesting that while there were differences in the perception of each website's reliability, clarity, and sources of information, there was greater rater agreement on the quality of information provided.

Overview of the PWQC Ratings

The overall mean score on the PWQC was 147 of a possible 250 points (Multimedia Appendix 5). Websites were rated most highly on the "Availability and Usability" subscale, where on average, websites achieved 84% of highest possible score (16.82 of possible 20), followed by "Design and Aesthetics" and "Objectivity" subscales, achieving 70% and 64% (7/10 and 19/30) of total possible scores, respectively. Websites performed poorly on remaining subscales, achieving 51%-59% of the total possible score for "Credibility," "Currency," and "Breadth and Accuracy" (21/35, 5/10, and 78/145, respectively).

The intraclass correlation coefficients indicate that the interrater reliability for most subscales was "moderate" (0.50-0.75). The "Breadth and Accuracy" subscale achieved "good" interrater reliability, while the interrater reliability for "Availability and Usability" was "poor." However, considering the wide confidence intervals, the true interrater reliability for most subscales is likely to be in the range of "poor" to "good."

The mean scores for each PWQC subscale and the total DISCERN score were grouped in accordance with organization type of the site, as proposed by Griffiths and Christensen [30]. There was no difference in website quality by organization category, except for the "Design and Aesthetics" subscale, which revealed a significantly poorer rating for commercial sites than for professional or consumer sites (Multimedia Appendix 6). Websites with an editorial board or review process were rated significantly more highly on overall PWQC and DISCERN scales, and on Credibility and Currency subscales.

There was room for comments on the rating sheet and these included notes on the lack of mention of suicide, other risks, and lack of information about the importance of early intervention, particularly for first episodes.

Correlations Between the DISCERN and PWQC Instruments

The relationship between the mean total DISCERN and PWQC scores was investigated using the Pearson product-moment

correlation coefficient. Preliminary analyses were performed to ensure that no violation of assumptions of normality, linearity, and homoscedasticity was observed in the 2 scores. There was a strong positive correlation between the DISCERN and PWQC variables (r=0.85, P<.001). Indeed, although the top-ranking website on each scale was different, 9 of the top 10 websites on each scale were the same.

Discussion

Principal Findings

This paper aimed to identify and explore the quality of websites with psychosis-related content found through a common search engine. While psychosis-related websites were generally easy to identify using common search terms, the quality of websites was overall poor to moderate, with little evidence of change in quality over a 4-year period.

Quality of Websites

Relevant websites were easy to identify with a common search engine using general search terms related to psychosis, and the search results were consistent over time. The "fair" performance of websites in this study is largely consistent with that reported in previous research examining website quality related to other mental disorders. When developing the BWQC, Barnes et al [27] reported that the 15 websites they evaluated were "disappointing" in their performance on both the BWQC and DISCERN scales. Similarly, Nemoto et al [35] evaluated 37 websites with the DISCERN scale, mostly focusing on mood disorders, panic disorder, and schizophrenia, and concluded that the information provided was generally inadequate, with an overall mean score of 46 of 75. More recently, Rathod, et al [36] reported that only 8 of 27 depression websites focusing on depression scored well on the DISCERN scale, while an evaluation of 20 websites on perinatal anxiety Kirby et al [37] reported that all websites were ranked low to moderate on the DISCERN scale. The Health of Nations Code provides an ethical code for websites and is based on eight principles, which are included in the DISCERN scale categories [38]: authority, complementarity, privacy policy, attribution and date, justifiability, transparency, financial disclosure, and advertising policy.

Findings Related to Specific Psychosis-Related Topics

Another finding was the generic nature of the information available on the websites and the lack of information on areas associated with controversy, such as recreational drug use or coercive treatment. The risks and benefits of medication were not detailed, nor were the importance of physical health aspects of treatment.

The assessors had different levels of experience (by design), and the greater agreement over quality of the website than the actual content is consistent with this observation. While some websites mentioned families and carers, most websites did not provide families with much information that would be potentially helpful in their interactions with the family member experiencing psychosis or treating clinicians. Although avoiding contentious areas may be understandable, these areas may be precisely the topics that consumers and carers want to learn more about for themselves, and we suggest that websites could at least provide a series of questions for consumers and carers to ask the treating clinicians. More recently, some US clinical groups have produced lists of question prompt lists for consumers and their families in relevant areas (and are available through Google), which seems to be a productive initiative [39].

While people with psychosis are seeking web-based information, which can be helpful as supplementary information in collaborative planning with clinicians [18], few websites mentioned the importance of early intervention or approaches to maximize recovery and long-term outcomes. These approaches are now established practice in the treatment of psychosis by mental health services in Australia [3]. We found that the same websites tended to perform relatively well on both the DISCERN and PWQC scales, although the DISCERN scale is a general measure of health information websites, and the PWQC was more psychosis specific. This enabled us to produce a relatively consistent "top 10" websites that clinicians may recommend to consumers and families with a psychosis-related condition. This is consistent with the findings of Barnes et al [27] when evaluating depression-related websites. The better-performing websites tended to display an editorial board or review process, regardless of website ownership type, suggesting that these content control measures are better indicators of website quality than organization ownership. These sites tended to belong to professional organizations associated with a government or professional body, and professional websites have previously been found to contain better-quality information on other conditions such as depression in previous research [31]. There have been mixed findings regarding the importance of website ownership type, with some studies finding that websites owned by professional or charitable organizations were of higher quality [40] and others revealed no effect [41]. It is important to note that categorizing websites was not a straightforward process when allocating to just one category. For example, many nonprofit websites still contained paid advertising and links to commercial products. As web-based advertising increases and the internet continues to evolve, these categories of ownership type may be less meaningful than that when originally conceived.

Of particular concern were our findings that website quality did not improve much over time. Although there were some nonsignificant improvements in the presentation of information on the sites, there was little change in the quality of the content of psychosis-related websites over the 4-year period of the study. This is consistent with the findings of Walsh et al [42], who reported that almost half of depression websites did not update their content over a period of 7 years, prompting them to conclude that "the internet is used more than it is trusted." Considering the importance of the internet as a source of information for people with a mental illness, as well as for their friends and family, it is concerning that many websites do not appear to provide current or comprehensive information and tend not to address issues such as early symptoms of psychosis and suicide risk, which are topics that consumers may be seeking, particularly early in their condition [17], but we have sought to identify the "best available" websites for clinicians to recommend in clinical conversation about psychotic disorders.

Limitations

Although most Australians speak English, the researchers recognize the ever-increasing diversity within the Australian population and worldwide. The inclusion of only English-language psychosis websites within this paper is a limitation, with research of websites in other languages an area of future need. Secondly, the selection of raters from a health professional background was intentional but meant that there was no consumer involvement. We intend to further investigate the process by which consumers and carers assess and judge the quality of health-related internet-based information. Finally, the interrater reliability on some subscales of the DISCERN and PWQC instruments was low, which may have influenced the accuracy of the results. Anecdotally, a lot of the variability between raters came from the ease of navigating the site, with some raters reporting that some websites required a high number of "clicks" through various tabs or pages to find the desired content.

Conclusions

The internet can provide clinicians with information that can improve decision-making with consumers and their families, but accessing helpful information can be overwhelming. However, most sites generally avoid contentious areas related to addressing illicit drug use, weighing up risks and benefits of medication or the role of coercive treatment. Insufficient emphasis is placed on providing detailed information on early intervention and the importance of lifestyle modifications, such as exercise programs or how families and friends can contribute. This is likely to be the very information that consumers and carers are seeking and thus contributes to the unmet needs of this group.

While higher-quality websites exist, there is generally no easy way to assess this on face value, as common markers such as website ownership type are not always associated with the breadth or reliability of information available. Generally, sites providing evidence of their editorial process were the most helpful. There remains significant room for improvement in website quality; however, through our review process, we were able to rank websites consistently on 2 quality scales, thereby producing a resource that may guide professionals when recommending web-based resources to consumers and carers. Our findings indicate a need for health care providers and government agencies to address the issues of poor quality, keeping information current and providing prompts about how to address more controversial areas to be available to consumers and carers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The Psychosis Website Rating Scale for first 3 websites (as example) and rating instruction manual.
[PDF File (Adobe PDF File), 399 KB - formative_v6i4e28135_app1.pdf]

Multimedia Appendix 2
Flowchart of inclusion and exclusion of websites.
[PDF File (Adobe PDF File), 30 KB - formative_v6i4e28135_app2.pdf]

Multimedia Appendix 3
Results of the Google search of psychosis-related terms.
[PDF File (Adobe PDF File), 43 KB - formative_v6i4e28135_app3.pdf]

Multimedia Appendix 4
Ranking of mean (SD) scores for identified websites by total DISCERN scale, Reliability and Quality subscales.
[PDF File (Adobe PDF File), 45 KB - formative_v6i4e28135_app4.pdf]

Multimedia Appendix 5
Mean (SD) total scores on the PWQC tool and subscales.
[DOCX File , 18 KB - formative_v6i4e28135_app5.docx]

Multimedia Appendix 6 [DOCX File , 16 KB - formative_v6i4e28135_app6.docx]

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Abbreviations

BWQC: Bipolar Website Quality Checklist
PWQC: Psychosis Website Quality Checklist

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Viewpoint

Digital Health–Enabled Community-Centered Care: Scalable Model to Empower Future Community Health Workers Using Human-in-the-Loop Artificial Intelligence

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Abstract

Digital health–enabled community-centered care (D-CCC) represents a pioneering vision for the future of community-centered care. D-CCC aims to support and amplify the digital footprint of community health workers through a novel artificial intelligence–enabled closed-loop digital health platform designed for, and with, community health workers. By focusing digitalization at the level of the community health worker, D-CCC enables more timely, supported, and individualized community health worker–delivered interventions. D-CCC has the potential to move community-centered care into an expanded, digitally interconnected, and collaborative community-centered health and social care ecosystem of the future, grounded within a robust and digitally empowered community health workforce.

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KEYWORDS

digital health; community-centered care; community health worker; artificial intelligence; AI; AI-enabled health delivery; eHealth; individualized delivery; interventions; collaborative health; community health; social care; digital empowerment; mobile phone

Introduction

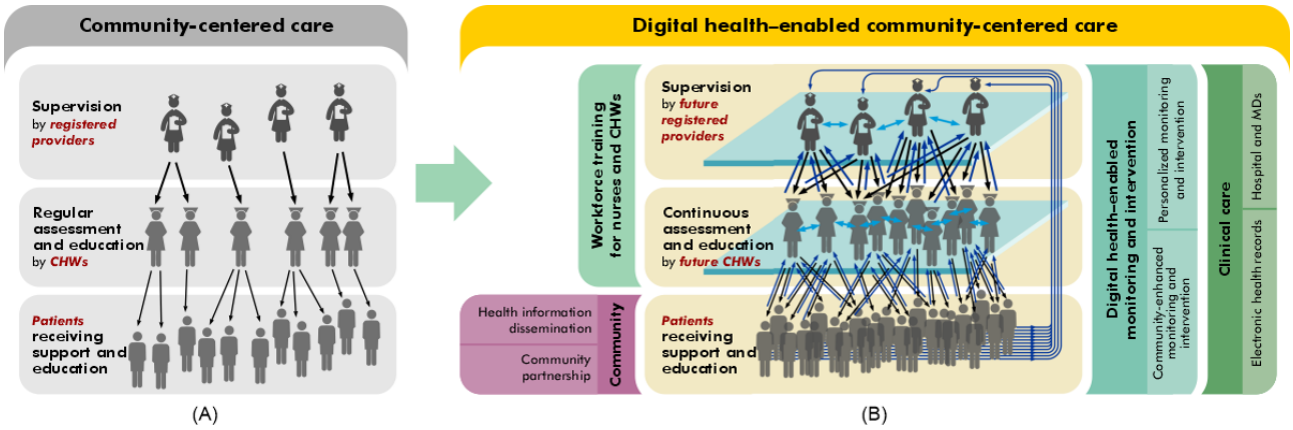
Background

Recent global health trends are necessitating a shift away from a patient-centered medical care system to an upstream health promotion approach that meets the health and social needs of individuals in the communities where they live [1]. A community-centered health and social care ecosystem, supported by a robust community health worker (CHW) workforce, aligns with this needed paradigm shift [1]. Throughout the United States, states are looking to build their CHW workforces and launch CHW initiatives as an alternative assistance to registered health care professionals to extend the reach of home-delivered services [2,3]. Recent data from the California Employment Development Department, for example, project that an additional 200,000 CHWs will be needed by 2024 to maintain current levels of coverage for home care services [4]. As the COVID-19 pandemic continues to amplify health and social support needs globally, a *rapid expansion of the* CHW *footprint is critically needed* to prevent unmet needs from escalating into expensive medical crises, particularly in vulnerable communities [5].

However, scaling the current community-centered care (CCC) model (Figure 1A) in a cost-effective manner while preserving the highly contextual and individualized care delivered by CHWs remains challenging. Increasing use of digital technologies within the CCC model demonstrate potential to expand the CHW footprint; however, existing digital technologies lack integration. In this paper, we present digital

health–enabled CCC (D-CCC) as an improved model to move CCC into the future. Through integrating future digital health technologies, the future CHW workforce, and the future health and social care needs of communities, D-CCC aims to connect the most vulnerable individuals within communities to needed health and social services.

Figure 1. (A) The current community-centered care model. (B) The proposed digital health–enabled community-centered care model. CHW: community health worker; MD: medical doctor.



CHWs as Vital Bridges

CHWs are lay members of the community whose in-depth understanding of community culture and language uniquely positions them to provide culturally appropriate health-related services and support to the community [6]. Through shared lived experience and deep familiarity with social networks and community resources, CHWs serve as vital bridges between vulnerable communities and health systems, connecting community members to critical information, resources, and services [6,7].

CHWs work in a variety of settings—from nonprofit community-based organizations to government agencies and health care systems [7,8]—and range from formal, salaried employees to informal, volunteer-based community educators [9,10]. Just as the activities and roles of CHWs are tailored to the unique health needs of the communities they serve [11], CHWs operate under a diverse set of titles, including but not limited to *promotoras*, community lay workers, outreach educators, peer support workers, home visitors, and community health volunteers [12]. In this paper we use *CHW* as an umbrella term intended to broadly capture the rich diversity of roles and titles held by this vital frontline workforce [6].

As trusted members of the community, CHWs are critically positioned to support vulnerable patient populations [13] and serve as agents of change by helping to reduce health disparities in underserved communities [14]. Documented positive impacts of CHWs include health promotion, improved patient engagement, support with adherence to treatment, improved referrals and access to care, financial return on investment, and improved quality of care and health outcomes [7]. CHW-delivered sociobehavioral interventions have demonstrated efficacy in improving health outcomes in chronic disease and noncommunicable disease (NCD) care and management [15], including cancer [16], diabetes [17-23], asthma [24,25], cardiovascular disease [26], multiple medical comorbidities [27], and mental health [28,29]. CHW-delivered interventions have demonstrated efficacy in reducing hospitalization and rehospitalization rates [27,30-32], and CHWs have proven to be powerful drivers of decreased health care costs, particularly among patients with high starting health care costs and underserved and minority populations [15,17,33,34]. The efficacy of CHWs lies in their close connection to the community, ability to influence client behaviors, and effective interaction with the larger health care team [34-36].

Recent global health trends (including the growing burden of chronic diseases and NCDs), a focus on social determinants of health and health equity, and lessons learned from the COVID-19 pandemic are necessitating a shift away from a patient-centered medical care system toward an upstream health promotion approach that meets the health and social needs of individuals in the communities where they live [1]. In place of the traditionally siloed existence of medicine, public health, and mental health [37], a community-centered health and social care ecosystem, *supported by a robust* CHW *workforce*, will be critical to realizing this shift [1] and preventing unmet needs from escalating into expensive medical crises [5].

The Current Use of Digital Technologies in CCC

Overview

Most CHWs operate within a facility-based CCC model (Figure 1A) [38]. Under the CCC model, a relatively smaller number of facility-based supervisors (most often registered health care professionals such as public health nurses, midwives, and community health officers) [38] supervise a relatively larger number of CHWs who, in turn, provide culturally tailored, language-appropriate, and individualized care to a yet larger number of clients. Although this *pyramidal* care model has demonstrated improved health outcomes and cost savings [27,32], scaling this model in a cost-effective manner while preserving the highly contextual and individually tailored care provided by CHWs remains challenging. Facility-based supervisors who themselves typically shoulder a heavy workload may additionally lack the time needed to provide supportive supervision to CHWs [38], resulting in lower quality of supervision [39] and strained CHW-supervisor relationships

[40]. However, the recent incorporation of digital health technologies into the existing CCC model is demonstrating potential for expanding the CHW footprint and improving CHW support and supervision. Existing digital technologies are discussed in the following section.

Current Digital Technologies Used in CCC

The use of digital technologies has recently been increasing among CCC organizations and is demonstrating potential to enhance CHWs' reach and diffusion of health information within communities [6,41,42]. In their scoping review of the use of mobile health (mHealth) technologies and interventions among CHWs globally, Early et al [6] highlighted some key benefits and challenges. Benefits included promotion of health equity; reduced time to diagnosis; extension of health information and services to diverse areas; improved adherence to treatment plans; increased self-efficacy of patients and CHWs; and improved attitudes of, and toward, CHWs and their role [6]. Challenges included a lack of evaluation of mHealth outcomes; development of mHealth tools and apps without cultural relevance; lack of access to, and knowledge of, mobile technologies within communities; need for effective training for CHWs to adopt mHealth tools; and need for improved communication among health care teams working with CHWs [6]. Similarly, in their narrative review of the literature, Mishra et al [11] identified key benefits and challenges to incorporating digitalization into CHW practice. Benefits included improved access and quality of services, increased efficiency in training and personnel management, and leveraging of data generated across grassroots platforms to further research and evaluation [11]. Challenges included funding for CHW programs; digital health literacy of CHWs; and systemic challenges related to motivating CHWs, including adequate CHW supervision [11].

Digital platforms currently used by CHWs within CCC-based organizations include mobile-based networking devices, web applications, videoconference, and mobile apps [11]. CHWs may use mobile phones, tablets, and other digital devices [43] in a task-specific manner (eg, digital blood pressure [BP] monitoring devices, glucometers, and spirometers) [11,44]. Digital alerts, reminders, notifications, checklists, and decision support tools may be used to facilitate compliance with protocols and improve the quality of CHW-delivered care [11,45]. In addition, although continuous monitoring of physiological parameters (eg, heart rate) has typically been available only in clinical settings because of the need for special equipment and medical expertise, the development of relatively low-cost, nonintrusive sensors present increased opportunities to enable ubiquitous home monitoring of clients' health and well-being. Current remote sensors distributed and managed by CHWs enable remote monitoring of electrocardiogram (ECG; eg, KardiaMobile [AliveCor]), BP (eg, Evolv [Omron]), blood glucose level, and physical activity [11]. Digital platforms are also being used to facilitate and augment CHW training and supervision [11,46,47] and to provide electronic decision support [11]. Digital platforms that support CHW-CHW communication and collaboration (eg, informal groups and learning networks [48-52]) may provide positive psychological benefits to care workers [50] as well as enable CHWs to exchange information and pose questions to peers [11,53]. Digitalization also presents increasing opportunities for data collection and analysis [11], allowing for critically needed outcome evaluation of CHW-delivered interventions and increasing opportunities for key CHW-focused policy advocacy. However, large-scale data acquisition, preprocessing, and validation for intelligent decision-making remain key challenges with existing methods. Limitations with current approaches are discussed in the following section.

Limitations of the Current Approaches

Although current digital technologies are demonstrating the potential to strengthen CHW capacity and quality of care [54-56], existing digital technologies targeted for use by CHWs lack integration. The current lack of ubiquitous, closed-loop monitoring and intervention within the CCC model restricts technologies used by CHWs to a passive, episodic, and reactive approach to client monitoring, education, and supportive care. CHWs engaged in NCD management and monitoring, for example, may typically provide infrequent (eg, monthly) home visits and rely on their own episodic observations and client-reported symptoms to inform care, direct education, or make referral decisions. However, direct CHW observation and client reporting of symptoms reveal only episodic snapshots of overall client physical and mental health and lifestyle. Under the CCC model, CHWs rely upon accurate reporting of health symptoms by the client or client caregivers (typically family members) [57] and must also rapidly synthesize their own observations with this information to decide an appropriate course of action (eg, educate, refer, recheck, or call for immediate medical assistance). This places a large burden of responsibility on the CHW, who must synthesize a large amount of information in a short span of time, as well as on the client or caregiver, who must accurately and honestly appraise and report their experiences to the CHW [57]. An integrated, intelligent, and automated closed-loop platform may improve upon this current model of care while maximally amplifying and expanding the CHW footprint within communities.

A New Model: D-CCC

Overview

We propose D-CCC as an improved model to move CCC into the future. Design conceptualization for the D-CCC model reflects a multidisciplinary collaboration among nursing, computer science, engineering, and human-computer interaction experts composing the D-CCC team. D-CCC constitutes a novel integrated, intelligent, and automated closed-loop technology platform designed for, and with, CHWs. By targeting the human-technology partnership at the level of the CHW, D-CCC aims to amplify human connection and collaboration while maximally expanding the CHW footprint within communities. By including development of personal models unique to each client, holistically represented within a high-dimensional cover of multiple knowledge layers, D-CCC additionally allows for an increased level of contextual and individualized care delivered by CHWs.

The D-CCC Model

The D-CCC model transforms manual and restricted aspects of CHW work into a scalable, digital, and intelligently automated space. By expanding CHW-client communication and CHW collaboration, supervision, and support, D-CCC aims to increase the quality of services delivered, in terms of personalization, cultural appropriateness, and timeliness. Through smart supervision, D-CCC may enable CCC organizations to employ and supervise a larger group of CHWs with the same number of CHW supervisors. A central aim of the D-CCC model is to expand the CHW footprint by enabling CHWs to serve a larger volume of clients or to provide more services to each client while critically striving to avoid increasing undue burden on this vital frontline workforce. Through automation of manual tasks; improved communication and connections between CHWs and clients, among CHWs, and between CHWs and supervisors; and increased modalities for ongoing education and training, D-CCC also aims to empower CHWs and improve worker experience.

Figure 1A illustrates the current CCC model. This model lacks integrated digitalization among *tiers* of care delivery and is additionally limited by unilateral communication and poor scalability. In comparison, Figure 1B illustrates the D-CCC model, which addresses these limitations and amplifies the CHW footprint by increasing CHW-client, CHW-CHW, and CHW-supervisor communication and collaboration. D-CCC constitutes a human-technology partnership integrating CHWs, supervisors, and clients through a scalable digital medium and aims to improve the efficiency and quality of care delivery. Through an intelligent and scalable artificial intelligence (AI) loop, D-CCC brings critical stakeholders under a unified communication, collaboration, education and training, and care delivery model.

D-CCC's AI-Enabled Closed-loop Health Platform

As CHWs occupy a variety of roles within communities and as CHW-delivered interventions and target outcomes vary according to the client populations served, a *one-size-fits-all* platform design will not be successful in empowering this diverse frontline workforce. D-CCC design must therefore be modular and allow for ongoing adaptability and flexibility. As cultural and contextual needs will vary according to the populations served, D-CCC design must also allow for portability across diverse communities, including translation and transferability to different languages spoken in local communities.

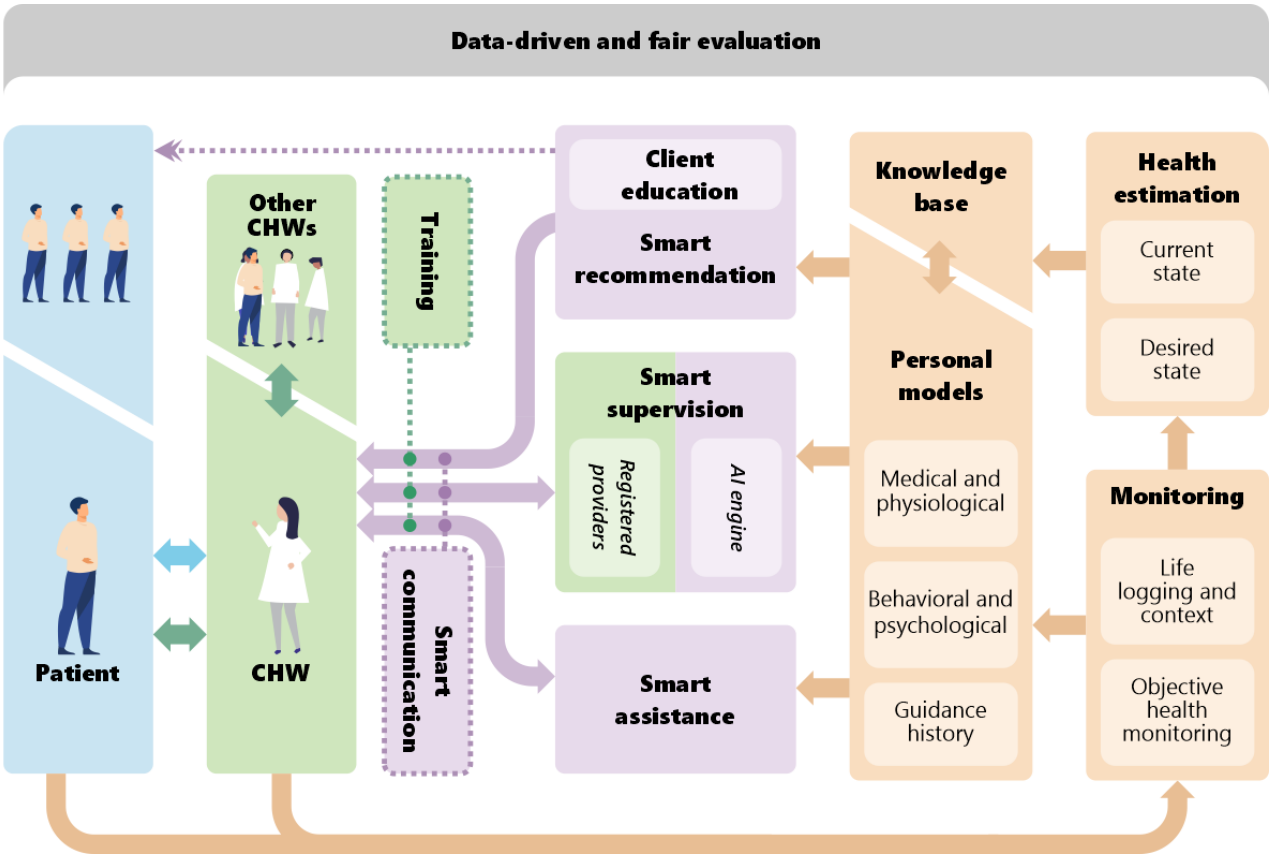
The D-CCC platform is designed to meet the diverse needs of different stakeholders, including clients, CHWs, and registered providers (RPs), and to handle diverse aspects such as communication among stakeholders, data collection and analysis, training and education, and autonomous and intelligent decision-making.

The D-CCC platform design is built on the following modules:

1. Multichannel stakeholders module: This module comprises the stakeholders who are interacting through different communication channels (including client-CHW, CHW-CHW, and CHW-supervisor) and enables the smart communication aspects of D-CCC.
2. Monitoring module: This module enables continuous monitoring and updating of physiological and contextual information collected both subjectively and objectively.
3. Health estimation module: This module enables ongoing analysis of the data collected from clients (through the monitor module, CHWs, and medical history) to determine client health status in real time.
4. Knowledge base module: This module manages the storage, access, and retrieval of built knowledge based upon data collected from clients, CHWs, and supervisors to enable personalized model building.
5. Personal models module: This module builds cognitive learning models from client physiological and contextual data to provide autonomous intelligent decisions for intervention recommendations individually tailored for each client.
6. Smart recommendation module: This module autonomously predicts appropriate health care and lifestyle recommendations for clients leveraging their personalized models. Recommendations may be delivered to CHWs or directly to clients, according to context and risk level.
7. Smart supervision module: This module supports RPs in supervising CHWs in specific areas determined through automating repetitive tasks and reflecting on personal models and the knowledge base.
8. Smart assistance module: This module improves quality of health care services by supporting CHWs making interventional, educational, or procedural decisions in the field.
9. Smart training module: This module provides training for CHWs to learn new digital technologies and enables web-based training modules to augment traditional, in-person methods of CHW training and education.

As shown in Figure 2, D-CCC's AI-enabled platform critically integrates these modules to create a holistic and data-driven approach to connect clients, CHWs, and supervisors in a continuous loop of measurement, estimation, guidance, and influence. Each module is further described in the following sections.

Figure 2. The digital health–enabled community-centered care model's artificial intelligence (AI)-enabled cybernetic platform. CHW: community health worker.



Multichannel Stakeholders Module

The D-CCC model critically enables multi-way communication among key stakeholders involved in CCC delivery networks through digital communication channels. Figure 2 shows the different combinations of multi-way communication channels among clients, CHWs, and supervisors, which can be further classified into the following communication channels:

1. Client-CHW channel: This is the point of communication between clients and CHWs. As a baseline, each client is assigned a CHW who is responsible for providing community health-related services. Traditionally, the client-CHW interaction is scheduled over fixed time windows or on demand, subject to the client's needs. D-CCC transforms this into a continuous interaction, and the digital communication medium may be made available to all clients served.
2. CHW-supervisor channel: This is the point of communication between CHWs and supervisors. As a baseline, each CHW has a supervisor assigned for supervision and feedback. As service delivery demands change, CHW supervision can be extended to include additional supervisors (eg, RPs) with expertise in different areas of care. D-CCC transforms CHW supervision to an on-demand, real-time interaction through the digital medium.
3. CHW-CHW channel: This is the point of communication among CHWs. Communication and collaboration among CHWs promote knowledge transfer and exchange of information, which may be adapted to different community-specific challenges as needed. D-CCC transforms CHW-CHW communication into an on-demand, real-time interaction through the digital medium.

Monitoring Module

This module is responsible for continuous monitoring of client physiological signs, contextual information, lifelogs, surveys, and ecological momentary assessments. State-of-the-art wearable (eg, smart rings, watches, and patches), portable (eg, smart ECG sensors, stethoscopes, and BP monitors) and stationary sensors (eg, smart beds and fall detection cameras) as well as mHealth (smartphone-based) solutions enable ubiquitous monitoring. D-CCC transforms the current landscape of disparately monitored parameters by providing a central collection point from which subsequent data integration and synthesis enable provision of smart recommendations and assistance to key stakeholders.

Health Estimation Module

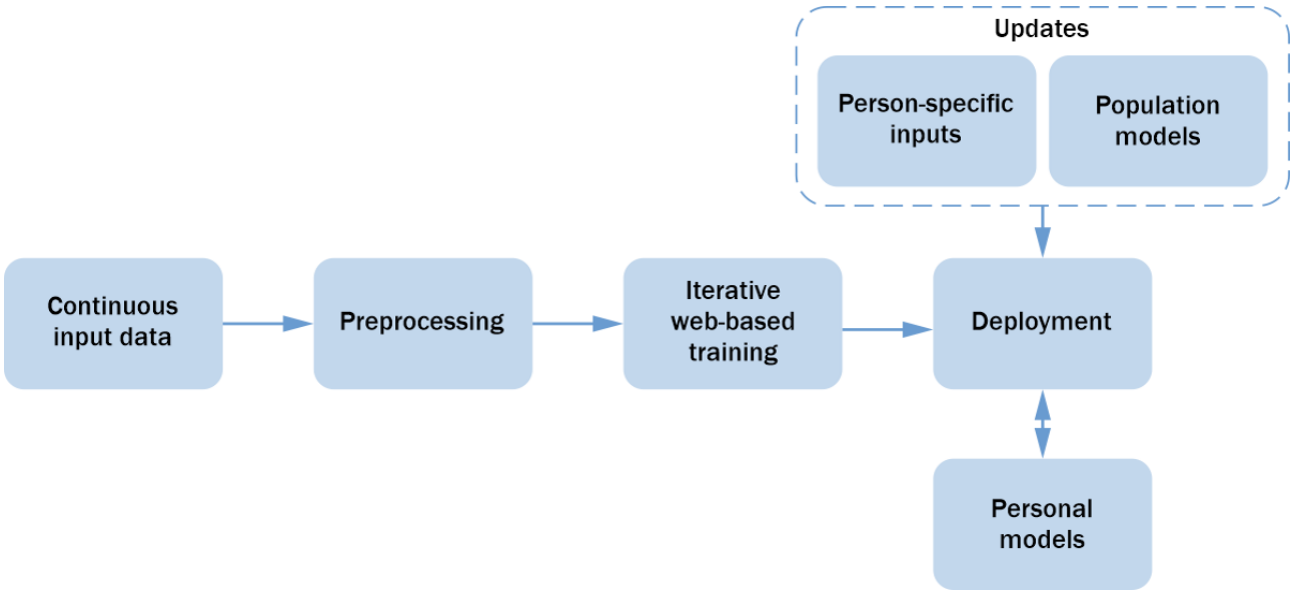
This module is responsible for determining the health status of the client. High-dimensional and holistic information collected and processed by this module identifies the client health state in real time. Each client is unique and presents multiple possibilities of health states. A key functionality of this module is to process different modalities to properly estimate health variables in different dimensions. For each client, this module holds a health status that is deemed to be safe, termed the client's *desired state*. This module continuously estimates the current state (ie, client's current health status) and compares the current state with the desired state to estimate the overall health safety

of the client. Client health status as determined by this module assists in building personal models and guides decision-making by recommendation engines.

Knowledge Base Module

This module consists of CCC-related facts, information, and skills acquired through past experience of different stakeholders (CHWs, supervisors, and clients), as well as theoretical or practical knowledge available in the CCC field. This module continuously learns and updates its knowledge based on new inputs extracted from the data generated by the entire pool of clients, CHWs, and supervisors. The knowledge base formulates knowledge graphs that represent different meaningful connections between cause-action pairs to develop a general consensus. For example, specific readings in physiological data can be connected to specific health criticality. The knowledge graphs will form the basis for developing population models that guide personal model development. Thus, the knowledge base implicitly enables reuse of key insights from a specific individual to develop comprehensive personal models for other individuals. Figure 3 illustrates the pipeline of deploying a generic learning analytics model, which can be updated with person-specific information to generate personalized models. Each client's data include physiological parameters monitored continuously and contextual information associated with each instance of lifelogging, as well as intervention procedures performed in the past and health estimation logs. Each CHW's data include the list of assigned clients, log of interventions performed per client, and effectiveness of these interventions, as well as supervision and training provided by supervisors. This module guides the building of learning analytics and cognitive models in the subsequent modules.

Figure 3. Deployment pipeline for personalized models.



Personal Models Module

This module builds analytical models for intelligent decision-making tailored to a specific individual based on a *predictive, preventive, personalized, and participatory* (P4) [58] approach to health care. The P4 approach holds that each individual constitutes a biological system that responds differently to different inputs [58]. To build an approach that makes P4 a persistent action to guide CHWs and clients, it is important to estimate and build a personal model of each client. In many areas relevant to personalization, a model is built by collecting data in the context of the application. Examples of this approach include Google, Facebook, Amazon, and Netflix, which generate personalized recommendations using models built for each individual when they interact with different applications on the platforms. The D-CCC personal models module relies on the physiological parameters, context, and health status data of each client collected by the monitoring module and the health estimation module. A variety of methods, such as machine learning, can be used for data analysis and cognitive modeling for autonomous decision-making. Figure 3 shows the deployment pipeline of individual learning models and person-specific input data to generate personal models. In the preprocessing phase, input data from different modalities are filtered to remove noisy components and motion artifacts. We use collaborative filtering to handle missing values from the data set of a specific modality by complementing the missing data with insightful information from other modalities. In the iterative web-based training phase, each modality of input data sets is used to train a suitable learning model that fits the corresponding modality. The trained models that are deployed in the initial phase are continuously updated with the iterative web-based training. From the knowledge base, we also create population models that contain heuristics to formulate rules for updating trained models with generalized person-specific inputs. As we collect person-specific data, the trained models are updated with these person-specific inputs to generate the personal models. The personal models are updated with new person-specific inputs every 6 months. As shown in Figure 2, we divide personalized modeling into three submodules, as described in the following paragraphs:

1. Medical and physiological profile: This submodule builds a personalized medical and physiological model for each client from the physiological data and health status estimate. This creates a baseline for each client's health status and

provides an intuition on determining the relative health safety under the current conditions. For example, although two clients, A and B, may have a history of the same condition, the specific health status of client A can be perceived as more alarming than that of client B based upon their personalized medical and physiological profiles.

2. Behavioral and psychological profile: This submodule builds a personalized behavioral and psychological model for each client from contextual data. This creates an insightful perspective on each client's health status and their response to interventions under specific circumstances. For example, a situation where two clients, A and B, have the same health status but different contexts would call for different intervention responses (eg, education or referral procedures). This allows CHWs to choose among actions that are customized to both the client's physiological status and their context.
3. Guidance history: This submodule logs the past health conditions of a client along with their contexts, the responsive intervention procedures imposed under each context, and the response of the client to each intervention use case. This allows for development of a baseline understanding for CHWs to decide on appropriate action in the current scenario. Given the history of interaction and guidance provided by CHWs in the past under similar situations, decisions on an improvised intervention or on reusing a previously successful intervention can be made.

We use multimodal data fusion strategy to combine the results from each of the aforementioned modalities of personal models. Data fusion improves the prediction accuracy of the personal models, particularly in instances where input data are missing from specific modalities.

Smart Recommendation Module

This module delivers autonomous health recommendations to clients and/or CHWs based on risk level and recommendation type. D-CCC combines each client's physiological and contextual data from the knowledge base module and personal models module to build smart recommendation systems. Smart recommendation is a proactive strategy to promote client self-management and improve quality of life, particularly in less-acute scenarios (eg, recommendations related to diet, physical activity, sleep, stress, and medication reminders). Smart recommendations sent to clients target everyday health maintenance and education regarding healthy life choices. This module infers to the cognitive and analytical models from the personal models module to make autonomous recommendations. The autonomous recommender primarily aims to bridge the gap between the increasing number of clients in need and the relatively lower number of CHWs and RPs and is based upon the acuity of client condition. Recommendations are also sent out to the responsible CHW to synchronize the information flow. The decision regarding whether a recommendation is delivered directly to the CHW, directly to the client, or delivered through the CHW to the client depends on the settings and recommendation type. For instance, some client populations (eg, older adults) with less access to, or comfort using, smartphones may prefer to receive recommendations through their CHWs, whereas other client populations (eg, pregnant women) with greater access to, or comfort using, smartphones may prefer to receive health promotion recommendations directly. This module adds a layer of cyber health care service delivery to D-CCC, enabling safe and timely interventions for different clients with varied needs.

Smart Supervision Module

This module automates workflow between supervisors (eg, RPs) and CHWs to improve supervision efficiency both qualitatively and quantitatively. There is a need for ongoing CHW-supervisor interaction for evaluation, feedback, and support. Under the current CCC model, supervisors manually organize supervisory tasks with different CHWs. D-CCC enables automated supervision support using AI models. Each CHW handling multiple clients in different contexts presents each RP with different supervisory challenges. The personal models module and knowledge base module contain cognitive analytical models about different clients. The smart supervision module integrates these personalized models into an AI engine that serves as the oracle to supervisors. This allows supervisors to hone their attention to specific issues that each individual CHW may have while accessing the collective record of clients specific to that CHW. In addition, enabling a common and more complete understanding of the clients' contexts may enable interactions between RPs and CHWs to become more qualitative while reducing overhead time. Supervisors may additionally choose to automate trivial repetitive tasks, allowing them to supervise a larger number of CHWs or provide more personal support and mentorship to an existing cadre of CHWs. Multi-way communication among CHWs and supervisors additionally allows for a range of choices to match supervision requirements of CHWs to expertise of the RPs. Effective supervision is an essential element of CHW programs [38]. Through improving CHW support and enabling more holistic CHW-supervisor interaction, D-CCC may enable scalability of CHW supervision strategies, leading to improved productivity, care delivery, and worker satisfaction.

Smart Assistance Module

This module supports CHWs to deliver continuous high-quality care services in the field, particularly in scenarios where CHWs may have limited access to resources. Applying intervention procedural knowledge for clients with diverse contexts can be challenging for CHWs in the field, and D-CCC supports CHWs to make client-specific decisions using personalized models. Smart assistance is a reactive and on-demand service intended to handle acute scenarios that may enhance decision-making of CHWs in the field when they do not have immediate access to supervisors; one approach includes implementing customized chatbots used by CHWs in real time to provide appropriate decisions regarding client care (eg, education, CHW-delivered intervention, and referral). This may be particularly useful when supervisors are not accessible or when CHWs encounter a situation with which they have limited expertise. Chatbots use natural language processing to parse textual information provided by CHWs to make sense of the client care situation. This module accesses the client's medical and physiological profile, behavioral and psychological profile, and previous history of CHW assistance provided from the knowledge base.

This module identifies the specific client and infers the client's personalized model to make autonomous decisions regarding CHW-delivered care.

Smart Training Module

This module enables ongoing training for CHWs to learn new digital technologies and augments traditional methods of CHW training and education for connected web-based and blended learning methods. Key challenges identified in the literature regarding current use of digital technologies include CHW digital health literacy [11] and the need for effective training for CHWs to adopt digital tools [6]. This module integrates ongoing CHW digital health training and provides CHWs with an automated technology *help desk* for ongoing additional assistance as needed. This module additionally augments traditional, in-person CHW training by providing ongoing case-based digital learning modules, which may be assigned by CHW supervisors and completed by CHWs in an independent and self-paced manner.

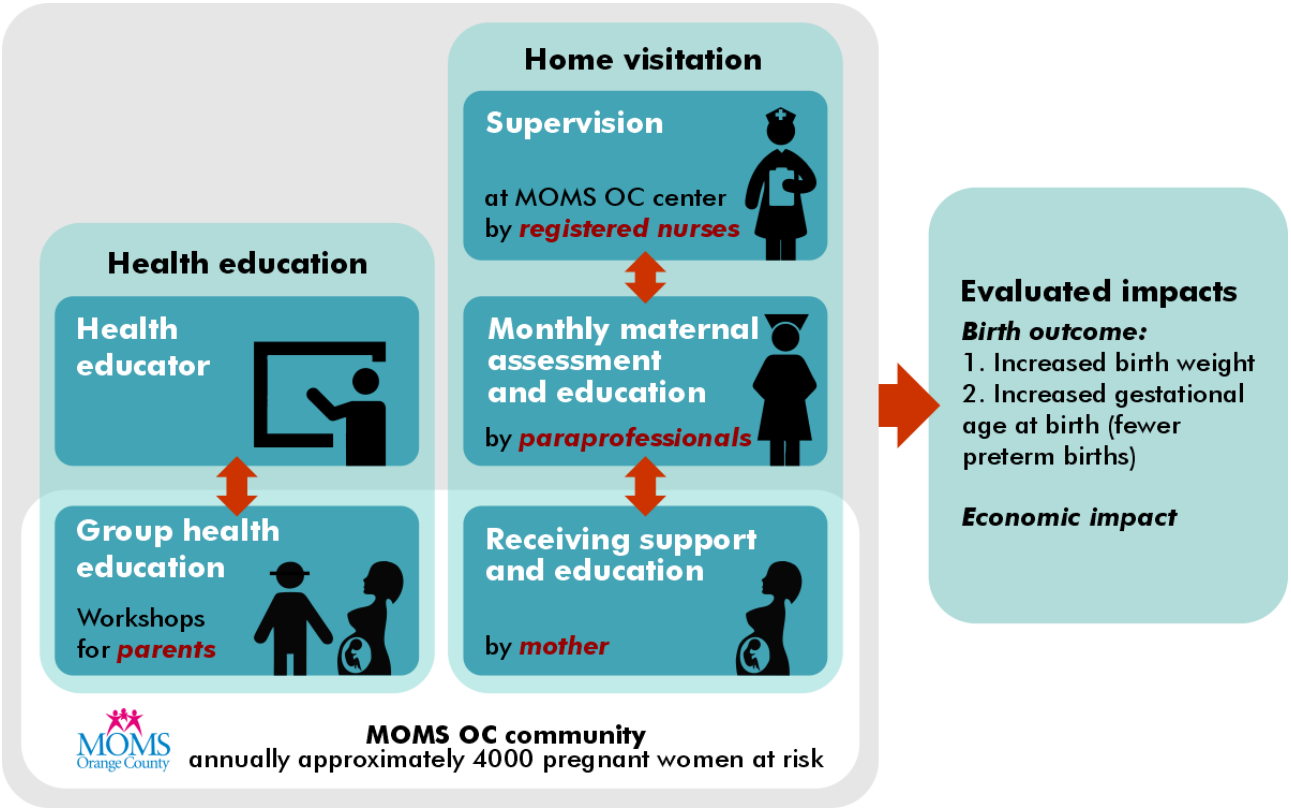
Case Study: Smart, Connected, and Coordinated Maternal Care for Underserved Communities

The D-CCC model is currently being piloted with community partner site MOMS Orange County (MOMS OC) [59]. We outline this proof-of-concept case study in the following sections.

MOMS Orange County

Registered nurse (RN)-delivered home visits for at-risk pregnant women became infeasible in the early 1990s in Orange County, California, because of the county's financial constraints. In response to the county's maternity care crisis, MOMS OC [59] was founded. MOMS OC is a nonprofit organization implementing a CCC model (Figure 4) for maternal care (MC) delivery. MOMS OC's CCC model is a CHW-delivered care coordination and home visitation program wherein RNs supervise and train CHWs, who in turn provide culturally and linguistically appropriate services, conduct home visits, and deliver group education to pregnant women considered to be at low to moderate risk and served by MOMS OC.

Figure 4. MOMS OC (Orange County) community-centered care model.



The MOMS OC CCC model has demonstrated cost efficiency [60] and improved birth outcomes [61]. However, it remains limited by barriers and gaps common to CCC models, which presents opportunities for the incorporation of technology. Barriers and gaps applicable to MOMS OC include the following:

1. *Limitations regarding outreach* using traditional mechanisms (eg, word of mouth, telephone calls, and advertisements), particularly among disadvantaged communities. This presents opportunities for technology-enabled community outreach.
2. *Limitations regarding timely intervention*, including early MC and education. This presents opportunities for new community-driven intervention enablement assisted by digital and social media.
3. *Limitations regarding monitoring* because infrequent CHW home visits (typically conducted monthly) and clients'

self-reported screenings both reveal only a snapshot of each woman's physical and mental health and lifestyle. This presents opportunities for incorporation of low-cost, nonintrusive wearable devices to enable ubiquitous monitoring.

4. *Limitations regarding communication among MC providers*, with CHWs typically unable to access health data stored as electronic health records and MC providers typically unable to easily access information collected by CHWs. This presents opportunities for networking, smart data mining, and community-enhanced recommendation systems.

A D-CCC Pilot Community Engagement Model for MC

Identifying opportunities for D-CCC to overcome these gaps and improve the quality of care delivered, we partnered with MOMS OC to launch Smart, Connected, and Coordinated Maternal Care for Underserved Communities (UNITE) [62], a D-CCC pilot community engagement model for MC that is smart (deploying ubiquitous monitoring and lifelogging), connected (bringing together a diverse cast of community members, including clients, families, RPs, and community resources), and coordinated (using technology to proactively reach out to the community and deliver personalized interventions and education for each client).

UNITE deploys technology-enhanced community care coordination and education coupled with a human-in-the-loop monitoring and intervention system to (1) proactively reach out to the community (pregnant women, families, and friends); (2) provide valuable personalized and community-enhanced information for CHWs and RNs to provide tailored support according to individual needs; and (3) combine fine-grained and personalized information together with monitoring and intervention and community outreach and education to promote healthier lifestyles for pregnant women through self-management.

UNITE leverages emerging technologies such as Wearable Internet of Things, community-enhanced learning and recommendation, big data analytics, context recognition, lifelogging, and social media, as well as a multidisciplinary partnership to bring connectivity, integration, and smartness to MOMS OC's existing CCC model. UNITE also brings ubiquitous monitoring, open information sharing, and community-enhanced personalized intervention and education to MOMS OC's CCC model. UNITE aims to strengthen connectivity among stakeholders and to improve connection and coordination across providers and agencies focused on pre- and postnatal health.

Through lifelogging, context recognition, and health monitoring, UNITE builds a holistic digital phenotype of participants using multimodal data capture. Smart mining algorithms are designed for cause assessment through personalized models. Maternal self-management is improved and incentivized through personalized community-enhanced recommendation systems and technology-enhanced community care coordination and education. The core components of the UNITE model are ubiquitous monitoring and a recommendation system capable of dynamically supporting a healthy lifestyle of enrolled women during and after pregnancy. UNITE recognizes how community-specific factors pertaining to each client enhance individual monitoring and interventions and enable more personalized recommendations to motivate better self-management. UNITE thus integrates culture- and context-sensitive mechanisms to enhance technology acceptance for improved maternal self-management and enhances connection and coordination with CHWs and other care providers and agencies focused on improving pre- and postnatal maternal health.

As part of the UNITE project, a proof-of-concept version of the AI-enabled closed-loop D-CCC platform has been implemented whereby a Wearable Internet of Things–based health-monitoring flexible and adaptable platform enables seamless capture of sensory data streams (using wearables and smartphones) and self-reported data from participants (using questionnaires and ecological momentary assessments). UNITE's dashboard allows for interaction between CHWs and the enrolled women, provides visualization and interaction with the backend system, and performs sophisticated analytics and data mining to build a holistic personal model of each participant. Each personal model combines physical and psychosocial data capture to generate feedback and recommendations to the enrolled women, their CHWs, and the CHW supervisors, as well as to other health providers with the goal of promoting healthy pregnancy outcomes.

An exemplar intervention delivered through the UNITE platform's closed-loop system is a home-based safe exercise program overseen remotely by CHWs [63]. This evidence-based exercise program, designed using the pregnancy and postpartum exercise guidelines provided by the American College of Obstetricians and Gynecologists, includes strength movement, aerobic movement, and mindful breathing. UNITE's real-time monitoring of intensity and duration of exercise using wearables (eg, by measuring heart rate elevation, maximum oxygen uptake [VO_{2max}], respiratory rate, and ratings of perceived exertion) critically enables individualization of the intervention as well as safety monitoring throughout the exercise program.

Completion of the UNITE pilot study will yield critical information regarding feasibility and user (client, CHW, supervisor, and RP) experience as well as effects on health outcomes, including cardiovascular response, sleep, physical activity, self-reported stress, depression, and anxiety.

Discussion

D-CCC as an Improved Model to Move CCC Into the Future

As current global health trends necessitate a shift away from a patient-centered medical care system to an upstream health promotion approach that meets the health and social needs of individuals in their communities, a community-centered health and social care ecosystem, supported by a robust and digitally connected CHW workforce [1], is needed to launch CCC into the future. A rapid expansion of the CHW footprint is critically needed to prevent unmet needs from escalating into expensive medical crises, particularly in vulnerable communities [5].

However, scaling the current CCC model in a cost-effective manner while preserving the highly contextual and individually tailored care provided by CHWs remains challenging. Although the recent incorporation of digital technologies into the CCC model demonstrates potential for expanding the CHW footprint, current technologies lack integration. Large-scale data acquisition, preprocessing, and validation for intelligent decision-making remain key challenges.

We propose D-CCC as an improved model to move CCC into the future and present our UNITE pilot study as an initial proof of concept in D-CCC implementation. Of note, UNITE represents *one iteration* of the D-CCC platform, designed to support the specific needs of a community partner organization providing CHW-delivered interventions to pregnant women considered to be at low to moderate risk within Orange County, California. UNITE was designed to leverage technology to facilitate client self-management as well as CHW-delivered support. However, D-CCC may also support CHW-delivered health-related interventions among client populations less able to engage in self-management or with less access to, or comfort with, technology (eg, older adults with dementia). Critically, because CHWs occupy a variety of roles within communities and because CHW-delivered interventions and target outcomes vary widely according to the client populations served, a *one-size-fits-all* platform design will not be successful in empowering the CHW workforce of the future. D-CCC is designed to be scalable and portable across diverse communities, and its modular design purposively allows for flexibility to meet the needs of different CCC organizations, populations served, and care delivery focus.

D-CCC's design addresses key challenges identified in the literature regarding current use of digital technologies by CHWs, including a lack of evaluation of outcomes; development of digital tools and apps without cultural relevance; lack of access to, or knowledge of, mobile technologies within communities; need for effective training for CHWs to adopt digital tools; inadequate CHW supervision; and the need for improved communication among health care teams working with CHWs [6,11]. Furthermore, D-CCC allows for fair and data-driven evaluation of CHW-delivered interventions, thereby increasing opportunities for key CHW-focused policy advocacy. Data-driven evaluation of CHW-delivered interventions is key to moving community organizations away from fee-for-service or grant-based governmental support models and toward value-driven models for CHW reimbursement.

However, there remain key challenges and limitations to consider. D-CCC design focuses on supporting CHWs operating within a facility-based CCC model of care delivery. Although most CHWs operate under this model [38], exploring how D-CCC might apply to other models of CHW-delivered community care remains a future endeavor. Certain aspects of digitalization (eg, BP monitors, ECG sensors, and blood glucose monitoring) may be more useful for CHWs focused on single or multi-disease management, and ubiquitous monitoring may require clients to use a smartphone and have home internet access. However, D-CCC is designed to be used by CHWs engaged in various community care roles, including use in client populations without access to smartphones or home internet. Through facilitating CHW communication (with clients, supervisors, and other CHWs), collaboration, and knowledge sharing, as well as CHW supervision, training, and decision support, D-CCC is designed to support CHWs engaged in myriad care roles. CHWs working on upstream health determinants such as job loss may also benefit from the D-CCC intelligent and integrated closed-loop digital platform designed to support communication, collaboration, and knowledge sharing of community-based resources.

In addition, the UNITE pilot is presented as a proof-of-concept case study to illustrate D-CCC deployment. However, this pilot is ongoing and limited by a lack of outcome data to present here (eg, regarding feasibility, user experience, or health outcomes). We highlight the larger need for studies conducting cost analyses of CHWs, digital technologies, and the combination of CHWs *and* digital technologies. Without these data, assertions regarding cost savings through incorporation of technologies targeted for use by CHWs remain speculative.

AI design must carefully consider the impact of digitalization on CHW relationships, workload, and workflow [64]. Deployment of AI systems will result in some additional work, most notably upon rollout and initial deployment. Some of this work may be readily apparent (eg, CHWs actually using the AI platform), but less-apparent aspects must also be considered (eg, CHWs introducing, explaining, and justifying the use of new technologies to their communities) [64]. As Okolo et al [64] highlight, AI developers must account for such added visible and invisible work shouldered by CHWs when assessing the benefits and limitations of incorporating AI systems into established CCC workflows. To this end, CHW collaboration and iterative feedback drive D-CCC design to maximize utility and acceptability while minimizing additional worker burden. Our multidisciplinary team also includes human-computer interaction experts to conduct ongoing assessments of CHW relationships and workflows during D-CCC design and implementation.

Finally, D-CCC's data-driven algorithms, key to building personalized models, also mean an unprecedented scope with regard to sensitive data collection, and the digital health ecosystem presents new ethical challenges and considerations, particularly in vulnerable populations. The D-CCC platform must critically protect data privacy and security through methods such as end-to-end encryption and distributed security schemes (eg, blockchain technology) and proper data governance policies and tools. Any commercial cloud infrastructure services used to store and manage data resources must provide Health Insurance Portability and Accountability Act–compliant services for storage and transmission of protected health information. Data privacy and shared responsibility clauses must additionally guarantee secure data management in compliance with the user and application deployer.

Although new human-technology partnerships have incredible potential to empower future workers and to promote health equity, the impacts of AI on future workers and communities must be considered, including identifying potential for inadvertent creation or exacerbation of health inequities, particularly among vulnerable populations. Consideration of

sociocultural aspects throughout D-CCC platform design and iteratively examining how these affect platform acceptability, feasibility, and reliability will be critical to avoid further propagating health inequities [65]. To this end, D-CCC design and implementation must occur iteratively and in close collaboration with all stakeholders, including CHWs, CHW supervisors, and clients.

Conclusions

The increasing use of digital technologies among CCC organizations is demonstrating the potential to expand the CHW footprint by enhancing CHWs' reach and diffusion of health information within communities [6,41,42]. However, existing digital technologies incorporated into CHW practice lack integration. We propose D-CCC as an improved model to move CCC into the future. D-CCC constitutes a human-technology partnership integrating CHWs, CHW supervisors, and communities through a scalable digital medium to improve the efficiency and quality of care delivery. By targeting a human-technology partnership at the level of the CHW, D-CCC aims to amplify human connection and collaboration while maximally expanding the CHW footprint within communities. Through integrating future digital health technologies, the future CHW workforce, and the future health and social care needs of communities, D-CCC aims to connect the most vulnerable individuals within communities to needed resources and health and social services.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BP: blood pressure
CCC: community-centered care
CHW: community health worker
D-CCC: digital health–enabled community-centered care
ECG: electrocardiogram
MC: maternal care
mHealth: mobile health
MOMS OC: MOMS Orange County
NCD: noncommunicable disease
P4: predictive, preventive, personalized, and participatory
RN: registered nurse
RP: registered provider
UNITE: Smart, Connected, and Coordinated Maternal Care for Underserved Communities

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Viewpoint

The Strategies for Quantitative and Qualitative Remote Data Collection: Lessons From the COVID-19 Pandemic

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Abstract

The COVID-19 pandemic has necessitated a rapid shift to web-based or blended design models for both ongoing and future clinical research activities. Research conducted virtually not only has the potential to increase the patient-centeredness of clinical research but may also further widen existing disparities in research participation among underrepresented individuals. In this viewpoint, we discuss practical strategies for quantitative and qualitative remote research data collection based on previous literature and our own ongoing clinical research to overcome challenges presented by the shift to remote data collection. We aim to contribute to and catalyze the dissemination of best practices related to remote data collection methodologies to address the opportunities presented by this shift and develop strategies for inclusive research.

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KEYWORDS

web-based research; remote research; remote data collection; blended design; electronic data collection; mobile phone

Introduction

Background

The COVID-19 pandemic is transforming the landscape of clinical research. The pandemic has necessitated the unexpected adaptation of ongoing clinical research activities to web-based or blended design (ie, part web-based, part in-person) models [1] and has rapidly accelerated a shift within clinical research toward web-based study designs. Despite the high levels of patient and health care provider satisfaction with telemedicine and virtually conducted clinical research [2,3], many challenges exist to the web-based conduct of rigorous, efficient, and patient-centered clinical research, particularly related to the engagement of diverse and marginalized populations [4]. The aim of this paper is to discuss practical strategies to guide researchers in the remote collection of quantitative and qualitative data, derived from both previous literature and our own ongoing clinical research.

Many health care providers and clinical researchers have marveled at the way the COVID-19 pandemic catalyzed the widespread adoption and expansion of telemedicine, seemingly overnight [5,6]. Despite the sluggish adoption of telemedicine observed in academic medical centers over the past several decades [7,8], the pandemic has spurred rapid changes in public and organizational policy regulating telemedicine in the United States, facilitating a tipping point toward the web-based provision of both health care and conduct of clinical research

[1,2,5,6]. Enabled by fast-tracked institutional review board policies and amendments [1], researchers have adapted clinical research study procedures in innovative ways: engaging in web-based outreach for study recruitment, collecting electronic informed consent, conducting study visits, delivering interventions over the phone or live video, and using remote methods to collect data [1]. Several studies have reported high satisfaction of both providers and patients with the use of telemedicine during COVID-19 and a willingness to continue using telemedicine after the pandemic, including for clinical research [2,3].

This shift toward virtually conducted clinical research creates many *opportunities* to increase the accessibility of clinical research. Virtually conducted research reduces many burdens on patients associated with research participation, including time and monetary costs involved in travel to research facilities. This enables researchers to include patients who lack access to transportation or the ability to travel independently. Furthermore, web-based patient outreach allows researchers to recruit geographically diverse participants, enabling researchers to target populations through disease-specific registries, internet-based patient communities, and advocacy groups without geographical constraints [9]. By centering patients rather than investigative sites in the study design and operation, virtually conducted research has the potential to increase the patient-centeredness of clinical research [9].

At the same time, the transition to virtually conducted clinical research also presents many *challenges* to patient engagement and data collection. Losing supervision of the physical setting of research activities challenges researchers' ability to ensure patients' adherence to study protocols, engagement and interest in research activities, and privacy protections. Researchers are faced with complex decisions regarding the appropriateness of data collection methodologies or specific measures and assessments for web-based delivery [10]. Furthermore, there are barriers associated with the technology used for remote data collection (eg, telephones, electronic databases, live videoconferencing software, and ecological momentary assessment), including a lack of technology literacy and challenges using technology among both patients and research staff [1,4,8,11]. Finally, some patients lack access to smartphones, the internet, or secure and stable housing, which may preclude their participation in web-based clinical research unless researchers can allocate funding to provide these devices. Consequently, the transition to virtually conducted clinical research may further marginalize people in low-income and rural settings [4].

Objective

To thoughtfully respond to the challenges associated with remote data collection and ensure that disparities in access to clinical research do not widen, there is a critical need for practical strategies for researchers. By integrating recommendations from previous literature with examples from the ongoing clinical research projects of this authorship team with extensive patient and provider populations (ie, adults and adolescents with neurofibromatosis, older adults with chronic pain and cognitive decline, adults with cancer and serious mental illness, adults with young-onset dementia, and orthopedic medical providers), we present a discussion of practical strategies for researchers to support the rigorous, efficient, and patient-centered collection of quantitative and qualitative data remotely. Summary tables present a list of strategies related to the remote collection of quantitative (Table 1) and qualitative (Table 2) data.

Table 1. Challenges in remote quantitative data collection and associated strategies.

Challenges	Strategy	Example approach
Study staff do not have sufficient technological experience or access to technology.	Equip study staff with technology as necessary and instruct them on foundational technological skills.	Ensure that all study staff have access to necessary technology to carry out study responsibilities (eg, laptops with webcams, phones, and software programs) and have been thoroughly trained in their use.
Validating participant credentials and ensuring data quality.	Incorporate eligibility, attention, and manipulation checks throughout surveys.	Attention check: for quality assurance, please select *strongly disagree* for this line. Manipulation check: who was in the video you just watched?
Study staff lack experience remotely communicating with study participants.	Train study staff on good clinical practices and foundations of verbal and nonverbal communication that are appropriate for web-based setting.	Study staff collecting measures should be educated on best practices for protecting participant privacy and confidentiality through remote methods (ie, use of secure software and calling from private locations). Study staff should be trained on verbal and nonverbal communication appropriate for web-based settings (eg, eye contact through webcams and body language from shoulders up) and be mentored with peer or hierarchical supervision.
Managing the secure electronic distribution of measures to study participants.	Use a secure web platform to distribute measures.	Study staff can use secure electronic platforms (eg, REDCap[a] and Qualtrics[b]) to distribute measures and use functionalities (eg, scheduling surveys and automatic reminders) to maximize efficiency and organization for study team.
Assisting study participants in using technology to complete remote study measures.	Proactively identify participants' comfort with technology and then tailor individualized supportive approaches.	Study staff should first engage in *meeting participants where they are* by determining participants' technology comfortability and then supply participants with training accordingly (eg, written instructions, prerecorded videos, and live assistance). Study staff may also coordinate with members of the participants' household to collaboratively support them with technology as needed.
Engaging participants who lack access to technology or lack technological literacy to independently complete remote study measures.	Allow flexible and multimodal alternatives for measurement completion, along with offering relevant instructions on using these modalities.	Study participants can be mailed letter copies of the self-report measures or give their answer to survey questions via phone calls with study staff. Study staff should communicate with study participants about their preferred modality and support with associated burden.
Adapting study protocol to determine new ways to gather non–self-report data that previously required in-person assessment.	Conduct a literature search to identify and implement innovative, creative, and flexible alternatives.	Study teams can use previously adapted and validated measures for remote delivery, such as a mobile app to measure distance walked in 6 minutes (ie, 6-minute walk test).
Burden on participants of completing remote electronic study measures.	Asynchronous distribution of study measures.	Study staff can send participants a link from a secure web platform so that participants can complete the measurement independently at a time and place most convenient for them.
Participants who require or prefer assistance in measure completion.	Provide live assistance to participants during measure completion (ie, synchronous completion) via phone or live video.	Pay attention to participants' focus, engagement, and comprehension during synchronous measure completion (eg, ask participants if they have any questions about the phrasing of measures and offer participants the option to take pauses during the assessment).
Participants who require or prefer visual aid during synchronous measure completion.	Use *screen share* functions of HIPAA[c]-compliant videoconferencing technologies.	Using secure and institutionally approved videoconferencing technology (eg, Zoom and WebEx), study staff can *screen share* the survey so that patients can see, read, and potentially better comprehend questions.
Protecting participant privacy and confidentiality during remote calls.	Proactively promote actions in coordination with the study participant to uphold good clinical practice and protect privacy and confidentiality.	Confirm with study participants if they are in a safe space to openly answer questions, advising them of the sensitive nature of questions before administering measures, and assisting participants with strategies to maximize their privacy (eg, scheduling calls at a participant's preferred time and wearing headphones).

Challenges	Strategy	Example approach
Building rapport with study participants while communicating virtually.	Focus on body language, tone of voice, and language appropriate for web-based settings.	Use verbal strategies appropriate for web-based settings (eg, establish a conversational tone, use participants' names, speak clearly and directly into microphone, and provide technological support so that participants feel comfortable) and nonverbal strategies appropriate for web-based settings (eg, smile at participants, make direct eye contact with webcam, and sit upright).
Promoting completion of unfinished surveys.	Schedule reminders at predetermined intervals for participants who have not completed measures.	Participants who do not complete the survey in a scheduled time can be prompted to do so via automated electronic reminders within the distribution platform or individual outreach (eg, calling, texting, reminding in person). Study staff should flexibly use different outreach methods and communicate in advance to the participant how often they will send reminders through each method.
Reaching participants who are difficult to reach via technological means or who are no longer responding to outreach.	Determine standardized study procedures about who will contact the participant, how many times, and through what method.	Decide on a number of times to call a participant before transferring the matter via an established chain of command. Use creative approaches such as considering the individual's circumstances and best ways and times to reach them, involving family members, and involving incentives as appropriate.

[a]REDCap: Research Electronic Data Capture (Vanderbilt University).

[b]Qualtrics Survey Distribution (Qualtrics XM Platform).

[c]HIPAA: Health Insurance Portability and Accountability Act.

Table 2. Challenges in remote qualitative data collection and associated strategies.

Challenges	Strategies	Example approach
Inclusive outreach to participants.	Multimodal outreach strategies.	Send physical letters with focus group information and offer both telephone only and videoconferencing modalities.
Coordinating a meeting time for web-based interviews or focus groups.	Provide flexible hours and focus on participants' schedule preferences.	Study staff can offer multiple times for web-based focus groups to assess times that would maximize attendance.
Securely conducting web-based interviews or focus groups.	Select HIPAA[a]-compliant videoconferencing platforms.	Platforms that are HIPAA-compliant have security features such as password-protected meetings and waiting rooms that study staff can use to protect participants' privacy and confidentiality.
Encouraging active participation in web-based interviews or focus groups.	Proactively plan the focus group structure to optimize participation.	Consider the target size of the focus group to promote participation. Study staff can also give an introduction at the start of focus sessions to set a tone of welcome and inclusivity (eg, build rapport and give overview of study topics) and be intentional about the use of verbal and nonverbal communication throughout the focus group to encourage participation.
Solving technological issues with participants.	Review technological features and any problems at the start of the session and then address emerging issues as needed.	Expend a portion of the focus group, ensuring that all technological components are functioning (eg, microphones and videos turned on as appropriate) and review features of the platform. Have a study staff member on call to assist with technological problems as needed.
Conducting interviews or focus groups in a timely fashion.	Coordinate the team approach to adhering to a predetermined schedule.	Determine allotted time for aspects of the focus group's discussion in advance and divide labor among the study staff during focus groups to maximize efficiency.

[a]HIPAA: Health Insurance Portability and Accountability Act.

Strategies for Remote Data Collection

Optimizing Quantitative Measures for Effective Remote Distribution and Delivery

Asynchronous distribution and measure completion (eg, electronic distribution of surveys) maximize efficiency for the study team and flexibility for study participants but necessitates additional consideration for participants with varying levels of familiarity with and access to technology. Secure web platforms (eg, REDCap [Research Electronic Data Capture], Vanderbilt University and Qualtrics, Qualtrics XM Platform) are ideal for asynchronous distribution because they have functionalities that promote study team efficiency and organization (eg, scheduling survey distribution in advance and automatic reminders to participants to complete surveys) while enabling participants to complete measures independently and at a time most convenient for them [9]. Although these platforms are widely compliant with Health Insurance Portability and Accountability Act (HIPAA) and regulatory requirements, study teams should

ensure that platforms are compliant with institution-specific clinical research regulatory requirements before use (and consider potential differences between clinical research and clinical care requirements).

Many of these platforms also offer participant screening, consenting functionality, and mobile device compatibility, which maximize the utility for study teams [9]. Study teams relying on web-based platforms and asynchronous measure completion should also consider the adoption of flexible alternative options for measure completion to maximize completion rates and the engagement of participants. For example, study teams might offer participants the option to complete measures on paper through physically mailed surveys or over the phone with a member of the study staff, depending on participant technology access and preference. Similarly, in addition to electronic reminders integrated within the distribution platform, study teams will likely need to use other methods to contact participants and remind them to complete measures (eg, calling, texting, and reminding in person). To decrease the burden on participants and increase adherence to study procedures, participants should be informed of how many of these reminders to expect.

Validating participant credentials in studies where research staff have no personal interaction with participants (ie, web-based survey studies) is another challenge with web-based research. Data quality checks, such as eligibility, attention, and manipulation checks (see Table 1 for examples) can be introduced to protect from duplicate responses or participants falsifying information. Enabling IP address tracking is another feature of some survey platforms (eg, Qualtrics). As with all data collection, it is imperative that participants are aware of how their information is being collected and researchers have been granted previous institutional review board approval.

We use REDCap and rely on predominantly asynchronous measure completion to collect quantitative data in an ongoing randomized controlled trial of a mind-body intervention to promote quality of life in adults with a genetic condition called neurofibromatosis [12]. Participants receive links via email to complete surveys at all time points (ie, baseline, posttest, and 6- and 12-month follow-ups), and we set automatic email reminders to go out at defined intervals every 3 days until participants complete surveys. The frequency of reminders should be determined by the study team to balance the burden on study staff and participants with the desire to have high survey completion rates. We find that participants enjoy the flexibility of completing measures at their convenience from the comfort of their homes and using personal devices.

For quantitative measures other than self-report surveys, study teams may need to use innovative methods to adapt data collection methods for remote delivery. Although not all measures can be adapted for remote delivery (eg, imaging data collection), many can through a combination of creative and flexible strategies, including using mobile device data collection, mailing materials and devices to participants, and conducting assessments over live videoconferencing. Even the collection of biomarker data, common in quantitative research clinical trials, can sometimes be adapted for remote conduct through mailing of devices and use of smartphone technology, such as mailing saliva or nicotine strips for the verification of tobacco abstinence or the provision of personal devices to measure expired carbon monoxide that are compatible with smartphones [1]. In adapting measures for remote delivery, it is essential to examine previous literature to assess the availability of remote alternatives and evidence to support the validity of remote alternatives or adaptations [10]. Study teams' attention to usability and patient burden is essential [10]. It may also be important to account for the modality of data collection during data analysis (eg, evaluating whether the mode of data collection is a confounder in multimodal studies).

In our randomized controlled trial with patients with chronic pain and cognitive decline, we conducted a literature search to identify remote methods for assessing cognitive functioning as well as performance-based physical function. The Montreal Cognitive Assessment [13], a measure we previously used in our in-person study [14], has been adapted and validated for remote administration over live videoconferencing [15,16]. Accordingly, we developed a standardized protocol for applying the Montreal Cognitive Assessment audiovisual procedures, including mailing participants a paper with items that required drawing and instructing them to display the paper to the camera for us to screenshot over videoconferencing [17]. Our literature review also identified a validated, free-of-charge mobile app that uses GPS coordinates to measure the distance walked in 6 minutes to replace the 6-minute walk test (6MWT) [18] that we had previously conducted in our in-person study [14]. Before using the app with participants, we piloted the app and developed a standardized protocol to assist participants in downloading the app, using the app, and reporting the results [17].

In the process of adapting quantitative measures for remote completion, the safety of the participants must be considered. For example, in our randomized controlled trial with adults with neurofibromatosis, we used the Patient Health Questionnaire-9, which contains an item assessing suicidal ideation, to measure depression. We developed a standardized protocol to respond to cases in which participants endorse suicidality, including collecting the name and number of an emergency contact for each study participant during enrollment, having the study clinician and principal investigator receive immediate notification from REDCap, and having the study clinician or principal investigator follow up over phone with the participant within 24 hours to complete a safety assessment [12]. Similarly, in our randomized controlled trial with older adults with chronic pain and cognitive decline, we considered the safety risks associated with asking participants to complete the 6MWT independently (eg, falls). Participants were asked to create a plan to complete the 6MWT on a familiar route at a designated date and time, with support from a friend or family member when possible [17].

Synchronously Assisting Participants in Remote Completion of Quantitative Measures

Depending on the study protocol and population, the best practice may be the synchronous completion of measures (ie, in which a study team member administers the assessment to

the participant in real time). The synchronous completion of self-report measures enables study staff to directly support participants in completing measures, including ensuring participants' best effort, attention, focus, and comprehension during measure completion. Assisting participants synchronously in completing self-report measures also allows study staff to ensure that data are supplied directly from intended participants and eliminate the possibility that participants are being influenced by others such as spouses or parents. The factors to consider when making this decision include participants' age, cognitive ability, previous experience with technology, and preference. When assisting participants with assessment completion remotely, multiple modalities that can be used. First, calling participants by phone requires minimal technology access and familiarity for participants and enables study staff to *catch* participants at an opportune moment and ensure prompt survey completion with minimal effort on the part of the participant. Over the phone, study staff can ensure comprehension of every item (important for data validity); however, reading aloud every question-and-answer option can also be tedious for both study staff and participants. Strategies to address comprehension and focus include pausing to ask if clarification is needed, breaking up longer questions, and asking participants if they wish to take a break throughout the conversation.

For some participants, the visual component was beneficial for enhancing their comprehension of measure items. Video calling a participant with HIPAA-compliant, secure platforms [1] (eg, with Zoom and WebEx) and *screen sharing* the measure is a novel strategy to support participants in completing measures remotely. This *screen share* method provides the opportunity for the participant to see the questions in addition to hearing them and can enable better comprehension as well as more efficient measure completion (eg, study staff may not need to read every answer choice for items when participants can read them on-screen). Mailing participants paper copies of surveys in advance of phone calls is another method for allowing participants to have questions in front of them while also receiving live assistance in responding.

We use this novel *screen share* strategy in an ongoing randomized controlled trial of a mind-body intervention to promote quality of life in geographically diverse adolescents aged 12 to 17 years with neurofibromatosis [19]. We decided to rely on synchronous measure completion for this population, given the age of participants and high rates of learning disabilities, leading to anticipated challenges with thoughtful independent measure completion, as well as anticipated challenges with comprehension of items. The method has been effective in engaging participants during data collection to ensure participant comprehension of items and thoughtfulness when selecting answer choices. This method has also allowed us to identify and eliminate situations in which participants' parents are inappropriately coaching participants during data collection. Notably, videoconferencing does require a higher level of access and familiarity with technology; therefore, creative problem-solving abilities with participants are essential. As with all forms of technology used in data collection, study teams should consider ease of use for participants and be prepared to provide both emotional and technical support [11].

For group-based interventional studies and situations in which study staff want to be available to answer potential questions related to measure completion (about either technology use or specific items) but do not want to walk participants through every item, a group support procedure could be used using videoconferencing. In this strategy, a member of study staff can email participants the links to complete surveys on their own devices and schedule a time in which the group of participants joins a videoconferencing call to complete the measures at the same time. We use this strategy in our randomized controlled trial for older adults with chronic pain and cognitive decline [17]. Participants in a group video call are supported in navigating to their email to open the secure link to complete the questionnaires. Although completing their questionnaires independently, participants turn their video on or off, and we mute all participants and the study staff host to enhance focus and privacy and to replicate an in-person visit [14,17]. This method allows us to assist as needed when a participant takes themselves off mute to ask a question, physically raises their hand, or privately chats us. In addition, we periodically ask if anyone needs assistance, particularly after noticing that participants are not progressing as expected because REDCap allows the ability to monitor progress in real time.

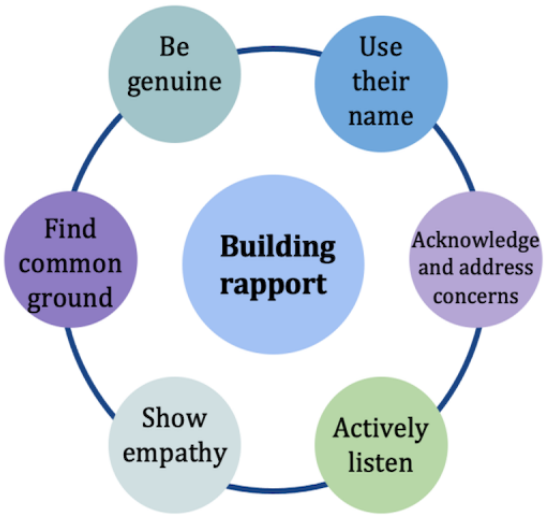
As with the shift to remote clinical care, the privacy and confidentiality of patients is not as easy to ensure as it is in person. Research staff have an obligation to ensure participant privacy and confidentiality to adhere to the principles of good clinical practice [20] and to ensure the acceptability of study procedures to participants for whom concerns of being overheard are common [11]. Informing (or reminding) participants of the sensitive nature of the questions (eg, pertaining to physical health, mental health, and intimate relationships) and ensuring that they are in a space where they feel comfortable to answer is the best practice. Working with participants to ensure the highest level of privacy may be necessary. Suggestions include using headphones (both participants and research staff), inquiring about participants' location and privacy, and allowing participants to determine the best time for the call [5,11]. Additional safety protocols are necessary when providing devices to participants, as they could be exposed to data theft or lose track of the device. We suggest enabling password protection on devices and limiting the data stored on the actual device to protect patient safety. Ultimately, although providing devices introduces the risk of needing to potentially replace the hardware, it is a readily integrable strategy to address the digital divide and increase access to research [21]. Participants should be reminded of the privacy risks associated with remote study participation (eg, possible breaches to the security of data collected remotely) and informed of the measures study staff are taking to safeguard against these risks (eg, encryption of devices and deidentification of data).

Motivating Participants to Complete Quantitative Measures Remotely

Building relationships with study participants is central to engaging participants in study procedures and ensuring thorough

and thoughtful data collection. Survey fatigue and general fatigue related to research participation pose real challenges to data collection as well as study retention [9]. Interactions with participants vary in length and frequency depending on study protocols; however, each interaction should be viewed as an opportunity to build rapport with participants. Strategies to build rapport include smiling (if on a video call), communicating clearly and confidently, and providing adequate emotional and technical support [5,11] (Figure 1). Researchers, clinicians, and patients alike cite increased mental health symptoms, stress, and added duties owing to the pandemic [22]. It is important to keep these additional burdens in mind when communicating with participants. Adjusting calls about study measures to be more conversational (eg, making time to ask participants about their day and how they are doing) can aid in establishing and maintaining rapport in the study team–participant relationship. The shared experience of COVID-19 is unifying and can be a source of common ground to relate to participants. Engaging in this way and expressing gratitude for participants' time can help build participant investment in the study.

Figure 1. Building rapport.



Study teams face additional challenges in prompting participants to complete measures when participants are difficult to reach or are unresponsive. Persisting in using creative outreach methods for calling and texting participants using HIPAA-compliant technologies (eg, Cisco Jabber and Twilio) [1] is essential. Study teams should consider adopting standardized procedures for attempted contact with participants to limit the burden on both participants and the study team. Often, research coordinators or research assistants are the first line of communication with participants and will attempt to call participants a certain number of times. It is helpful to consider when participants are usually home (ie, what time of the day is best to call) and to try different times throughout the day to achieve higher response rates. Study teams should standardize the maximum number of outreach attempts by research coordinators. Once that number is reached, it has proven useful in our experience to pass the communication up the chain to a study clinician or principal investigator. Study teams can also use this approach to allow a clinician to assess whether disengagement may be related to any concerns regarding the participant's well-being. Other strategies to bolster participant motivation include involving family members in study procedures, accommodating participants' preferred methods of communication (eg, texting, email, and phone call), and providing monetary or other forms of incentives [9,11].

Promoting Health Equity and Overcoming Barriers to Web-Based Engagement Among Participants With Varying Levels of Technology Access and Familiarity

As the COVID-19 pandemic continues to lay bare the existing health disparities in racially, ethnically, and socioeconomically minoritized groups, concerns that the increased reliance on digital technologies for clinical care and research will exacerbate the digital divide rather than mitigate systemic health inequities are prevalent [23]. Indeed, digital access is considered a social determinant of health, with 21 million adults in the United States lacking access to broadband internet [24]. With the transition to web-based research, we risk compounding this structural disadvantage and not realizing the potential to expand research access to increasingly diverse and underrepresented populations [1] without targeted measures to address digital access and literacy [21,25,26].

Building capacity for person-centered, equitable research can be facilitated by providing smartphones or internet plans to participants if access to these technologies is an inclusion requirement [1,11] as well as using multiple outreach modalities. Enabling outreach through multiple modalities has led to successful data collection during the pandemic in our ongoing randomized controlled trial for patients with serious mental illness and a new cancer diagnosis [27]. In this trial, we use multiple traditional outreach methods for data collection (ie, phone, email, and letter mail) in addition to nontraditional methods such as partnering with family caregivers and staff in congregate living settings. Despite a slower study accrual because of fewer new oncology consultations during the

pandemic, we maintained consent and survey completion rates for a marginalized population with flexible, multimodal, patient-centered outreach [28].

Providing adequate technology support is also of utmost importance. Study teams must provide training to participants for all forms of technology used, through manual documentation, prerecorded videos, or live assistance (eg, over the phone) [11]. Proactive outreach to individuals for technology coaching can promote efficiency and decrease participant frustration. Test-driving technologies and creating a short list of common technology challenges encountered by participants can help study teams troubleshoot and identify unnecessarily confusing aspects of instructions or procedures that can be changed. Study teams can also consider engaging family members in study procedures, which has been shown to aid in the adoption of technology for older populations with cognitive impairment [11]. We commonly use the approach of *meeting participants where they are* by first assessing participants' comfort with technology during a study enrollment phone call. This allows us to provide extra support where necessary, such as detailed instructions on software installation, test calls with study staff, and encouragement. We also prioritize conducting qualitative exit interviews to obtain feedback on study procedures to refine study protocols and participant instruction materials [14]. Technical support activities may increase the total time spent both preparing for and conducting a session with a participant. However, the time invested in participants proactively will contribute to improved data quality by ensuring patient understanding of the technology and study measures. Furthermore, digital solutions tailored for specific populations can aid in realizing the potential for web-based research to increase accessibility to underrepresented individuals.

Practical and Logistical Considerations to Conducting Qualitative Interviews and Focus Groups Remotely

Focus groups, or interviews, are conducted synchronously; therefore, time (and time zone) coordination is required. For individual interviews, offering flexible hours that prioritize participants' preferences may assist in study enrollment because participants will be able to schedule and mark their calendars for a *study visit* in real time. To coordinate a focus group, study staff can ask participants about their availability within multiple potential time blocks to choose a time to maximize attendance. Once a specified time frame has the minimum target focus group size, study staff may call unavailable *participants* to assess whether there has been a change in schedule or continue recruiting to reach the maximum focus group limit, ranging anywhere from 4 to 12 participants [29], with smaller groups often preferred for web-based conduct. In general, participants should be made aware before the interview or group what the policies will be (ie, how long the group will run, expectations for video on or off, and audio-recording plan).

HIPAA-compliant videoconferencing software (eg, Zoom and WebEx) is necessary for the conduct of remote qualitative interviews or focus groups (as opposed to phone calls) to facilitate rapport building between study staff and participants to ensure that participants feel at ease. Many types of videoconferencing software contain features, such as waiting rooms and passcodes, that maximize participants' security and confidentiality. Still, participants should be informed of the privacy risks associated with participation in remote focus groups (eg, the unsanctioned audiotaping or videotaping of groups) and the rules for participation (eg, use of headphones and being against recording of groups) should be clearly articulated at the start of every group. Features such as *breakout rooms* can also be innovatively used to conduct multiple interviews at one time, such as in the case of exit interviews after focus groups. Microphone and video camera positioning should be considered for both the interviewer and the interviewee, and 5 to 10 minutes should be allotted to ensure the proper placement and functioning of microphones and video cameras to enhance the quality of data. Automated live captioning of the interview conversation (closed captions) may also benefit participants who have difficulty hearing.

Having study staff on call during interviews and focus groups is essential to provide technological support to participants in case of issues. Study staff can provide individual support to participants and troubleshoot issues related to remote participation, including poor connectivity with the internet, audio or camera issues, the use of videoconferencing software, and environmental disruptions [11]. In the case of challenges that cannot be solved within a reasonable amount of time, study staff should have backup strategies in place to conduct interviews over the phone, allow participants to join focus groups by phone, or reschedule meetings flexibly. These procedures were used in qualitative interviews with patients with young-onset dementia and their caregivers [30], as well as in focus groups with orthopedic medical providers to enable the recruitment of geographically diverse participants.

We used these strategies at the beginning of the pandemic to transition from an in-person focus group study investigating barriers to smoking cessation clinical trials for Hispanic, Latino, or Latina individuals to remote procedures. Before the pandemic, we recruited Hispanic, Latino, or Latina individuals for focus groups conducted in both English and Spanish. After transitioning to remote research, we ran the web-based focus groups with smaller numbers than intended in person (3-4 people) to ease the burden on the study team while we navigated the new technology and ensured that each participant was able to receive one-on-one assistance. We faced challenges with technology, including finding solutions for individuals who did not have email or webcam access, a noted disparity among older Hispanic individuals [31]. To increase access, we mailed information to all participants (eg, study information sheet and materials to be discussed during the group) 1 week before the group and expanded our protocol to include both telephone conference calls and videoconferencing calls to accommodate participants' varying levels of technology access. Despite technological challenges, we found that offering web-based focus groups was helpful for both participants and study staff because we could more flexibly schedule groups with the bilingual study staff member who facilitated the groups. We also offered participants the option to have a *test call* with a member of the study staff to ensure adequate internet connection, microphone or camera functioning, and confidence navigating the video software. An alternative method would be

to include a brief introduction to the video software at the beginning of a qualitative interview or focus group and encourage participants to test different functions (eg, toggling audio and video on and off).

Adapting Facilitation Strategies for Remote Qualitative Data Collection

Although remotely conducted interviews and focus groups may pose some challenges to interviewers in engaging participants, connecting with participants, and encouraging open and active dialogue among participants, there are many verbal and nonverbal strategies that interviewers can adopt. Before the interview, study staff should begin building rapport with participants (Figure 1), explain who will be conducting the interview with their credentials, and provide information on what topics the interview will cover (particularly important for sensitive topics). At the start of the interview or focus group, interviewers should warmly introduce themselves and provide additional reminders to set the appropriate tone. For example, interviewers should encourage participants to be in a quiet and private space (or use headphones) with efforts to minimize environmental distractions (eg, participants should not be driving, doing chores, or eating) [11]. Interviewers may want to encourage participants to keep their camera on if they are able to facilitate engagement and rapport building but to mute themselves when they are not talking to reduce background noise. If participants are muted, interviewers should be prepared to probe them more enthusiastically than usual to motivate active dialogue and participation. It may be helpful for interviewers to continually encourage participants to share, particularly those who have been quiet. Encouraging diversity of opinion among groups can also help participants feel comfortable expressing their personal experiences and differing perspectives.

Assuming that they are visible to participants, interviewers should also pay attention to their nonverbal communication. If interviewers must take notes during qualitative data collection and are therefore unable to maintain eye contact throughout the interview or focus group, participants should be informed to avoid potential nonverbal miscommunication. Reactive facial expressions are critical in remote qualitative data collection, as body language cannot be observed as it typically would be in person, although some aspects such as posture may be observed. Nonverbally reacting appropriately to what participants share is vital to encourage participants to be open and honest during an interview. The key aspects of nonverbal communication include eye contact (toward the participant or the camera), using facial expressions to demonstrate understanding and listening, and body language, including nodding [11].

For structured and semistructured interviews and focus groups, keeping track of the timing during the interview is also necessary to ensure that all questions are answered, with appropriate time allocated to each section or question. This is particularly important for remotely conducted interviews, in which participants may only reserve the exact expected amount of time for the call (eg, 60 minutes) and when adequate attention and focus might be more difficult to maintain than in person. To support interviewers in managing time, we commonly include time stamps in interview guides and denote the questions to be prioritized. In focus groups, it is recommended to have 2 interviewers on the call if possible. That way, at least one interviewer can be primarily concerned with active listening and engagement with the participants, whereas another interviewer can focus on note-taking and timekeeping.

In our recent qualitative study with patients with young-onset dementia and their caregivers (dyadic interviews), we found it critical to consider the specific cognitive challenges of persons with dementia in facilitation as well as the sensitive nature of dyadic interviews. All questions were piloted with experts in young-onset dementia before the interviews to ensure clarity. Interviewers were prepared to repeat questions several times as well as define or explain keywords as needed. Because couples were asked to share their perspectives regarding the person with dementia's symptoms and illness progression as well as relationship satisfaction in front of each other, we prefaced the interview by validating the difficulty of openly sharing and encouraging participants to be as open as possible. When participants were hesitant in sharing, we found that *sitting with the silence* before moving on to a new question encouraged participants to reflect and add to the conversation. Before asking about relationship challenges, the interviewer acknowledged that this might be the first time couples are discussing certain questions and assured couples that we would be available to provide support to the couple together or individually after the interview as well. It is particularly important to consider participant emotional safety and sense of support in the case of remote interviews.

Essential Training Competencies for Study Staff

At the forefront of training competencies to conduct remote data collection is ensuring study staff have familiarity with practices to promote participant privacy and security, including encrypting computer devices; using secure, encrypted video and audio software; and conducting qualitative data collection in private, quiet locations. Equipping the study team with institutionally encrypted equipment (laptops with webcams and phones) and software programs facilitates standardized and HIPAA-protected data collection [1]. It is essential that study staff have sufficient familiarity with all technologies used so that they can troubleshoot any problems that may arise for either themselves or the participants and provide technical support as needed [11]. Therefore, study staff must be thoroughly trained in the use of any relevant technology as well as provided with resources to contact in the case of questions or issues.

Given the unique challenges to rapport building and participant engagement through remote encounters, it is also important to provide study staff with adequate training in verbal and nonverbal communication. For study staff with less experience with participant interaction and without clinical training, providing some level of peer or hierarchical supervision may be helpful in supporting them in developing effective communication skills.

Discussion

Summary

In this paper, we integrated recommendations from previous literature with examples from our ongoing clinical research to identify and respond to specific challenges to remote data collection (Tables 1 and 2). We hope to catalyze other research teams to think critically about the strategies they use in remote data collection and contribute to the collective body of knowledge on best practices through the publication of protocol papers and other methodologically oriented works. It is imperative that research teams thoughtfully and creatively solve problems in response to the challenges they face in remote data collection to ensure the validity and quality of data as well as the patient-centeredness of study procedures.

Future Directions

Future research is needed to evaluate whether data collected through web-based study designs are of the same nature and quality as data collected through traditional in-person approaches and to continue to identify strategies to maximize the validity of data collected remotely. The shift toward more web-based designs prompted by the COVID-19 pandemic brings with it the opportunity to remove many barriers of access to clinical research and engage more diverse participant populations while minimizing the burden on participants. However, without proper capacity building for web-based research, we risk widening the digital divide perpetuating existing disparities. We discussed our experiences with conducting web-based research with different populations, including individuals underrepresented in research such as Hispanic, Latino, or Latina individuals, those with serious mental illness, and those who face increased barriers to research participation, such as older adults with dementia and adolescents with learning disabilities. The strategies presented (eg, device provision, increasing technological support, and using multiple modalities to conduct research) are examples of mechanisms to promote equity in research participation. We acknowledge the significant participant burden in using technology for research and that the same digital health solutions do not work for all individuals. Therefore, it is imperative that researchers assess barriers specific to their study designs and populations of interest to mitigate the threat of increasing existing disparities. Additional research is needed to further characterize strategies that can be used to ensure accessibility of virtually conducted research to marginalized and underrepresented populations.

Conflicts of Interest

None declared.

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Abbreviations

6MWT: 6-minute walk test
HIPAA: Health Insurance Portability and Accountability Act
REDCap: Research Electronic Data Capture

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Viewpoint

Open-Source Clinical Machine Learning Models: Critical Appraisal of Feasibility, Advantages, and Challenges

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Abstract

Machine learning applications promise to augment clinical capabilities and at least 64 models have already been approved by the US Food and Drug Administration. These tools are developed, shared, and used in an environment in which regulations and market forces remain immature. An important consideration when evaluating this environment is the introduction of open-source solutions in which innovations are freely shared; such solutions have long been a facet of digital culture. We discuss the feasibility and implications of open-source machine learning in a health care infrastructure built upon proprietary information. The decreased cost of development as compared to drugs and devices, a longstanding culture of open-source products in other industries, and the beginnings of machine learning–friendly regulatory pathways together allow for the development and deployment of open-source machine learning models. Such tools have distinct advantages including enhanced product integrity, customizability, and lower cost, leading to increased access. However, significant questions regarding engineering concerns about implementation infrastructure and model safety, a lack of incentives from intellectual property protection, and nebulous liability rules significantly complicate the ability to develop such open-source models. Ultimately, the reconciliation of open-source machine learning and the proprietary information–driven health care environment requires that policymakers, regulators, and health care organizations actively craft a conducive market in which innovative developers will continue to both work and collaborate.

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KEYWORDS

machine learning; artificial intelligence; medical economics; health policy; healthcare innovation

Introduction

Background

Machine learning (ML) is a subset of artificial intelligence (AI) that uses training on existing data to generate insights on novel data. ML applications can augment physicians' ability to make evidence-based decisions by synthesizing and applying more data points into practice than can any one individual. Currently, at least 343 AI-enabled tools have been cleared or authorized by the US Food and Drug Administration (FDA) to assist with functions including reading radiographs, classifying ophthalmic imaging, and interpreting electrocardiograms [1]. However, these technologies are still relatively novel, with the potential for widespread use in the near future.

Commercial innovations in modern medicine have largely taken advantage of proprietary information. However, software has had a longstanding paradigm bifurcation into proprietary and open-source software. Open-source software differs from proprietary software in the accessibility of its underlying code. Unlike proprietary software, open-source tools make their underlying code accessible to users. The use of proprietary software in American health care systems generally exceeds the use of open-source software [2]. However, select examples, such as the United States Veterans Affairs' open-source VistA system, have found success in clinics and facilities [3].

Open-source software solutions have also been successfully implemented in developing nations' health care systems [3].

Open source looks to be an important part of the health care ML landscape. This entry has already begun; for instance, developers building clinically oriented models often share source code as part of distribution. Examples of such models include those indicated for patient risk stratification [4], cancer therapeutic selection [5], pneumothorax detection [6], and pneumonia classification [7]. Activity in this space currently exists outside of structured market, regulatory, or implementation frameworks. In this paper, we evaluate the consequences of and raise considerations for the development and distribution of open-source ML models in health care settings. We consider factors contributing to the feasibility of deployment, the advantages of open source, and challenges faced by those seeking to develop and distribute open-source models.

Feasibility

A total of 3 factors contribute to the feasibility of deploying open-source deep learning models. First, developing deep learning models, as compared to other health care solutions, requires relatively little capital on the part of developers. The collection of data is often passive, taking place routinely during encounters and hospitalizations. Although the curation of data may take effort, resources expended in collecting information for deep learning models are far less than those required while collecting information for drug development. Likewise, proving efficacy through retrospective and prospective validation can occur in a randomized fashion in the background of standard clinical operations. Performance standards can be assessed without changing the course of care. ML models also do not require the design and execution of randomized controlled clinical trials, which cost on average US $20 million per trial for stage III drug candidates [8]. Thus, open-source models require fewer incentives to recoup development costs. Given the favorable risk profile of constructing and deploying deep learning tools, developers have less incentive to keep their algorithms secret.

Second, the concept of open-source products is already familiar to the technology and information technology (IT) industries. Commonly recognized examples include Linux, the Apache HTTP Server, and Mozilla Firefox [9]. The global market for open-source projects across sectors was almost US $9 billion in 2016 and is expected to rise, with North America having the largest share [10]. Even in health care, the development of open-source models is nothing new. Scoring systems such as the PORT (Patient Outcomes Research Team), APACHE II (Acute Physiology and Chronic Health Evaluation II), and the Charlson Comorbidity Index are all open source and freely available [11]. These are all relatively simple models that apply logistic regression or points-based systems. The advent of deep learning and other sophisticated models may be considered in the context of these simpler models. Cultural, organizational, and policy factors have contributed to the notoriously slow adoption of technology in clinical settings [12]. Having strong precedents for the widespread utilization of open-source tools may decrease the magnitude of this barrier.

The third and most uncertain factor is the regulatory landscape for the entry of tools into the market. Regulation of ML in health care involves its own complex set of issues [13,14]. Many models developed and deployed in-house are unlikely to face much regulatory oversight, for various reasons that are still developing. Models developed in-house and shared noncommercially for in situ modification and deployment may still receive relatively little scrutiny. However, even at the most intense end of the scale of regulatory scrutiny, ML models under the FDA's jurisdiction are typically eligible for the 510(k) approval process, allowing for the approval of a device via proof of equivalency to another device [15]. Thus, a deep learning model that is equally performant to an existing product can gain expedited approval. As of January 2022, at least 90% of AI-enabled models gained approval via the 510(k) pathway [1]. Open-source developers can utilize this same process to release models into the market.

Advantages

There are 4 primary advantages to the development and integration of open-source ML models. First, the transparent nature of open-source software can potentiate enhanced integrity and performance. Unlike proprietary software, for which only purchasers can run models, anybody who has access to available open-source code can assess the model's performance [16]. These circumstances thus allow for validation by greater numbers of people and on greater numbers of data sets. For tools requiring FDA approval, open-source models must either undergo a process demonstrating safety and efficacy or, more feasibly, undergo a process establishing performance equivalency to a model already in existence [13]. However, these validation processes are dependent on the data used to test the models at the time of appraisal. The FDA does not yet have a neutral third-party data set to validate individual developers' models. Given these regulatory shortcomings, models require rigorous postmarketing surveillance [17]. Current efforts to interrogate proprietary software often reveal performance issues well after the commercial software has been widely distributed and implemented [18,19]. As compared to proprietary software, open-source tools would enable greater ability to detect deficits such as poor generalizability, previously unaccounted biases, and model drift.

Second, open source allows for the customization of models for a hospital's specific population. ML tools, like therapeutics, are developed on data sets of large cohorts but ultimately applied to individuals. Thus, safety and efficacy vary among individuals and between specific populations [20]. When applied to medical informatics, this phenomenon is known as the "curly braces problem": implementing models in new settings degrades their performance [21]. Facilities and departments using open-source models can somewhat mitigate this problem by calibrating the model weighting to achieve optimal performance on their unique patient populations. A cancer center, for instance, may want image reading models calibrated slightly differently from an emergency department. The capability to adjust source code to deliver increasingly personalized care may increase safety and efficacy.

Third, low-cost open-source options may speed up the adoption of ML technology in clinical settings. Inherent to the notion of open-source models is the availability of their code. Due to the nature of their transparency, open-source tools have historically been lower in price compared to their proprietary counterparts [22]. Despite a projected US $6.6 billion investment by developers and investors [23], health care facilities have proven slow to adopt ML technologies [24]. Among other reasons, hesitancy by clinicians and administrators due to potential financial or value-based consequences of using such technology hold back its implementation [24,25]. Decreasing the financial risks of adoption may encourage operational experimentation, particularly for hospitals that are naïve to ML tools.

Fourth, low-cost open-source options may increase competition, influencing price and functionality. The emergence of open-source models is not likely to end the development of proprietary technology. From word processors to COVID-19 decision support algorithms, the uptake of open-source tools has occurred alongside proprietary tools [9,26]. However, proprietary models, often priced higher than open-source models, will have to compete with effective "generic" models. Facilities looking to use deep learning for any given use case may confront a combination of proprietary and open-source options. The very existence of comparable open-source models forces proprietary developers to increase functionality in return for the higher cost [21]. Results may include a smoother user interface, enhanced integration with existing health care IT systems, or augmented implementation guidance or maintenance.

Challenges

The implementation of open-source deep learning models also faces 4 primary challenges. First, engineering issues impact the feasibility of development and maintenance. A model is one piece of a multicomponent production pipeline. The code and infrastructure around the model, known as ML operations (MLOps), are necessary to make the model production ready. For the most part, commercial services include MLOps services with the purchase of proprietary models. These services would not be included with the implementation of isolated open-source model code.

The monitoring of inputs, an important component of MLOps, ensures that the model works as intended. Changes in inputs can cause a model to produce unexpected outputs. For example, a recent electronic health record upgrade at New York University (NYU) Langone Health caused a monitoring system to flag changes in model inputs, and we were immediately able to flag the change and fix the input mappings. Alternatively, the underlying population or treatments may change. For example, NYU Langone Health researchers trained a model to predict 2-month mortality [27]. In prospective validation, the team identified a subgroup of patients with lung cancer who were unexpectedly surviving beyond 2 months. In the intervening time between model training and prospective validation, the FDA approved pembrolizumab (Keytruda) for clinical use. Patients treated with Keytruda were no longer at high risk of short-term death.

Second, increased accessibility to source code exposes models to manipulation, especially by adversarial machine learning. Adversarial machine learning techniques involve feeding models misleading data to produce faulty outputs. Researchers have used such techniques to deceive models processing multiple forms of media, including images and text [28]. Reports have described engineered attacks in which experts have been unable to distinguish between data from patients and manipulated data [29,30]. Adversarial attackers with access to model source code could release models deliberately designed to negatively impact patient care. Alternatively, because these models are open source, the attacks are transparent and thus mitigatable. Additionally, the monitoring infrastructure still exists and if done correctly, should immediately flag these attacks.

Third, the intellectual property and incentive landscape for open-source medical ML models is complex. Attempting to maintain exclusivity for models is contrary to the spirit of open-source sharing. Even if developers were to attempt to seek some intellectual property protection, patents provide relatively weak protection for models (and no protection at all for the data on which models are based), based in part on US Supreme Court decisions that expansively defined the set of abstract ideas and natural laws that cannot be patented [31]. Secrecy, the principal alternative to patents, is similarly incompatible with an open-source model, though a combination of secrecy and licensing does enable variants such as open-source products solely for noncommercial uses.

The lack of exclusivity-based supracompetitive pricing limits the incentives available for the development and validation of open-source models. This especially constrains the activities model developers would be willing to undertake; cheaper work, such as model development based on existing in-house data sets or in silico validation, is substantially easier to justify and support than more expansive and expensive work, such as prospective clinical trials to validate model performance or generalizability across contexts, that is necessary for the evidence-based adoption of an AI model [32].

Fourth and finally, developers of open-source medical ML models face complex possibilities around the question of liability, namely, whether a model developer can face liability when patients are harmed based on the use of an arguably faulty model. Fully expanding upon the possibilities of liability is outside the scope of this work, not least because courts have yet to clarify the doctrine. The frequent finding of liability for upstream open-source model developers seems relatively unlikely [33]. Among other things, courts have been reluctant to impose product liability on software developers because software is only disputably a product. Intervening actors, such as the health system implementing (and perhaps modifying) an open-source model and the health care provider caring for the patient, further complicate the causal chain and the assignment of liability. Finally, licensing terms that include indemnification for liability and the reassignment of liability by insurers both add complexity to the liability landscape. Suffice it to say that liability remains an area of uncertain concern but seems unlikely to deter a substantial amount of open-source model development and collaboration, as evidenced in part by the sharing already

occurring. Still, the area is one that developers should likely continue to monitor.

Conclusions

In this viewpoint, we have evaluated factors involved in the development and deployment of open-source ML models for use in clinical settings, considering feasibility, advantages, and challenges inherent to such a framework. The benefits of open-source technology are largely known and accepted within the technology community. The forces holding back the adoption of the proposed technology, however, lie in the lesser-known aspects of the intersection between the data sciences, clinical sciences, and health care policy. Questions surrounding regulation, liability, and market forces predominate concerns about furthering the development of tools in a manner that potentially limits the extent of profit margins.

Given these outstanding questions, we believe that policymaker interventions have a fundamental role in enabling developers. A pragmatic start would be to ensure model generalizability. An overarching concern in the applicability of open-source models is the ability to use models in different settings while trusting that performance will remain strong, especially given the MLOps factors noted above and the possibility of patient injury (and potential liability) that might result from improper translation. Demonstrating generalizability, however, is expensive and as noted, patents, since they are not available, do not create incentives for incurring that expense. Policymakers could both encourage generalizability testing and reduce attendant expenses by helping to develop a unified infrastructure to enable such testing before sharing. Such an infrastructure could involve routinely updated test data sets, mock settings, and challenge queries. Generalizability infrastructure would make it easier to develop responsible open-source models and could also reduce redundant infrastructure effort by those whose resources could be better spent developing and improving models. Although we do not take a strong view as to who could best design such an infrastructure, the FDA seems a logical contender.

More generally, the role of forward-thinking governance remains critical to the development and deployment of open-source models. The FDA has recently announced that it was considering changes to its standard approval process directed at establishing more appropriate regulation regarding ML programs [13]. Changes include a precertification pilot program where companies are approved before they develop and release models. This allows for the release of new versions without subsequent safety and efficacy trials. Similar innovations may be required in regulatory bodies, clinical facilities, and the law to provide guidance that supports a sector that intertwines proprietary and open-source models. In the meantime, developers may need to shoulder some of the risk of promoting innovations to improve patient care, including through the sharing of open-source models.

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Authors' Contributions

KBH, WNP, and YA contributed to the conception of this viewpoint, framework, paper writing, and review of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
APACHE II: Acute Physiology and Chronic Health Evaluation II
FDA: US Food and Drug Administration
IT: information technology
ML: machine learning
MLOps: machine learning operations
NYU: New York University
PORT: Patient Outcomes Research Team

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Original Paper

Effects of COVID-19 on Physical Activity and Its Relationship With Mental Health in a US Community Sample: Cross-sectional, Convenience Sampling–based Online Survey

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Abstract

Background: COVID-19 restrictions may make it difficult for people to engage in the recommended amounts of physical activity (PA).

Objective: The influence of the COVID-19 pandemic on PA, as well as the links between PA and mental health, was investigated in this study.

Methods: Participants were recruited using convenience sampling and responded to an online survey between April 15 and July 1, 2021, with ages ranging from 18 to 24 years (n=156, 40.9% of the sample) to ≥55 years (n=28, 7.4% of the sample). To assess general psychological distress, depression, anxiety, and pandemic anxiety, a battery of mental health assessments was used. The International Physical Activity Questionnaire - Short Form was used to collect PA data from participants, who were then classified as inactive, minimally active, or highly active. Participants also indicated the locations where they performed PA before and during COVID-19.

Results: A sample of 381 individuals was included in this research. The logistic regression analysis results were interpreted as odds ratios (ORs), where an OR higher than 1 indicated a greater chance of an event occurring and an OR less than 1 implied a lower likelihood of an event occurring. Logistic regression results revealed that inactive individuals were more likely to develop psychological distress (OR 2.17, 95% CI 1.27-3.69, *P*=.004), depression (OR 3.81, 95% CI 1.92-7.57, *P*<.001), and anxiety (OR 1.86, 95% CI 0.99-3.47, *P*=.05) as compared to highly active individuals. Furthermore, when compared to highly active people, those who were only minimally active had a higher risk of depression (OR 2.14, 95% CI 1.05-4.33, *P*=.04). Wilcoxon signed-rank tests revealed that COVID-19 has a greater impact on reducing the chances of less active individuals engaging in PA outside and in public spaces. Highly active people's physical exercise locations had changed less, and their exercise frequency at home increased.

Conclusions: Programmatic and policy interventions geared particularly toward enhancing PA among those less active may be a helpful strategy for addressing the worldwide pandemic's mental health crisis.

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KEYWORDS

physical activity; COVID-19; mental health; depression; anxiety; United States; survey; cross-sectional; distress; risk

Introduction

Background

The current COVID-19 pandemic has swept the world since the first confirmed case in Wuhan, China. COVID-19 is characterized by rapid transmission via droplets or close contact between humans. In the United States, over 33 million COVID-19 cases were reported as of July 1, 2021. Due to a lack of suitable treatments and vaccinations during the early stages of the pandemic, most countries adopted World Health Organization (WHO)-recommended protocols. Individuals worldwide were advised to stay at home and avoid contact with anyone who was not a close family member. Several studies have been published in recent months on the effects of COVID-19-related restrictions on psychological well-being, physical activity (PA), and general life satisfaction [1-9]. Although these self-quarantine methods were critical in reducing the spread of COVID-19, they may have limited people's capacity to engage in sufficient amounts of PA to preserve health and avoid illness.

During the pandemic, people worldwide were urged to stay at home and avoid contact with others. Businesses, organizations, and institutions, for example, encouraged their workers to work from home to ensure their own safety. People who worked from home had fewer opportunities to interact with coworkers and participate in fewer PAs, such as walking between meeting locations [10]. Students were no longer allowed to participate in school-based PA, such as physical education classes or walking to and from transportation, as they moved to online learning. The majority of team sports, league training, and games were canceled. Due to lockdowns and other restrictions, people found it impossible to access gyms, parks, and other places where they might exercise. Although prepandemic PA levels were already insufficient for many, pandemic management efforts are likely to have had the unintended consequence of further lowering PA. Early investigations did, in fact, show a substantial decrease in PA levels since the pandemic began [11].

The relationship between the COVID-19 restrictions and PA may be particularly significant, given that frequent and considerable physical exercise is essential for health and well-being in general [12]. Exercise has a main effect in treating depression [13,14]. Physical inactivity, in contrast, has both acute and long-term negative psychological consequences, as well as negative effects on people's metabolic, vascular, and immune systems across a wide range of age groups, races, genders, health conditions, and body shapes [15]. To maintain psychological and physical well-being during the pandemic, WHO recommended that people engage in physical exercise, particularly while in self-quarantine.

According to a study performed in the United States during the early stages of the COVID-19 pandemic in April 2020, participants reporting decreased PA experienced higher depression, loneliness, and stress [16]. Similarly, research conducted in April 2020 on adults in Italy and Australia revealed that participants reporting decreased PA following the pandemic were more likely to have negative psychological health and well-being [6,17]. Research conducted on Canadian participants from April to May 2020 revealed that those who were more physically active had better mental health and those who became more active or who had more PAs in the outdoors had less anxiety [18]. A survey study conducted between 2015 and 2020 discovered that during the pandemic in 2020, there was a significant decline in PA and mental health among college students, while PA did not appear to protect against deterioration in mental health, with participants drawn from a large northeastern US university and predominately females and non-Hispanic Whites [1]. In a rapid systematic review of COVID-19 research on physical exercise and depression and anxiety, the authors indicated there were methodological weaknesses in some of the studies, such as the use of unvalidated instruments and failure to provide standardized statistics [5]. Furthermore, since most of previous research was performed shortly after the pandemic outbreak [3], a new study of PA and its relationship with psychological health may be needed to generate further findings after the effect of a year-long pandemic restriction.

Aims of This Study

In sum, there have been few up-to-date studies on the impact of pandemic restrictions on physical exercise and their connections to mental health. This research investigated whether physical exercise is linked to a decrease in anxiety and depression. In addition, we investigated whether there were any changes in the locations of participants' PA before the COVID-19 outbreak and during the pandemic.

Methods

Participants and Procedure

Data were collected via an online, anonymous survey via Qualtrics from April 15 to July 1, 2021. The study used convenience sampling to recruit individuals aged 18 years and above from a public university campus community located in the metropolitan region of New Jersey, United States. The research was publicized to the university community, including students, faculty, and staff, through email, flyers, and campus announcements. The completed questionnaire was submitted by 381 respondents. The questionnaire included questions about demographics, lifestyle, and socioeconomic position, as well as key variables examined, such as mental health and PAs. The data provided here were centered on factors associated with changes in physical and mental well-being. Participants would enter the draw for a $50 gift card by providing their email addresses. As an added precaution, a range of security mechanisms in Qualtrics and a human check were implemented in the survey for removing potential bots and preventing multiple submissions.

Ethics Approval

Before taking the survey, participants provided their electronic informed consent. Participants had the right to agree or refuse to participate in the research and withdraw at any time. The research was approved by the university's institutional review board (IRB).

Measurements

Mental Health Problems (Psychological Distress, Depression, and Anxiety)

A broad and well-validated 4-item Patient Health Questionnaire (PHQ-4) was used to measure psychological distress [19,20]. The PHQ-4 includes 2 items that assess depressive symptoms ("feeling down, depressed or hopeless," "little interest or pleasure in doing things") and 2 items that assess anxiety ("feeling nervous, anxious, or on edge," "not being able to stop or control worrying"). The questionnaire begins with the broad question, "Over the last 2 weeks, how often have you been bothered by the following problems?" Participants rate the number of times these problems have bothered them on a 4-point scale of 0 (*not at all*), 1 (*several days*), 2 (*more than half the days*), or 3 (*nearly every day*). The total score for the PHQ-4 ranges from 0 to 12, with higher scores indicating more symptoms of psychological distress. Following established protocols, the total score was transformed into 4 categories, which indicated various psychological distress levels: *none-to-minimal* (≤2), *mild* (3-5), *moderate* (6-8), and *severe* (9-12).

The PHQ-4 can be divided into 2 ultrabrief screening scales [21,22]: the 2-item Generalized Anxiety Disorder (GAD-2) scale for screening anxiety disorders and the PHQ-2 for screening depression disorders [23,24]. PHQ-2 and GAD-2 subscales have values ranging from 0 to 6, with higher scores suggesting more symptoms of depression and anxiety. A subscale score of 3 suggests a cut-off point between the normal range and probable clinical depression or anxiety disorder [20]. Using a cut-off value of 3, the PHQ-2 and GAD-2 scales were converted into binary variables, indicating a greater risk of depression and anxiety.

The PHQ-4 has been evaluated for construct validity in general [20,21,25], and it has been shown to correspond with suitable self-report measures and known demographic risk factors for depression and anxiety. In this research, the PHQ-4 had a Cronbach α of .88, while the GAD-2 and PHQ-2 subscales had a Cronbach α of .88 and .83, respectively. The reliabilities were comparable to those of other research that used the same scale in a similar context.

Pandemic Anxiety

A survey item assessing the prevalence of symptoms of physical anxiety linked to the COVID-19 outbreak was used to assess pandemic anxiety [26,27]. The survey question asked participants how often they had physical anxiety symptoms over a certain week, reflecting their COVID-19 experience: "In the past 7 days, have you had physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart, when thinking about your experience with the COVID-19 pandemic?" Participants chose from the following list of options: *rarely or none of the time* (less than 1 day), *some or a little of the time* (1-2 days), *occasionally or a moderate amount of time* (3-4 days), or *most or all of the time* (5-7 days). This question has been modified from the Impact of Event Scale used by the American Psychiatric Association to capture reported physical discomfort following traumatic events. The criteria used are defined in the *Diagnostic and Statistical Manual of Mental Disorders* as symptoms of posttraumatic stress disorder [28]. Based on previous research, a binary measure was created by keeping the lowest variable level, *rarely or none of the time* (less than 1 day), as 0 and the 3 highest variable levels as 1 [27].

Physical Activity

The International Physical Activity Questionnaire - Short Form (IPAQ-SF) was used in the assessment of the levels of individuals' PA and had good reliability, as measured [29,30]. This questionnaire asks about PA done in the previous 7 days and details on the frequency and duration spent on 3 distinct levels of PA: vigorous-intensity activity (eg, aerobics), moderate-intensity activity (eg, carrying light load, bicycling at a regular pace), and walking activities. According to the official IPAQ scoring procedure, the participants of the study were classified into 3 different categories of PA (*highly active*, *minimally active*, and *inactive*), with the IPAQ analytic algorithms considering both the total PA volume and the number of days/sessions. Individuals who were highly active surpassed the minimal public health PA guidelines and accumulated enough exercise to maintain a healthy lifestyle. Individuals who were minimally active got the minimum amount of exercise recommended for adults in current public health guidelines but not enough to be highly active. Individuals that were inactive were engaged at the lowest level of PA, meaning they did not fulfil the minimal active requirements.

Physical Activity Locations

Participants were asked to report the frequency of the types of locations they used for PAs before the pandemic and during the COVID-19 outbreak to determine whether the pandemic impacted how individuals engaged in physical exercise. The following options were provided: parks/trails, botanical gardens, recreational sports/intramural facilities, neighborhoods, home-based activities (eg, workouts, housekeeping, fitness video games), fitness facilities (eg, gyms), time outdoors with animals, transportation to the workplace, and the workplace. Participants of the study indicated how often they used each of these locations for PA purposes over a 1-month period, on a scale of 0 (*never*), 1 (*rarely*), 2 (*sometimes*), and 3 (*frequently*), before and during the pandemic. This tool was developed by Michigan State University as part of the PhenxTookit for COVID-19 [31].

Data Analyses

First, descriptive statistics on the main variables analyzed were reported, and gender differences (female vs male) were examined using chi-square and *t* tests for categorical data and continuous data, respectively. Differences between PA groups were investigated and are reported in Multimedia Appendix 1. Second, a series of ordinal and binary logistic regression analyses were conducted to examine the effects of PA (independent variable) on the probability of experiencing mental health issues (dependent variables), considering potential confounders (age, gender, education, marital status, smoking, and ethnicity) [32-35]. Dependent variables included psychological distress (categorical data), depression (binary data), anxiety (binary data), and pandemic anxiety (binary data).

The results of the logistic regression analyses were presented as odds ratios (ORs) and their 95% CIs [36]. Third, we used Wilcoxon signed-rank tests to explore changes in the locations of participants' PA between the pre-COVID-19 period and the COVID-19 period by different PA groups. Effect sizes were reported for the relevant statistics.

Participants were given the option of stopping the survey at any time or skipping a question if they did not feel comfortable answering it. Following the cleanup of missing and irregular data, there were a small number of participants lacking PA data (n=51, 13.4%) due to unanswered questions on the scale. For PA location data, missing data varied from 0.3% to 3.9%. The percentage of missing data for questions related to pandemic anxiety was 0.3%. Many sociodemographic variables (eg, gender, education, ethnicity, marital status) had missing data ranging from 0.3% to 1.6%. There was no difference in demographic distribution between individuals with missing data and those with full data. Missing data were preserved in the analysis sample and deleted pairwise. All analyses were accomplished with SPSS Statistics version 27.

Results

Sample Characteristics

Table 1 presents the sociodemographic and health characteristics of the sample. There were 287 (75.9%) females, 88 (23.3%) males, and 3 (0.8%) others. In addition, there were 156 (40.9%) participants in the 18-24-year age range, 164 (43.0%) in the 25-44-year age range, and 61 (16.0%) in the ≥45-year age range. Over half (n=249, 66.4%) of the participants were single or never married, and 207 (54.5%) of the individuals had a bachelor's degree or above. About half of the participants (n=213, 56.3%) resided either in big cities or small cities. Almost three-quarters (n=278, 73.0%) of the sample reported being employed before COVID-19, while 67 (17.6%) reported having lost their job since the pandemic. The sample was racially diverse, with 41 (10.9%) Asians, 55 (14.6%) Black/Africans, 112 (29.7%) Caucasians, 124 (32.9%) Hispanic/Latino, and 35 (9.3%) others. Most of the participants did not smoke (n=338, 88.9%).

As assessed by the PHQ-4 (mean 4.4, SD 3.6), 134 (35.2%) of the individuals had none-to-mild, 123 (32.3%) had mild, 64 (16.8%) had moderate, and 60 (15.7%) had severe symptoms of psychological distress. In addition, 133 (34.9%) of the participants were likely to suffer from depression, whereas 145 (38.1%) of the individuals had probable anxiety. Nearly a quarter of the sample stated that they were concerned about a pandemic (n=89, 23.4%). Finally, according to the IPAQ-SF, 122 (37.0%) of 330 participants were categorized as inactive, 96 (29.1%) as minimally active, and 112 (33.9%) as highly active.

Table 2 depicts that no gender differences were observed for the majority of the variables examined, although females reported greater psychological distress and anxiety and were also less likely to be physically active (all $P<.05$).

Table 1. Sample sociodemographic characteristics.

Sociodemographic characteristics	Participants, n (%)
Age (years; N=381)	
18-24	156 (40.9)
25-44	164 (43.0)
45-54	33 (8.7)
55-64	17 (4.5)
≥65	11 (2.9)
Relationship status (N=375)	
Single, never married	249 (66.4)
Married/domestic partnership	99 (26.4)
Other	27 (7.2)
Gender (N=378)	
Male	88 (23.3)
Female	287 (75.9)
Other	3 (0.8)
Ethnicity (N=377)	
Asian	41 (10.9)
Black/African	55 (14.6)
Caucasians	112 (29.7)
Hispanic/Latino	124 (32.9)
Other	35 (9.3)
Prefer not to say	10 (2.7)
Education (N=380)	
High school/some high school	37 (9.7)
Some college/associate degree	136 (35.8)
Bachelor's degree	114 (30.0)
Graduate/professional school	93 (24.5)
Employment/student status (pre-COVID-19; N=381)[a]	
Employed (full-time, part-time, self-employed)	278 (73.0)
Student (full-time, part-time)	158 (41.5)
Employment/student status (post-COVID-19; N=381)[a]	
Still employed/studying but with decreased hours	56 (14.7)
Still employed/studying but with increased hours	35 (9.2)
Still employed/studying, moved to remote or hybrid work	105 (27.6)
Lost job	67 (17.6)
No change	124 (32.5)
Household income change (post-COVID-19; N=377)	
My household income is more.	57 (15.1)
My household income is less.	152 (40.3)
My household income is about the same.	168 (44.6)
Living location (N=378)	
Large city	114 (30.2)

Sociodemographic characteristics	Participants, n (%)
Small city	99 (26.2)
Suburbs of a large city	59 (15.6)
Town or village	80 (21.2)
Rural area	12 (3.2)
Don’t know	14 (3.7)
Smoking (N=380)	
No	338 (88.9)
Yes	42 (11.1)
Psychological distress (N=381); mean (SD)=4.4 (3.58)	
None to mild	134 (35.2)
Mild	123 (32.3)
Moderate	64 (16.8)
Severe	60 (15.7)
Depression score≥3 (N=381); mean (SD)=2.09 (1.94)	
Yes	133 (34.9)
No	248 (65.1)
Anxiety score≥3 (N=381); mean (SD)=2.35 (1.96)	
Yes	145 (38.1)
No	236 (61.9)
Pandemic anxiety (N=380)	
Rarely or none of the time	291 (76.6)
Some or a little of the time	64 (16.8)
Occasionally or moderate amount of time	20 (5.3)
Most of all the time	5 (1.3)
PA[b] (N=330)	
Inactive	122 (37.0)
Minimally active	96 (29.1)
Highly active	112 (33.9)

[a]Participants may choose multiple responses that apply to their situations.
[b]PA: physical activity.

Table 2. Sample characteristics split by sex.

Characteristics	Female, n/N (%)	Male, n/N (%)	Gender differences	
			χ^2 (*df*)	*P* value[a]
Age (years)			2.05 (2)	.36
18-24	114/287 (39.7)	37/88 (42.0)	N/A[b]	N/A
25-44	122/287 (42.5)	41/88 (46.6)	N/A	N/A
≥45	51/287 (17.8)	10/88 (11.4)	N/A	N/A
Relationship status			1.87 (2)	.39
Single, never married	186/281 (66.2)	57/88 (64.8)	N/A	N/A
Married/domestic partnership	72/281 (25.6)	27/88 (30.7)	N/A	N/A
Others	23/281 (8.2)	4/88 (4.5)	N/A	N/A
Ethnicity			11.02 (5)	.05
Asian	28/284 (9.9)	12/88 (13.6)	N/A	N/A
Black/African	46/284 (16.2)	8/88 (9.1)	N/A	N/A
Caucasians	84/284 (29.6)	27/88 (30.7)	N/A	N/A
Hispanic/Latino	96/284 (33.8)	26/88 (29.5)	N/A	N/A
Others	26/284 (9.2)	9/88 (10.2)	N/A	N/A
Prefer not to say	4/284 (1.4)	6/88 (6.8)	N/A	N/A
Education			1.97 (3)	.58
High school/some high school	24/286 (8.4)	11/88 (12.5)	N/A	N/A
Some college/associate degree	99/286 (34.6)	33/88 (37.5)	N/A	N/A
Bachelor's degree	90/286 (31.5)	24/88 (27.3)	N/A	N/A
Graduate/professional school	73/286 (25.5)	20/88 (22.7)	N/A	N/A
Smoking			0.28 (1)	.60
No	256/286 (89.5)	77/88 (87.5)	N/A	N/A
Yes	30/286 (10.5)	11/88 (12.5)	N/A	N/A
Psychological distress: female mean (SD)=4.57 (3.65), male mean (SD)=3.761 (3.09), $t_{167.71}$=2.05, *P*=.04			7.12 (3)	.07
None to minimal	101/287 (35.2)	32/88 (36.4)	N/A	N/A
Mild	85/287 (29.6)	37/88 (42.0)	N/A	N/A
Moderate	54/287 (18.8)	10/88 (11.4)	N/A	N/A
Severe	47/287 (16.4)	9/88 (10.2)	N/A	N/A
Depression: female mean (SD)=2.105 (1.99), male mean (SD)=1.921 (1.69), $t_{167.81}$=0.86, *P*=.39			0.06 (1)	.81
Yes (score≥3)	97/287 (33.8)	31/88 (35.2)	N/A	N/A
No	190/287 (66.2)	57/88 (64.8)	N/A	N/A
Anxiety: female mean (SD)=2.46 (1.98), male mean (SD)=1.841 (1.69), $t_{167.43}$=2.91, *P*=.004			5.23 (1)	.02
Yes (score≥3)	117/287 (40.8)	24/88 (27.3)	N/A	N/A
No	170/287 (59.2)	64/88 (72.7)	N/A	N/A
Pandemic anxiety			0.64 (1)	.42
Less than 1 day	223/286 (78.0)	65/88 (73.9)	N/A	N/A
At least 1 day	63/286 (22.0)	23/88 (26.1)	N/A	N/A
PA[c]			27.10 (2)	<.001
Inactive	106/253 (41.9)	16/74 (21.6)	N/A	N/A
Minimally active	79/253 (31.2)	14/74 (18.9)	N/A	N/A

Characteristics	Female, n/N (%)	Male, n/N (%)	Gender differences	
			χ^2 (*df*)	*P* value[a]
Highly active	68/253 (26.9)	44/74 (59.5)	N/A	N/A

[a]The *P* values represent chi-square/*t* tests of independence, indicating associations between sex and categorical variables. Categories were created for age (18-24, 25-44, and ≥45 years).

[b]N/A: not applicable.

[c]PA: physical activity.

Logistic Regression Analyses

We used ordinal and binary logistic regressions to estimate the ORs (and 95% CIs) for the association of PA (independent variable; categorical) with various mental health outcomes, with the confounding factors of gender, age, race, educational level, marital status, and smoking considered (Tables 3-6). Psychological distress (categorical), depression (binary), anxiety (binary), and pandemic anxiety (binary) were dependent variables.

Table 3. ORs[a] for logistic regression analyses for physical levels and mental health outcome (psychological distress).

Characteristics	OR (95% CI)	*P* value
Gender (reference "male," n=74)	1.75 (1.01-3.02)	.05
Age (years; reference≥45, n=46)		
25-44	2.98 (1.37-6.49)	.006
18-24	3.60 (1.39-9.32)	.008
Ethnicity (reference "Caucasians," n=99)		
Black/Africans	1.38 (0.67-2.83)	.39
Asian	1.79 (0.85-3.77)	.13
Hispanic/Latino	0.89 (0.51-1.56)	.68
Others	1.18 (0.54-2.61)	.68
Prefer not to say	4.58 (0.96-21.79)	.06
Education (reference "graduate/professional school," n=77)		
Bachelor's degree	1.53 (0.83-2.84)	.18
Some college/associate degree	2.56 (1.28-5.14)	.008
High school/some high school	4.37 (1.71-11.19)	.002
Marriage status (reference "married/domestic partnership," n=84)		
Single/never married	2.49 (1.35-4.59)	.003
Others	1.99 (0.75-5.25)	.16
Smoking (reference "no smoking," n=280)	4.35 (2.26-8.38)	<.001
PA[b] levels (reference "highly active," n=111)		
Minimally active	1.52 (0.87-2.65)	.14
Inactive	2.17 (1.27-3.69)	.004

[a]OR: odds ratio.

[b]PA: physical activity.

Table 4. ORs[a] for logistic regression analyses for physical levels and mental health outcome (depression).

Characteristics	OR (95% CI)	*P* value
Gender (reference "male," n=74)	0.87 (0.44-1.71)	.69
Age (years; reference≥45, n=46)		
25-44	4.50 (1.36-14.92)	.01
18-24	5.23 (1.32-20.76)	.02
Ethnicity (reference "Caucasians," n=99)		
Black/Africans	0.93 (0.37-2.34)	.88
Asian	0.77 (0.30-1.95)	.58
Hispanic/Latino	0.46 (0.23-0.94)	.03
Others	0.64 (0.23-1.76)	.39
Prefer not to say	1.03 (0.15-7.24)	.98
Education (reference "graduate/professional school," n=77)		
Bachelor's degree	1.33 (0.59-3.02)	.50
Some college/associate degree	2.88 (1.19-6.99)	.02
High school/some high school	7.14 (2.19-23.25)	.001
Marriage status (reference "married/domestic partnership," n=84)		
Single/never married	1.67 (0.76-3.63)	.20
Others	1.57 (0.42-5.90)	.50
Smoking (reference "no smoking," n=280)	3.42 (1.56-7.51)	.002
PA[b] levels (reference "highly active," n=111)		
Minimally active	2.14 (1.05-4.33)	.04
Inactive	3.81 (1.92-7.57)	<.001

[a]OR: odds ratio.

[b]PA: physical activity.

Table 5. ORs[a] for logistic regression analyses for physical levels and mental health outcome (anxiety).

Characteristics	OR (95% CI)	*P* value
Gender (reference "male," n=74)	1.91 (0.98-3.70)	.06
Age (years; reference≥45, n=46)		
25-44	1.57 (0.60-4.12)	.36
18-24	1.85 (0.59-5.81)	.29
Ethnicity (reference "Caucasians," n=99)		
Black/Africans	1.57 (0.68-3.65)	.29
Asian	1.36 (0.56-3.30)	.50
Hispanic/Latino	0.80 (0.41-1.57)	.52
Others	0.99 (0.38-2.56)	.98
Prefer not to say	1.53 (0.24-9.73)	.65
Education (reference "graduate/professional school," n=77)		
Bachelor's degree	1.76 (0.82-3.77)	.15
Some college/associate degree	1.97 (0.84-4.66)	.12
High school/some high school	2.17 (0.71-6.62)	.18
Marriage status (reference "married/domestic partnership," n=84)		
Single/never married	3.08 (1.45-6.55)	.003
Others	1.25 (0.35-4.55)	.73
Smoking (reference "no smoking," n=280)	2.16 (1.02-4.56)	.04
PA[b] levels (reference "highly active," n=111)		
Minimally active	1.60 (0.83-3.08)	.16
Inactive	1.86 (0.99-3.47)	.05

[a]OR: odds ratio.

[b]PA: physical activity.

Table 6. ORs[a] for logistic regression analyses for physical levels and mental health outcome (pandemic anxiety).

Characteristics	OR (95% CI)	*P* value
Gender (reference "male," n=74)	0.77 (0.38-1.56)	.47
Age (years; reference≥45, n=46)		
25-44	4.23 (1.10-16.22)	.04
18-24	2.90 (0.61-13.69)	.18
Ethnicity (reference "Caucasians," n=99)		
Black/Africans	2.29 (0.84-6.20)	.10
Asian	1.11 (0.39-3.15)	.85
Hispanic/Latino	2.01 (0.92-4.35)	.08
Others	0.84 (0.24-2.90)	.78
Prefer not to say	2.78 (0.41-18.99)	.30
Education (reference "graduate/professional school," n=77)		
Bachelor's degree	0.98 (0.41-2.38)	.97
Some college/associate degree	1.39 (0.54-3.58)	.49
High school/some high school	1.72 (0.51-5.79)	.38
Marriage status (reference "married/domestic partnership," n=84)		
Single/never married	0.74 (0.33-1.64)	.45
Others	0	.99
Smoking (reference "no smoking," n=280)	1.84 (0.84-4.03)	.13
PA[b] levels (reference "highly active," n=111)		
Minimally active	1.41 (0.65-3.06)	.39
Inactive	1.72 (0.84-3.54)	.14

[a]OR: odds ratio.

[b]PA: physical activity.

Psychological Distress

According to ordinal logistic regression, inactive people were 2.17 times more likely than highly active people to have higher levels of psychological distress (OR 2.17, 95% CI 1.27-3.69, *P*=.004).

Regarding confounding factors, individuals aged 18-24 years (OR 3.60, 95% CI 1.39-9.32, *P*=.008) and 25-44 years (OR 2.98, 95% CI 1.37-6.49, *P*=.006) were more likely to experience psychological distress than those aged ≥45 years. Females were 1.75 times more likely to experience greater psychological distress than males (OR 1.75, 95% CI 1.01-3.02, *P*=.05). Those who had just finished high school or some high school (OR 4.37, 95% CI 1.71-11.19, *P*=.002) and some college or associate degree (OR 2.56, 95% CI 1.28-5.14, *P*=.008) were more likely to experience psychological distress than those who had completed a graduate or professional school program. Single individuals had a higher risk of distress (OR 2.49, 95% CI 1.35-4.59, *P*=.003) than married people or those in a domestic partnership. Participants who smoked had increased odds of psychological distress (OR 4.35, 95% CI 2.257-8.381, *P*<.001).

Depression

Logistic regression results revealed a significant relationship between PA levels and depression (*P*<.001). Minimally active individuals were 2.14 times more likely to suffer from depression than highly active people (OR 2.14, 95% CI 1.05-4.33, *P*=.04). The odds of having depression were 3.81 times greater among inactive individuals than among highly active individuals (OR 3.81, 95% CI 1.92-7.57, *P*<.001).

Furthermore, individuals aged 18-24 years (OR 5.23, 95% CI 1.32-20.76, *P*=.02) and 25-44 years (OR 4.5, 95% CI 1.36-14.92, *P*=.01) had higher odds of depression than those aged ≥45 years. Completing just high school or some high school (OR 7.14, 95% CI 2.19-23.25, *P*=.001) and some college/associate degree (OR 2.88, 95% CI 1.19-6.99, *P*=.02) was connected to greater odds of having depression. Individuals who smoked were 3.422 times more likely to suffer from depression than those who did not (OR 3.422, 95% CI 1.56-7.51, *P*=.002).

Anxiety

We found no significant relationship between PA levels and anxiety disorder in binary logistic regression, though the odds of anxiety were marginally higher among inactive participants than among highly active participants (OR 1.86, 95% CI 0.99-3.47, *P*=.05).

Gender marginally predicted the odds of anxiety (*P*=.06), where females had 1.91 more chances of having anxiety than males (OR 1.91. 95% CI 0.984-3.702). Single individuals had greater odds of having anxiety than married people or those in a domestic partnership (OR 3.08, 95% CI 1.45-6.55, *P*=.003). Smoking increased the odds of anxiety 2.16-fold (OR 2.16, 95% CI 1.023-4.555, *P*=.04).

Pandemic Anxiety

We found no significant connection between PA levels and pandemic anxiety in logistic regression analysis or between major demographic factors and pandemic anxiety; however, those aged 25-44 years (OR 4.23, 95% CI 1.10-16.22, *P*=.04) were more likely to suffer from pandemic anxiety than those aged ≥45 years.

Changes in Locations of PA Following COVID-19

Wilcoxon signed-rank tests were conducted to examine the changes in the frequency of usage of various PA-performing locations before and during the COVID-19 outbreak and how they might vary for inactive, minimally active, and highly active people (Table 7). Inactive individuals during COVID-19 were less likely to engage in physical exercise at parks/trails (Z=–4.01, *P*<.001), botanical gardens (Z=–2.02, *P*=.04), recreational sports or intramural facilities (Z=–3.04, *P*=.002), neighborhood sidewalks and parks (Z=–3.78, *P*<.001), and fitness facilities (Z=–4.35, *P*<.001); during commuting to work (Z=–4.696, *P*<.001); and at their workplace (Z=–3.19, *P.*<001). The results for the minimally active individuals were largely the same as those for the inactive individuals such that the probability of performing PA at parks/trails (Z=–1.90, *P*=.06), botanical gardens (Z=–2.52, *P*=.01), recreational sports and intramural facilities (Z=–2.52, *P*=.01), and fitness facilities (Z=–4.29, *P*<.001) and during transport to the workplace (Z=–3.53, *P*<.001) were ranked less frequently during COVID-19. However, minimally active individuals spent a comparable amount of time performing PA in their neighborhood (*P*=.91) and at work (*P*=.52). For highly active people, although the frequency of performing PA in botanical gardens (Z=–2.545, *P*=.01) and fitness centers (Z=–4.71, *P*<.001), during transit to work (Z=–3.82, *P*<.001), and at the workplace (Z=–2.33, *P*=.02) decreased, the frequency of performing PA in parks/trails (*P*=.17), recreational sports/intramural facilities (*P*=.16), and neighborhoods (*P*=.45) did not change significantly. Furthermore, only highly active individuals increased their PA at home (eg, workouts, housekeeping, yard work, gardening, exercise, video games) during the pandemic (Z=2.93, *P*=.003). Finally, the likelihood of engaging in PA outdoors with animals did not change, and this was the same for all 3 PA groups (all *P*>.30).

Table 7. Wilcoxon signed-rank tests: comparing locations[a] of PA[b] before and during COVID-19 (split by 3 PA groups).

Ranks	Parks/trails	Botanical gardens	Recreational sports/intramural facilities	Neighborhoods	Home-based activity	Fitness facilities	Time outdoors with animals	Transportation to workplace	Workplace
Inactive									
Negative ranks[c]	40	15	17	40	29	30	12	39	19
Positive ranks[d]	13	4	4	15	22	5	13	7	5
Ties[e]	64	96	93	61	65	82	92	69	91
Z value[f]	–4.01	–2.02	–3.04	–3.78	–1.59	–4.35	0.18	–4.70	–3.19
P value[f]	<.001	.04	.002	<.001	.12	<.001	.86	<.001	.001
Minimally active									
Negative ranks	28	21	24	20	21	34	17	26	14
Positive ranks	15	6	8	16	19	5	11	7	9
Ties	52	66	63	59	54	56	67	61	72
Z value	–1.90	–2.52	–2.52	–0.11	–0.10	–4.29	–1.00	–3.53	–0.65
P value	.06	.01	.01	.91	.92	<.001	.32	<.001	.52
Highly active									
Negative ranks	18	25	25	15	15	44	11	34	18
Positive ranks	34	7	15	18	31	9	14	7	7
Ties	59	77	68	77	65	57	86	68	83
Z value	1.37	–2.55	–1.39	0.76	2.93	–4.71	0.32	–3.82	–2.33
P value	.17	.01	.16	.45	.003	<.001	.75	<.001	.02

[a]Frequency scores of PA locations were rated as 0=never, 1=rarely, 2=sometimes, and 3=frequently.

[b]PA: physical activity.

[c]Negative ranks: during COVID-19 < before COVID-19.

[d]Positive ranks: during COVID-19 > before COVID-19.

[e]Ties: post-COVID-19 score=pre-COVID-19 score.

[f]Z and *P* values represent Wilcoxon signed-rank tests indicating differences.

Discussion

Principal Findings

In this study, we examined the impact of pandemic restrictions on physical exercise and its connections to mental health in a community sample of adults. Our results showed that those who engaged in greater PA during the COVID-19 pandemic had less psychological distress, depression, and anxiety than those who engaged in less PA. Furthermore, COVID-19 was found to make it hard for people to keep up with their PA habits, especially for people who were less active in using outdoor and public PA facilities.

According to the data, approximately 133 (34.9%) and 145 (38.1%) of the sample scored above the cut-offs for depression and anxiety, respectively; about two-thirds of individuals reported mild-to-severe psychological distress. The logistic regression illustrated that not engaging in PA during COVID-19 was related to about 1.86-3.81 times' higher risks of psychological discomfort, depression, and anxiety disorders. The highest degree of PA (exceeding the minimum public health PA recommendations and accumulating enough activity for a healthy lifestyle) but not moderate PA (fulfilling minimal PA recommendation) appeared to be associated with lower psychological risk during a pandemic [9]. These results were essentially consistent with the majority of prior studies on the relationship between PA and COVID-19, showing that PA would protect people's mental health in general and lessen their risk of depression and anxiety [5,6,9,17,18,37]. The outcomes of this study might help people live healthy, resilient lives both during and after the worldwide pandemic.

When examining the different types of mental health problems, there was some evidence from logic regression analyses that PA might affect depression more than anxiety. Participants who were inactive had marginally higher odds of anxiety than those who were highly active, while those who were inactive or minimally active had higher odds of depression than those who were highly active. One explanation might be a stark temporal differentiation between the natures of depression and anxiety. For example, participants reported depression-triggering events taking place in their past, relating to loss and failures in

achieving goals, whereas anxiety-triggering events were related to fears about the future [38]. In the unique case of the COVID-19 pandemic, 1 of the most salient factors individuals were challenged with was the inherent inability to predict how long restrictions and legitimate health risks would prevail, putting enormous doubt on life in the future. Although an inability to control current circumstances might be combatted by decreasing cortisol levels and achieving personal fitness goals through PA, positively affecting depression levels, remedies for anxiety about the prevalence of the pandemic and an inability to project what is to come cannot be manufactured. Our findings were consistent with a recent study performed during COVID-19 on a Chinese sample between February and March 2020, which found that the link between PA and depression was more robust than the association between PA and anxiety [39]. Research conducted in a sample of older adults over the age of 50 years who lived in North America in April 2020 found that PA was not a significant predictor of anxiety symptoms after controlling for age, sex, and education, while PA was a significant predictor for depressive symptoms [7]. A meta-analysis of the relationship between PA and depression and anxiety in nonclinical adult populations found that PA decreased depression with a medium effect size and anxiety with a small effect size [40], independent of the pandemic. A quick systematic review conducted during the pandemic found a similar result: the relationship between PA and depression was more consistent than the relationship between PA and anxiety [5]. Further analysis is needed to find the other additional factors that are linked to anxiety in the global pandemic.

Our results revealed that the amount of time people spent on PA at various locations varied before and after the start of COVID-19. In general, reduced PA seemed to be linked to a lack of sporting opportunities. COVID-19 had a greater impact on reducing the use of PA resources (such as parks/trails, recreational sports, neighborhoods) by people who were classified as less active or minimally active. Highly active individuals might have been affected less and have adapted to doing their PA in the comfort of their homes. Individuals who participated vigorously in regular physical exercise might have acquired PA-related health literacy, which enabled them to use it as a typical coping technique for negative emotions, resulting in the fast adoption of new sports routines. Health care providers and the government may urge inactive individuals to include PAs in their everyday lives to reduce the rise in mental health issues during the current pandemic. Given the uncertainties surrounding the return to normalcy, encouraging at-home activities seems to be a viable solution. Virtual reality (VR) technologies (eg, Oculus Quest) and other home-based commercial video games (eg, Nintendo Switch) have been shown to improve PA in settings that are more pleasant and entertaining, which is especially appropriate when movement in the outdoor world is restricted [41-43].

Demographic factors associated with mental health risks included age, gender, smoking, education, and marital status, although their effects might vary depending on the kind of mental health problems studied. Females were more prone to stress, anxiety, and depression than males according to previous research [44,45]. We found that females had higher psychological distress and anxiety odds than males during the pandemic. Previous research revealed that younger people were more likely to have worse mental health than older people, and risk factors, such as loneliness and financial hardship, were more likely to impact younger people than others during the COVID-19 pandemic [45-47]. Our study found that those over 45 years had the lowest psychological distress and depression ratings. Smoking is frequently associated with poor mental health, regardless of the pandemic [48]. According to our results, individuals who smoked had higher levels of psychological distress and higher levels of depression and anxiety. In contrast to marriage, being single or divorced has been associated with poorer mental health [49]. Our study reported that those in marriage or domestic relationships experienced lower stress and anxiety during the pandemic. Our findings also revealed that higher levels of education were critical determinants related to greater positive well-being [50]. Furthermore, our supplementary analysis results indicated gender, racial, and age differences in PA, consistent with previous research [51]. To sum up, many of these health-related demographic variables had been identified in previous research prior to the pandemic. These findings suggest that sociodemographic risk factors would be linked to the risk of physical and mental health during the pandemic.

We have achieved considerable progress in studying the effects of physical exercise on psychological health during the pandemic. Wolf et al [5] noted methodological issues, such as using unvalidated measures and the inability to offer standardized coefficients, in their most recent review paper published in 2021 evaluating publications on associations between PA and depression and anxiety during COVID-19. Wolf et al [5] also stated that studies included in their review used heterogeneous statistical approaches (eg, multiple linear regression, logistic regression) and study designs (eg, cross-sectional, longitudinal design), which would have yielded a more sophisticated overall effect estimate of the relationships between PA and depression and anxiety. Based on our effect size measures, our study found similar effects of physical exercises on reducing mental health problems as prior studies conducted in a comparable context [9,52]. Furthermore, our study included data from later in the pandemic, enabling future researchers to get a more complete picture of the effect of PA on pandemic mental health.

Limitations

The study's limitations included the use of a cross-sectional research methodology. As a result, the causal nature of these relationships was unknown. PA was not linked to the pandemic anxiety and could have been attributed to lower COVID-19-related physical anxiety symptoms in individuals. Of 380 participants, 291 (76.6%) reported that they had few or non-pandemic-related concerns. Participants might have been expected to be increasingly adapted and prepared as the pandemic progresses. Furthermore, although we followed the previous study of measuring pandemic-related anxiety [27], a single question measuring anxiety related to the pandemic in the past week may not possibly sum up all the characteristics of pandemic-related stress, and additional research is necessary. Another limitation worth mentioning was the sampling method

[53]. The study used a convenience sample approach by recruiting university community members. Such samples could attract volunteers who were already engaged and interested in the issue and had internet access. Previous research suggested that people who were currently suffering from or had a serious mental illness might be less likely to participate online than those who were not [53-55]. The study also included a larger female sample, although a more balanced sample was anticipated. As we have seen, the sampling method is an important issue in research, and we will continue with caution when extrapolating our findings to a different population setting.

Because of the COVID-19-related restrictions on human subject research during the pandemic, we were unable to examine the mechanisms through which physical exercise could help people's mental health via collecting neurobiological data in the study. This warrants further investigation by other researchers. The biological pathway through which PA affects mental health is likely via the hypothalamic-pituitary-adrenal (HPA) axis regulation [56,57]. Physical fitness and physical exercise, for example, were shown to be associated with reduced cortisol release when subjects were subjected to psychosocial stressors [58]. Additionally, recent research indicated that exercise's positive benefits on the brain were associated with possible underlying biological processes, including the gut-brain, muscle-brain, and liver-brain axes [59]. Future studies may also explore the effect of COVID-19 on PA in countries with more substantial or fewer restrictions to see whether there are differences. Research in the future may focus on establishing and evaluating interventions that help people maintain regular exercise as part of their daily lives throughout and after the pandemic.

Conclusion

In summary, the results from this study showed that people who did more PA during the COVID-19 pandemic had less psychological distress, depression, and anxiety than people who engaged in less PA. Additionally, it was found that COVID-19 interrupted people's opportunities, particularly those less active in using outdoor and public PA facilities to keep PA habits. Without a doubt, the pandemic's influence, particularly the long-term effects, cannot be predicted at the moment. Promoting and encouraging PA behavior is a cost-effective way of creating a necessary distinction between those who have a basic mental health need and those who are mentally well. This strategy is particularly beneficial in communities with inadequate health resources [60].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary analysis.
[DOCX File , 10084 KB - formative_v6i4e32387_app1.docx]

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Abbreviations

GAD-2: 2-item Generalized Anxiety Disorder
IPAQ-SF: International Physical Activity Questionnaire - Short Form
OR: odds ratio
PA: physical activity
PHQ-4: 4-item Patient Health Questionnaire

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Original Paper

The Impact of COVID-19 on the Delivery of Educational Programs in Native American Communities: Qualitative Study

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Abstract

Background: Despite the availability of culturally responsive sexual health educational programs for American Indian and Alaska Native (AI/AN) youth, barriers to their uptake and utilization persist in tribal communities. These challenges were exacerbated by the COVID-19 pandemic, which required flexible program delivery using both in-person and virtual classrooms.

Objective: This exploratory study provides a preliminary understanding of the extent to which pre-existing challenges impact the delivery of culturally responsive sexual health education programs in Native communities and to what extent they were exacerbated by the COVID-19 pandemic. It also highlights the challenges faced by adolescent health advocates when adapting culturally responsive health curricula to online platforms. Finally, this study discloses major socioeconomic, health, and mental challenges experienced by AI/AN youth during the pandemic.

Methods: An exploratory, descriptive, qualitative design approach was adopted to carry out 5 individual and 1 collective in-depth key informant interviews. A total of 8 Native and non-Native sexual health educators served as key informants and shared their personal experiences with the delivery of sexual health education programs for youth during the COVID-19 pandemic. The interviews were conducted virtually from October to November 2020 using Zoom to reach participants dispersed across different regions of the United States. We followed the consolidated criteria for reporting qualitative research (COREQ) as a reference for the study methodology. We also used the Braun and Clarke framework (2006) to conduct a thematic analysis.

Results: Experts' opinions were structured according to 5 main themes: (1) competing community priorities during COVID-19; (2) moving to web-based programming: skills, training, support; (3) recruiting youth; and (4) challenges for implementation in a household environment; and (5) recommendations to overcome implementation challenges. These themes are complementary, connected, and should be considered holistically for the development, dissemination, and implementation of online sexual health programs for AI/AN youth, specifically during the COVID-19 pandemic. The results raised the following points for discussion: (1) Building partnerships with schools and community organizations facilitates program adaptation and implementation, (2) there is a need to adopt a holistic approach when addressing youth sexual health in AI/AN communities, (3) a systematic and culturally responsive adaptation approach ensures effective virtual program delivery, and (4) community and youth engagement is essential for the success of virtual sexual health programs.

Conclusions: Findings can provide recommendations on actions to be taken by sexual health educators and guidelines to follow to ensure cultural sensitivity, effective adaptation, and successful implementation when setting out to advocate for online sexual health programs for AI/AN youth.

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KEYWORDS

online sexual health programs; COVID-19; COVID-19 pandemic; AI/AN youth; sexual health educators; culturally responsive adaptation; program implementation; sexual health; implementation; Native communities; American Indian youth; Alaskan youth; education; tribal communities; online; virtual

Introduction

In the United States, racial and ethnic disparities in teen births and sexually transmitted infections (STIs) persist [1]. American Indian and Alaska Native (AI/AN) females aged 15-19 years have the highest teen birth rate [1,2] and the highest prevalence of repeat teen births [3,4] compared to other racial/ethnic groups. AI/AN youth are also disproportionately affected by STIs, including HIV, gonorrhea, and chlamydia [5-7].

To address these disparities, culturally responsive programs have been receiving significant attention as a means to help public health specialists deliver culturally sensitive, evidence-based preventive practices to diverse racial/ethnic populations [8-10]. Culturally responsive programs are defined as the degree to which the cultural values, norms, beliefs, and practices of the target population are integrated into the design, delivery, and evaluation of an intervention [11]. This principle is supported, in part, by research assessing the impact of certain cultural values on several psychosocial outcomes [12]. For instance, researchers have highlighted that parental involvement in a culturally responsive, technology-based intervention to improve parent-child communication on sexual health can moderate and protect AI/AN youth from engaging in early sexual debut [13-17]. The familial system in Native culture has been consistently reported to be a protective factor for major risky behaviors among AI/AN youth [18]. Hence, efforts to address sexual health disparities among AI/AN youth through evidence-informed and culturally responsive programs are essential to improve the overall health outcomes of this underrepresented population [19,20].

Despite the availability of culturally responsive sexual health educational programs on websites, such as that of Healthy Native Youth [19], barriers remain to their uptake and utilization in tribal communities [13,21-30]. Many of these challenges were exacerbated by the COVID-19 pandemic, which required flexible delivery using both in-person and virtual classrooms [31]. Since the start of the pandemic, access to sexual and reproductive health care services for AI/AN youth has become limited in scope [22]. Native youth have also experienced challenges trying to access confidential and private sexual health information when switching to the telehealth platform, along with their inability to participate in in-person school-based sexual health education programs or attend in-person appointments in health clinics [32-36]. Maintaining youth's access to appropriate and culturally tailored sexual health education programs to increase awareness of sexual health promotion and contraceptive use is essential to prevent a peak in unintended pregnancies and STIs among this vulnerable population group [37,38].

Across the United States, many health educators relied on schools as the primary channel to deliver sexual health education to youth prior to the pandemic [39-41]. Others relied on technology-based platforms as feasible mechanisms to disseminate culturally adapted sexual health content for AI/AN youth [13,20]; enhance community expertise and resources to adopt, implement, and maintain evidence-based programs; and improve the likelihood of attaining positive sexual and reproductive health outcomes [15,21,22,24-27]. However, COVID-19 restrictions significantly affected the continuity of school-based in-person programs, since health educators were faced with the challenge of tailoring health lessons to the online platform in a short period, while ensuring the cultural sensitivity of the shared material [31]. Participation in ongoing in-person programs and recruitment for new virtual programs both were impacted by school shutdowns, particularly when trying to reach youth with limited internet connectivity or unsupportive parents in conservative areas [42].

Additionally, barriers to disseminating virtual programs in tribal communities, similar to those identified for in-person programs, continue to exist for several reasons. First, the lack of community readiness and the limited availability of resources to address sensitive topics, such as adolescent sexual health, hinders the delivery of sexual health education programs in AI/AN communities [20]. Second, inconsistencies in tribal policies, protocols, and schoolboard approval processes may generate delays in program adoption and implementation [28]. Third, poverty may result in high personnel turnover or temporary closures for AI/AN youth–serving agencies, which might negatively influence implementation fidelity and program maintenance [15]. Fourth, limited access to remote villages and rural AI/AN reservations creates a recruitment challenge for adequate program implementation [15]. Finally, competing priorities in AI/AN communities, such as food insecurity and the need to focus on other academic skills (ie, math, reading, writing) for limited virtual teaching time, might lead to a lack of support from key stakeholders. This in turn results in limited knowledge of evidence-based sexual health programs and low self-efficacy to adapt and implement them [29,30].

This exploratory study shares lessons learned by educators involved in the implementation of online sexual health programs for AI/AN youth during the pandemic. It also provides an understanding of the extent to which pre-existing challenges in the delivery of culturally responsive sexual health education programs in Native communities were exacerbated by the COVID-19 pandemic. Challenges faced by tribal health experts while adapting culturally responsive health programs to the online delivery platform are also highlighted. Finally, this study describes major socioeconomic, health, and mental challenges experienced by AI/AN youth during the pandemic. Emerging themes may assist sexual health educators in the development

of key strategies for effective dissemination and implementation of virtual sexual health education programs to mitigate the impact of the COVID-19 barriers and the effects of existing underlying challenges throughout program delivery. Such guidance is of utter importance to tribal health experts who are struggling to manage new and pre-existing COVID-19 challenges influencing the successful delivery of culturally sensitive sexual health programs.

Methods

Study Design and Setting

An exploratory, descriptive, qualitative design approach was adopted to carry out 5 individual and 1 collective in-depth key informant interviews. A total of 8 Native and non-Native health educators served as key informants and shared their personal experiences with the delivery of sexual health education programs for youth during the COVID-19 pandemic. They also shared their diverse perspectives on the utility of using online sexual health education platforms and programs to increase reach and accessibility to youth during uncertain times. Some of the key informants were newly adapting their sexual health program to an online platform, while others were already acquainted with online delivery and had been implementing such programs for an extensive period. The interviews were conducted virtually from October to November 2020 using Zoom (Health Insurance Portability and Accountability Act of 1996 [HIPAA]-compliant Zoom session) to reach participants dispersed across different regions of the United States (Northwest, Southwest, and mid-Atlantic Pacific). We followed the consolidated criteria for reporting qualitative research (COREQ) as a reference for the study methodology (Multimedia Appendix 1).

Ethical Considerations

The study was approved by the Committee for the Protection of Human Subjects at the University of Texas Health Science Center Houston (HSC-SPH-11-0577). The lead author obtained oral recorded informed consent from the participants prior to the start of the interview. Since the interview covered topics solely related to their professional experience, a waiver of written consent was granted, and each participant was provided, instead, with a letter of information (Multimedia Appendix 2), which described the goals and topics of the study, along with an emphasis on the voluntary nature of participation.

Research Team

The research team comprised experts in the design and implementation of sexual health education programs for Native youth (authors CM, BH, RS, and MP) and a doctoral public health student (author LS), who served as the principal investigator of the study. LS was well trained on how to conduct qualitative research and how to effectively moderate the key informant interviews in an ethical manner.

Participant Recruitment

In total, 15 health experts working with AI/AN youth in the United States were identified from existing publications in which they were named as authors, as well as evidence-based sexual health programs in which they were credited as principal investigators or significant collaborators. These experts had different functions in diverse fields of expertise, including adolescent sexual health, mental health, and suicide prevention. Experts were eligible to participate in the study if they (1) had experience in the adoption, implementation, and maintenance of sexual health education programs (at least 1) for AI/AN youth; (2) served tribal regions within the United States; (3) had personally experienced the impact of COVID-19 on the accessibility of sexual and reproductive health services by AI/AN youth and on the delivery of adolescent sexual health education programs; and (4) identified as Native or non-Native. Experts were invited to participate in the study by email. An attached letter of information was included in the invitation to provide additional insight into the goals and objectives of the study. Of the 15 identified experts, 8 (53%) agreed to participate. The characteristics of the participant experts are presented in Table 1. No monetary incentives were provided for participation.

Table 1. Expert characteristics (N=8).

Characteristics	Participants, n (%)
Gender	
Female	8 (100.0)
Male	0
Organization type[a]	
Government agency	2 (25.0)
Nonprofit organization	5 (62.5)
Academic institution	2 (25.0)
Occupation/role	
Consultant	2 (25.0)
Project management	4 (50.0)
Project staff	1 (12.5)
Faculty	2 (25.0)
Program analyst	1 (12.5)
Evaluation coach	1 (12.5)
Content creator	1 (12.5)
Specialization[a]	
Sexual health	8 (100.0)
Mental health	4 (50.0)
Suicide prevention	2 (25.0)
Youth empowerment (voting program)	1 (12.5)
Region	
Northwest	4 (50.0)
Southwest	2 (25.0)
Mid-Atlantic	2 (25.0)

[a]Some experts work in different organizations and have multiple specializations, in addition to adolescent sexual health.

Data Collection and Data Management

The lead author (LS) conducted the semistructured interviews via Zoom at a day/time based on the interviewees' preferences [43]. Each interview ranged from 35 to 65 minutes. Interviews were audio-recorded and transcribed verbatim using Otter.ai software [44] after receiving the interviewees' permission. The interview guide included open-ended questions based on 3 constructs (adoption/adaptation, implementation, and maintenance) within the broader dissemination and implementation field [43,45]. Questions prompted the interviewees on sharing challenges faced in the adoption, implementation, and maintenance of sexual health education programs for Native youth during the COVID-19 pandemic, as well as actions taken to address these challenges to implement sexual health education programs (Multimedia Appendix 2) more effectively.

The interview guide was divided into 3 main sections (Introduction, Impact of COVID-19 on the Delivery of Sexual Health Education Programs, and Use of Online Sexual Health Platforms in Response to COVID-19), with open-ended questions regarding their experience addressing COVID-19-related challenges and adapting to online delivery and recommendations for developing and implementing online sexual health programs for AI/AN youth. Most of the interviews were with individuals; however, 1 small group interview was held with 3 experts who worked together.

To protect participant confidentiality, all records were stored in locked cabinets and password-protected computer systems for use by the research team only. All (n=8, 100%) participants' records were given a unique study ID number for data management purposes. No names were included in the data analysis files or in reports.

Data Analysis

We used the Braun and Clarke framework [46] to conduct a thematic analysis. This framework comprises 6 phases: (1) familiarizing yourself with your data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. In the first phase, the lead author (LS) thoroughly read each transcript to get acquainted with the collected information. In

the second phase, detailed descriptive coding was conducted using the comments section in Microsoft Word. In the third phase, an initial list of all codes and subthemes was generated by the lead author. In phase 4, a codebook of all potential themes and subthemes was created, including a list of definitions and quotes to support identified themes and subthemes (Multimedia Appendix 3). In phase 5, a list of candidate themes and subthemes was refined and condensed to highlight important recognizable issues and relationships between themes. In phase 6, the findings were presented in narrative form with quotes from key informants to support the identified themes and subthemes. A synthesis of the results was prepared to guide sexual health experts in the development of online sexual health programs for Native communities, while considering unprecedented challenges that might be encountered in the process.

Data analysis was conducted in a precise, consistent, and exhaustive manner by ensuring the credibility, transferability, dependability, and confirmability of our analysis, as well as the use of audit trails [47]. To check for credibility, peer debriefing was adopted to provide an external check on the research process, as well as referential adequacy, which allows for the checking of preliminary findings and interpretations of raw data [48]. Transferability was established by involving sexual health experts from diverse tribal regions to ensure generalizability of results [49]. Dependability was achieved by ensuring clear documentation and traceability of results [49]. All 3 criteria led to confirmability, along with a clear explanation of the analytical framework used in the study. Finally, keeping records of the raw data, field notes, and transcript for clear reporting of the data all contributed to an audit trail (ES Halpren, *Auditing Naturalistic Inquiries: The Development and Application of a Model*, unpublished doctoral dissertation, 1983).

Results

Main Themes and Subthemes

Experts' opinions were structured according to 5 main themes: (1) competing community priorities during COVID-19; (2) moving to web-based programming: skills, training, support; (3) recruiting youth; (4) challenges for implementation in a household environment; and (5) recommendations to overcome implementation challenges. These themes are complementary, connected, and should be considered holistically for the development, dissemination, and implementation of online sexual health programs for AI/AN youth, specifically during the COVID-19 pandemic. The themes and subthemes are presented in Textbox 1 (also see Multimedia Appendix 3 for representative quotes).

Textbox 1. Key themes and subthemes identified in the interviews.

Theme 1: Competing community priorities during COVID-19

- Food security and water sanitation measures
- Financial hardship
- Mental health impact
- Focusing on COVID-19 response in clinics and centers
- Sexual health as a secondary concern

Theme 2: Moving to web-based programming: skills, training, support

- Adaptation of programs to the online platform
- Lack of sufficient time and staff support in the stressful adaptation process
- Youth missing a 1-on-1 connection

Theme 3: Recruiting youth

- Using social media platforms for youth outreach
- Differences in the online program youth participation rate
- Distribution of flyers in community locations

Theme 4: Challenges for implementation in a household environment

- Challenge of youth program participation from a home environment
- Low bandwidth and network connectivity issues
- Dealing with youth internet access

Theme 5: Recommendations to overcome implementation challenges

- Building partnerships with schools and community organizations for program adaptation and implementation
- Adopting a holistic approach when addressing sexual health in American Indian and Alaska Native (AI/AN) communities
- Adopting a systematic and culturally responsive approach for effective virtual program delivery
- Community and youth engagement for the success of virtual sexual health programs

Competing Community Priorities During COVID-19

Food Security and Water Sanitation Measures

The impact of COVID-19 on food security and water sanitation in AI/AN communities led sexual health experts to shift their roles toward food relief and building water sanitation stations. An expert highlighted the hidden food insecurity crisis in AI/AN households that is rarely mentioned in the news (Int1, where "Int" refers to "interview"). Another participant shared that there is a struggle in some households to find baby formula, which encourages AI/AN mothers to breastfeed their infants (Int2-P3, where "P" refers to "participant"). Hand-washing stations provided running water to take care of the necessary hygienic procedures during COVID-19 (Int4).

> *I mean, the food insecurity, I feel like we never hear about that on the news. But, um, the food insecurity is a major, major issue, like meeting the basic needs of households has been a primary thing that I've been hearing from…from Native communities and…and others, you know, that they're…they're either doing contact tracing, or they're doing food relief.* [Int1]

> *And we've also been building hand-washing stations. So, like I was saying earlier, people don't have running water. And you can ask people to wash their hands; if they don't have running water, they need to save that water to drink and to clean themselves and to, you know, cook their food. So, we've been creating hand-washing stations that we've also been delivering to our various partners.* [Int4]

Financial Hardship

Of the 8 experts, 4 (50%) highlighted the financial hardship AI/AN families are struggling with as a result of the COVID-19 pandemic (Int1, Int4-Int6); 1 (25%) of them expressed the financial burden caused by COVID-19 on AI/AN parents and youth because youth had to exchange the opportunity to participate in a sexual health program with the need to find a job to support their families (Int1). A participant also reflected on the long-standing economic inequities that became more apparent during the pandemic (Int4).

> *They have to deal with food insecurity and, like, unemployment, so the kids have to help their parents; that is a national dilemma, right, you know…everybody sort of, kind of everything sort of*

> *falling away. But the basics, you know…and you know, it's an unfortunate thing about this pandemic, is it's really just shedding a light on long-standing inequities and deep-seated inequities between groups in this country. And you know, it's really just shining light on that. And hopefully, some good will come of it.* [Int4]

Mental Health Impact

Many participants expressed concerns regarding youth's mental health during the pandemic. Based on her experience, 1 (12.5%) expert described the detrimental mental health impact of COVID-19 on youth due to the stress, anxiety, and worries associated with the unknown duration of the pandemic and the severity of the disease (Int2-P2). The lack of stability and the loss of elder lives were devastating at a community level (Int3, Int4). An additional concern was having youth feeling "zoom fatigue" as they also complete their schoolwork online (Int3). An expert emphasized the need to support youth since even though they seem to be handling the pandemic well, a spike in mental health conditions is emerging among this population (Int5). Another warned about the trends in youth mental health impacts over the next decade (Int6).

> *And I think, we're at real risk of, like, a widespread mental health crisis for young people, for teens, particularly. So, we cannot…we cannot not address that, like young people's lives are at stake when it when it comes to a time like this. So that would be like mental health piece is 1 of…my number 1 thing to do would be to build competence in how to do this and be really, really thoughtful about how you plan and prepare and deliver your programming.* [Int1]

> *And we've all kind of heard this; like zoom fatigue is such a thing where you're just on video calls all day, and you're exhausted. So, we didn't want this to be 1 more thing that a kid has to do that it's something that they want to do.* [Int3]

Focusing on COVID-19 Responses in Clinics and Centers

A common subtheme across all interviews was the shift in clinic focus away from providing core public health services toward COVID-19-related relief efforts. A participant explained how their Tribal Epidemiology Center pivoted to deal with the COVID-19-related testing and contact tracing, whereby all project-related staff were helping manage the COVID-19 surge in AI/AN communities rather than focusing on youth sexual health programs (Int3). Hesitancy to seek sexual health care during the COVID-19 pandemic was pointed out by an expert in the Northwest, as people did not want to increase their risk of exposure in small clinic spaces for regular checkups (Int2-P3). An expert shared about the switch to telehealth platforms to increase youth access to sexual health programs; however, accessibility differed across tribes (Int6).

> *And through our partnerships with [the Indian Health Service] (IHS), we've also been asked to help them with other COVID-related efforts. So, some of that, but all that work is new, and not necessarily what our team was doing prior to COVID. And it's constantly changing, and in flux…that both of the communities that we work with the most closely, there have been weeks where we have our team back, and it's almost as if, you know, it's not COVID, staff attendance, and availability, but then, you know, the surge…and we lose some of our staff members to necessary COVID-related work.* [Int3]

Sexual Health as a Secondary Concern

Of the 8 experts, 5 (62.5%) reported that sexual health moved from a community-wide health priority to a secondary concern due to challenges imposed by COVID-19 at the mental, economic, and nutritional levels. In addition, 1 (12.5%) participant expressed the need for a holistic approach to sexual health as people are prioritizing their basic needs and ensuring that all their family members are safe (Int2-P2). In terms of prioritizing needs, an expert emphasized the importance of relationship building by reframing messages in an informal context (Int6).

> *And now we're seeing a federal response saying here is a curriculum, a list that can be utilized for some of these programs. I think what's interesting is that it's just not the silo of physical sexual health. It's more holistic—mental health, social health, cultural health, and physical health.* [Int2-P2]

Moving to Web-Based Programming: Skills, Training, Support

Since the start of the COVID-19 pandemic, the majority of in-person and hybrid sexual health education programs had to be adapted to online learning platforms. Experts discussed major challenges faced in the delivery of virtual programs from their own perspective and from the youth's and communities' perspectives. The challenges were most apparent among experts adapting and translating health education programs to virtual platforms for the first time (Int3-Int5).

Adaptation of Programs to the Online Platform

Of the 8 participants, 1 (12.5%) described the challenge of trying to figure out how to coordinate with schools to plan and deliver virtual sexual health programs for youth while managing their ongoing hybrid learning platform (Int1). Other experts expressed struggling to identify which program components to keep, since most activities were designed for in-person delivery (Int3, Int4). A concern shared by most experts was ensuring that the adaptation process was not completed hastily to ensure they met youth's needs (Int1-Int4). In addition, 2 (25%) experts indicated that the in-person sessions were too long when adapted to the virtual platform and had to be shortened to ensure youth engagement throughout the session (Int3, Int4). Furthermore, 1 (12.5%) expert shared that a lot of adaptations needed to be made even for programs that used the online platform for content delivery, since these programs had a physical component to some extent prior to the COVID-19 pandemic (Int3).

> *It can be very quick to open up a Zoom account and get started on Zoom, right? You can do it in minutes. But that doesn't mean that you're prepared to*

implement a program online. So, I think that 1 of the challenges is that people are going to, I think, initially hastily put their programs together, and they're not going to be good. And they're not going to actually meet the needs of young people. [Int1]

You know, very quickly, we had to start adopting our own programming for virtual settings, and, you know, kind of identify which components of our work we're going to get [to] continue happening in community settings, because most of our tribal clinics closed, our tribal schools closed, public schools closed. So, kind of being in touch with our tribal health educators and our clinic staff to see which services and programs were continuing, what was being paused, what priorities they had for moving forward and trying to respond to those. [Int2-P1]

Lack of Sufficient Time and Staff Support in the Stressful Adaptation Process

Experts described the adaptation process as stressful for staff due to the limited time frame available. Of the 8 experts, 1 (12.5%) disclosed that staff were begging for support because meeting young people's needs was substantial during the pandemic. Another highlighted the gap in resources provided for employees working from home (Int5). In addition, 2 (25%) experts from the collective interview (Int2) described the process as "trial and error" due to the time constraints tribal employees encountered while becoming "Zoom savvy" for virtual programs. A common subtheme shared by all experts was the need for continuous staff training to get acquainted with the online platforms and software available to maximize youth learning and engagement. Participants believed that professional development is needed to help staff feel equipped to navigate virtual platforms (Google Classroom, Zoom, Jamboard, etc; Int3).

Secondly was how to coordinate our schedules and utilize a virtual platform such as Zoom and become Zoom savvy for us as professionals, and I can tell you, I think we've talked about it, we've been more busy now in a virtual setting than we have when we were in the office. [Int2-P2]

So, although some of these were presented in person, there was a lot of adaptation to go online, and what that looked like, so a lot of trial and error, a lot of challenges, and a lot of different avenues of communication and having to be also creative and also still innovative, too. [Int2-P3]

We had to incorporate an entire tech training on how to use Zoom and how to use, like, the internet to do a lot of things. And I mentioned our team, our paraprofessionals, which means they're from the community, but they may not always have all of the skills. So, for us, training is really important to make sure that we're helping our team members reach their best potential so they can do all of these things. [Int3]

Youth Missing a 1-on-1 Connection

Of the 8 experts, 4 (50%; Int3-Int6) emphasized that youth were missing the 1-on-1 connection established in in-person programs. Therefore, experts had to delete or modify online activities to engage youth as much as possible. The in-person component was pointed out as an integral part of the AI/AN culture (Int6).

We have had some Zoom sessions where there are, you know, siblings together with their parent, and there's a couple kids, but their original program, you know, kids are in groups, and they're doing all these fun activities, and they're laughing, and they're really engaged. It's very much like an interactive process. And so, you know, some of the activities that were like that originally—that we knew we couldn't do on Zoom—we either took out or modified. [Int4]

But for tribal communities, the in-person part is such a major piece. And I don't see that changing in any capacity. I do think that the virtual piece will be really amped up, and I think it will be smoothed over quite a bit [of time]. [Int6]

Recruiting and Retaining Youth

Using Social Media Platforms for Youth Outreach

Based on the 2020 nationwide Youth Health Tech Survey [50] mentioned by 1 (12.5%) of the 8 participants, certain social media platforms were identified as preferred channels by AI/AN youth to receive sexual health messages and lessons (Int6). A participant pointed out that facilitators used their personal social media to reach out to youth and families in their community. One expert also mentioned that social media facilitated recruitment during the pandemic, since social messaging was popular among youth (Int2-P2). Another expert emphasized the effective role of social media in allowing lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth to open up about their sexual health and body image in a positive manner due to the support received from the online platform (Int2-P3). All experts stated that TikTok is less often used to reach youth than are Instagram, Facebook, YouTube, and Twitter. We R Native, a multimedia health resource for Native youth, has a large and growing presence on social media. Instagram and Facebook were the main channels used by We R Native to promote sexual health resources during the pandemic, due to their popularity and national reach. Since then, they have seen expansive growth on TikTok, too—addressing healthy relationships, condoms, STI testing, and birth control with an "indigenous" lens.

Differences in the Online Program Youth Participation Rate

Recruitment and retention of youth for online sexual health program participation was reported as problematic by 2 (25%) of 8 experts (Int5, Int6). Most health educators relied on schools to locate participants and increase recruitment and retention rates (Int5). However, since the start of the pandemic, schools were shut down, and more youth sought mental health services rather than focusing on their sexual health (Int6). A participant described the negative impact of school shutdown due to COVID-19 on youth recruitment for online sexual health

programs. Schools were considered a major hub for recruitment and created an organized structure for outreach efforts (Int1). Parents are also more comfortable when their youth participate in school-based curricula rather than having an outside organization deliver the program (Int1). Most AI/AN villages and reservations are considered remote, which renders schools a hub for recruitment purposes (Int3).

> *I think the programs that are going to be successful at recruitment is programs that are operating through a school. It's much harder already; like some of my teams in the Midwest have been trying to get the young people together, and they're just now getting to the point. And it's because school has created this, like, sort of organizing opportunity, like kids are having a more structured day than what they have over the summer. And in the early days of the shutdown.* [Int1]

> *Yeah, there's definitely…the recruitment and the retention in a virtual setting…versus an in-person implementation. Yes, there is a dramatic difference. Only because of the fact that, you know, that we're trying ourselves as an organization, and educators trying to find resources and tools that they can implement, if they were to implement a [curriculum], trying to adapt that. The upside that we're seeing is an uptick in our social messaging for youth. That's a very popular resource.* [Int2-P2]

Distribution of Flyers in Community Locations

Prior to the COVID-19 pandemic, in-person recruitment was highlighted as 1 of the most effective ways to reach out to AI/AN communities and inform them about the program. A participant indicated that there still needs to be an in-person component to ensure high engagement and excitement about the program despite the restrictions imposed by the pandemic (Int3). Operating through channels available in the community facilitated getting the word out about programs and overcame the challenge of limited network connection and bandwidth (Int1).

> *That's 1 of the effective ways. I mean, flyers in a place that people are still going, in some of the smaller Native communities. There may be people [who] actually go and visit a bulletin board, or they go and visit, like, something in a primary building. Or especially, where the food pickups are happening…a flyer on a bulletin board or a flyer in a location like that can be a good tool for getting the word out.* [Int1]

Challenges for Implementation in a Household Environment

Challenge of Youth Program Participation from a Home Environment

Another challenge discussed by experts (Int3-Int6) was youth's compromised participation in online sexual health programs from their households due to conflicting parent schedules, sharing equipment with siblings, and being surrounded by family members when learning about sexual health. Unreliable internet connections and the limited access to computers in rural AI/AN households have been described by 1 expert as an ongoing "digital divide" (Int2-P2). Many youths do not have access to computers at home or have to share their laptops with their entire family, which makes it harder to participate in virtual sexual health programs (Int3, Int5, Int6). Additionally, 1 of the main program delivery challenges discussed by these experts was having youth in unsafe households (physical and sexual abuse) to participate in such programs, as well as parents perceiving sex as a taboo topic. Delivering these programs through schools helped overcome these barriers, because health educators did not have to worry about conservative parents monitoring the programs' content. As a participant pointed out, even in virtual clinical visits, health care providers are asking whether youth are in a safe place to discuss their health concerns (Int1). Some programs are even including parents in sessions to increase parent-youth communication and appease their fears about having their kids participate in online sexual health programs (Int2-P2, Int3, Int5).

> *But you know, there's lots of need around, you know, with intergenerational families sharing technology. So, you know, maybe the youth was assigned a computer that or, you know, a tablet that did have data on it, but then that youth might have to be sharing it with siblings or the adults. And then also family schedules. So, you know, if there's a family and this youth is supposed to be on a sexual health lesson, but then mom needs to go grocery shopping, just take all the kids with her.* [Int6]

> *So, for instance, young people that are living in homes that aren't safe, and that may be like participating in a sexual health program, in a household where that is not accepted. Whereas a young person could have previously like said, "Oh, my after-school program is, like, [a] spirit club or something," when it was actually a sexual health program. Um, you know, now, if they're doing something at home, they are in a home where other people may see what they're doing and know what they're up to. And in homes that are not safe to do that, that can be a real barrier.* [Int1]

> *But we've also heard collectively what the needs are. And…and that's pretty compelling from the field, infrastructure, needs. You know, there is a digital divide out there. So, not everybody can utilize a computer and a laptop or enroll America in most places. So, that's been pretty compelling.* [Int2-P2]

Low Bandwidth and Network Connectivity Issues

One of the main challenges encountered by experts in the delivery of online sexual health programs is the low bandwidth in rural households and network connectivity issues in tribal communities. It is thus important to be mindful of youth's network connection when designing program activities, because it might take youth some time to connect with their facilitators and ensure a stable internet connection without dropping out of sessions (Int3, Int4). Most youth have reported adequate access to technology resources. However, an expert pointed out the

need to continuously provide technical support for tribes with varying capacity and resources to ensure engagement in virtual programs (Int6).

> *Yeah, I think overall, we know that youth are able to access and have technology resources. And so, if that's the case, then this is the best platform to do it. It's a pretty small number of folks who have absolutely no IT capacity whatsoever; it seems like most tribes, at least, you know, can lend a laptop and a thumb drive. And it's not a perfect scenario. But that's an adaptation that folks are making.* [Int6]

Dealing with Youth Internet Access

Building partnerships with schools was described by a participant as the gold standard due to tribal preference of working with schools to reach youth in remote areas through a streamlined process (Int6). Schools can help resolve the issue of limited internet connection and bandwidth that youth have in their households, which can affect program access and completion (Int4, Int5).

> *And then, at least in schools, they can still access the program and complete everything, and they don't have to worry about [the] internet connection or, like, the bandwidth.* [Int4]

Recommendations to Overcome Delivery Challenges

Building Partnerships With Schools and Community Organizations

All (n=8, 100%) participants emphasized the necessity of building partnerships with schools and community organizations as essential for online program adaptation and implementation during the COVID-19 pandemic. Prior to the pandemic, schools were considered a major hub for youth recruitment and facilitated youth's access to adequate internet bandwidth and computers to participate in virtual sexual health programs [51,52]. However, the pandemic forced health educators to think of alternative ways for maintaining program delivery due to school shutdowns and restrictions on in-person activities [53]. This in turn led educators to adapt lessons for in-person and hybrid delivery [53]. Experts shared the need to collaborate with schools when preparing to transition to online platforms. Partnerships can also facilitate the provision of continuous staff support and training to simplify the adaptation process.

> *You know, parents often do trust what's happening at school a lot more than they trust an outside organization; they're a lot more suspicious of even things like a Boys and Girls Club, you know. So well established, like doing a social good in the world. So yeah, I do think that working in partnership with a school or another bigger organization that can give you a little bit of cover and decrease the suspicion now, you know, the alternative may be true in some Native communities if the institution is a non-Native institution, because there's a lot more suspicion around those types of organizations [than] there might be in White communities, so things like a university [are] not necessarily a great implementation partner in some Native communities that have suspicion around, you know, universities that have historically done research on them.* [Int1]

> *There are collaborations happening between, for example, health, community health, [and] behavioral health departments within a health setting, partnering with their local school, you know, their PE or health teacher, their program, and you know, so you have 2 entities coming together to offer this class. So, that's becoming very popular; it can be done for credit recovery…it could be done just for the sheer fact that this is a tribal school on tribal land that's looking for tribal self, sexual health. Very, very popular. It's the trend.* [Int2-P2]

> *I think that's always the gold standard, too, is that most tribes want to…most programming want to work with schools, because that's the easier way to get to youth and it's a more organized and streamlined process. So, I think that will always be the goal—to collaborate with schools.* [Int 6]

Adopting a Holistic Approach When Addressing Sexual Health in AI/AN Communities

Addressing sexual health holistically was 1 of the major themes emphasized by the interviewed experts in this study. For years, sexual health educators have been emphasizing the need to have a holistic approach to sexual health interventions as STI/HIV prevention interventions were not inclusive of other important adolescent health issues [54-56]. Social and emotional learning, along with physical and mental health issues, must also be addressed in these interventions to promote positive youth development [56]. Since the start the COVID-19 pandemic, downward trends in mental health became apparent in AI/AN communities, due to parental unemployment, food insecurity, and home-based learning with limited social connection [57].

> *If your tribe has behavioral health services, or mental health services, that can support you in integrating those topics into your sexual health program, I think that this is the time to do it, because young people are struggling. And I think our we're at [a] real risk of, like, a widespread mental health crisis for young people, for teens, particularly.* [Int1]

Adopting a Systematic and Culturally Responsive Approach for Effective Virtual Program Delivery

Experts disclosed the benefits of adopting a systematic approach for effective implementation of online programs during the pandemic. Their recommendations included making a leap to identify what is working in AI/AN communities, rather than getting paralyzed just thinking it through; knowing which specific tools are relevant for the program rather than using all available tools and websites; and being patient since program adaptation is a strenuous learning process, particularly during the pandemic, where things are changing all the time. An additional recommendation was the need to have sexual health programs that are reflective and inclusive of the health belief systems of Native cultures and Native traditions since there is

so much to learn from Native cultures when it comes to health and well-being.

> *I think another tip to a part of that was just like, you know, technology can be big and intimidating. I heard a lot of people say that—multigenerational, from the youth all the way to adults. And so, I think it's…it's okay if there's patience, you know; technology's not going anywhere. Even if they feel that they want to get a good grasp of what that looks like, or how to do it. I think it's nice to just kind of get your bearings and then proceed on.* [Int2-P3]

> *I guess some general advice would be to just make the leap. I think sometimes, you get paralyzed by thinking it through. But you just have to act and try to see what's going to work and know that have a flexible approach that you can change things around if things aren't working.* [Int3]

> *I think that there's so much to be learned from Native cultures when it comes to health and well-being. And so, ensuring that programs are inclusive and reflective of that and are rooted in the culture and the community itself [is] really important, really essential. You're not going to get a program off the ground without those things.* [Int4]

Community and Youth Engagement for the Success of Virtual Sexual Health Programs

Interviewed experts emphasized the need to continuously engage youth and community members, to listen to their feedback and carry out the suggested improvements, while considering the impact induced by the pandemic on their overall well-being. Focus groups with program participants and community members can improve program sustainability by highlighting the COVID-19-related challenges that need to be addressed.

> *And what can be helpful for the youth as well as for the adult audience to know, the 1 thing that resonates across the board is—Natives like Natives, you know—we want to see ourselves in the products in the curriculum, in the videos in the messaging, and [in] the theme. And if you tie it back to culture, then that's the tagline—culture is prevention.* [Int2-P2]

> *I think the first thing is, you have to have real community engagement, and willingness and belief that the program is important, and that the program needs to come from the community itself.* [Int4]

Discussion

Principal Findings

This study aimed to (1) better understand the extent to which pre-existing challenges were exacerbated by COVID-19, (2) examine barriers encountered when adapting programs to an online environment, and (3) highlight socioeconomic challenges experienced by youth. Both experts who had extensive experience adapting and translating health programs to online platforms and experts who were going through the process for the first time were interviewed. Such diversity in perspectives allows for a broader exploration of the impact of COVID-19 on the adoption, implementation, and maintenance of youth sexual health programs across different tribal regions in the United States. One of the strengths of this paper is that experts did not restrict themselves to sharing their professional point of view. Rather, they shared the experience of participating in online health programs from the perspectives of youth, parents, and families in tribal communities. Further, they provided advice and recommendations for future sexual health programming, with flexible options for program delivery.

As described by the key informants, AI/AN youth experienced significant and prolonged disruptions to sexual health education and sexual health services during the pandemic. Many also experienced socioeconomic and mental health challenges, juggling virtual learning while supporting their family's basic needs. There is a need for cross-agency funding opportunities that holistically support the health and development of AI/AN youth [56,58-62]. Many tribes are small, which makes it challenging to apply for issue-specific funding. Holistic funding opportunities will provide tribal health educators with the opportunity to address the social determinants of health and the risk factors leading to adverse health outcomes among AI/AN youth [56].

To better disseminate culturally responsive resources for future program adopters, experts recommended Healthy Native Youth [63], We R Native [64], and iknowmine [65] websites that share resources, tools, and curricula to get people engaged and excited about topics, ideas, and strategies that communities have used to address AI/AN youth sexual health. Even though technological tools can be intimidating at a multigenerational level (youth and adults), experts stressed the importance of being patient with technology, as well as the need for facilitators to have a good grasp of technological tools before moving on with program adoption or implementation.

Collaborative partnerships between AI/AN communities have been reported as an effective strategy to improve program delivery [50]. Successful programs implemented in AI/AN communities have been attributed to all the connections made across different project partners and collaborators [51]. One expert shared that all things are rooted in relationships in Native communities. Another expert emphasized the importance of attending meet-and-greet sessions to learn from the personal experiences of program implementers working in the field. A common recommendation highlighted across interviews was the power gained from leveraging community-mobilizing efforts during the pandemic, along with believing and trusting in the project staff who bring their strengths and talents to the table. As mentioned by 1 (12.5%) of the 8 experts, even though COVID-19 has altered the way sexual health programs are being delivered to youth, patience and perseverance will create the needed answers in these uncertain times.

Findings from this study reiterated the importance of community and youth engagement in the dissemination, adaptation, and evaluation of health promotion programming in Native communities. In a systematic review looking at the elements of a successful implementation framework in indigenous communities, two-thirds of included studies demonstrated high

levels of community engagement from a culture-centered approach, while two-thirds of the studies included structural changes and researcher reflexivity [58]. Similarly, a review of effective youth engagement strategies for mental health and substance use interventions indicated that comment boxes and evaluation surveys as well as primary decision-making authority at every stage of program design, implementation, and evaluation contribute to high youth engagement [59]. Other strategies for youth engagement include having youth sit on boards and committees within an organization and having youth participate as peer support workers [60]. Findings from the included studies emphasized that youth participation in program adaptation established a dissonance between their behavior in using substances and their prevention role adopted through program participation [61]. Additionally, youth participants who were able to better identify with the program content recorded a significant reduction in adverse health behaviors [62].

Limitations

This study has several limitations. Given that participant recruitment was conducted using a nonrandom sampling approach, selection bias cannot be ruled out. However, the purposive sampling approach allowed us to reach a diverse group of sexual health experts across different US regions. The small sample size is attributed to the low response rate to recruitment emails and the hard-to-reach sexual health experts who were likely overburdened with the challenges in program delivery imposed by COVID-19. This is an inherent limitation of the recruitment methodology that was addressed through the detailed descriptions, thoughts, and themes provided by the key informants, along with the diverse demographic characteristics of the sample. Furthermore, the diversity of experts interviewed made it possible to obtain opinions from organizational, field, and academic professionals. Finally, another limitation was having 1 collective key informant interview encompassing 3 key informants who might have influenced each other's opinions; yet the allocation of questions for each participant helped control for any kind of potential biases.

Conclusion

This exploratory, qualitative study examined COVID-19-related challenges in the adaptation and delivery of sexual health programs on virtual platforms. Recommendations for future efforts included building partnerships with schools and community organizations, adopting a holistic approach to sexual health in AI/AN communities, adopting culturally responsive approaches, and engaging youth and community members in the design and delivery of sexual health programs in AI/AN communities. Findings can provide guidance on strategies to follow when selecting or preparing online sexual health programs for AI/AN youth. Future studies should explore the impact of COVID-19 on sexual health programs from the perspectives of youth themselves and empower them to share their own thoughts and recommendations for effective sexual health programs when delivered in hybrid and virtual spaces.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ checklist. COREQ: consolidated criteria for reporting qualitative research.
[DOCX File , 18 KB - formative_v6i4e32325_app1.docx]

Multimedia Appendix 2
Letter of information, interview guide, codebook, and theme generation.
[DOCX File , 67 KB - formative_v6i4e32325_app2.docx]

Multimedia Appendix 3
Quotations for themes and their relevant subthemes.
[DOCX File , 35 KB - formative_v6i4e32325_app3.docx]

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Abbreviations

AI/AN: American Indian and Alaska Native
STI: sexually transmitted infection

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Original Paper

Decreased Physical Activity Among Youth Resulting From COVID-19 Pandemic–Related School Closures: Natural Experimental Study

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Abstract

Background: The COVID-19 pandemic has resulted in the closure of schools and may have inadvertently resulted in decreased physical activity for youth. Emerging evidence suggests that school closures due to the COVID-19 pandemic could have hastened the inactivity of youth, possibly due to a lack of structure outside of school and increased access to sedentary activities.

Objective: The purpose of this study was to assess changes in physical activity from pre–school closure (before the pandemic) to post–school closure (during the pandemic) among youth in spring 2020.

Methods: This study used a natural experimental design; youth were enrolled in a physical activity study prior to the lockdown, which was enforced due to the pandemic. The number of device-assessed steps per day and moderate-to-vigorous physical activity minutes per week were measured by using a Garmin Vivofit 4 (Garmin Ltd) accelerometer over 8 weeks. Mixed effects models were used to compare physical activity variables, which were measured before and during the COVID-19 pandemic.

Results: Youth were primarily Hispanic or Latinx (8/17, 47%) and female (10/17, 59%). The number of daily steps decreased by 45.4% during the school closure, from a pre–school closure mean of 8003 steps per day to a post–school closure mean of 4366 steps per day. Daily moderate-to-vigorous physical activity decreased by 42.5%, from a pre–school closure mean of 80.18 minutes per week to a post–school closure mean of 46.13 minutes per week.

Conclusions: Youth are engaging in roughly half as much physical activity during the school closure as they were prior to the school closure. If additional evidence supports these claims, interventions are needed to support youths' engagement in physical activity in the Midwest.

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KEYWORDS

intervention; physical activity; nutrition; adolescents; formative research; COVID-19; pandemic; school closure; children; youth

Introduction

The lack of youth physical activity (PA) is a pervasive public health issue. Less than one-quarter of youths aged 6 to 17 years in the United States engage in the recommended 60 minutes of moderate-to-vigorous PA (MVPA) per day [1,2]. Regular PA can improve children's physical health [2] and cognitive performances [3,4]. Physical inactivity can result in being overweight or obese [3] and increase one's risk for cardiovascular disease [5,6] and type 2 diabetes [7], among other negative health conditions. Further, physically active youth

are likely to have better school attendance, grades, classroom behavior, and cognitive function [3,4].

Children spend a substantial amount of time at school, making it an ideal place to embed PA within the day [2]. Youth have been found to be more physically active during the school year than during the summer [8,9], and this pattern is even more pronounced for certain subgroups, such as Hispanic or Latinx youth [9]. One explanation for this may be the structured day hypothesis, which posits that the presence of structure (preplanned, segmented, and adult supervision) may regulate obesogenic behaviors, including physical inactivity and sedentary behaviors, in youth [10].

In March 2020, the World Health Organization declared COVID-19 a pandemic [11]. In response, many schools closed for the academic year 2 months earlier than usual to curb the spread of COVID-19. Students participated in web-based schools for the remainder of the school year. As a result, past research has hypothesized that overall PA would be further reduced due to school closures during the COVID-19 pandemic [12]. Therefore, the purpose of this study was to objectively measure changes in youth PA from before to during COVID-19 pandemic–related school closures.

Methods

Participants

Beginning in January 2020, middle school youth from an urban school district in a Midwest city were recruited to participate in a 2-arm quasi-experimental study. All students in the school district qualified for free lunches [13]. Students from 2 middle schools were recruited to participate as controls, and 2 schools were recruited to participate in an after-school PA and nutrition intervention. The intervention would have provided sports sampling programming, during which 4 sessions of sports instruction would have been provided weekly. The focus sport would have rotated every 2 weeks to provide a variety. Weekly distributions of produce kits that were designed to make at least 1 meal for a family of 5 would also have been distributed. The study activities were planned to continue throughout the remainder of the school year (May 2020) and were planned to resume in fall 2021. During the recruitment process and baseline testing and prior to intervention implementation, schools closed for spring break. Following spring break, the schools remained closed, and students did not return to in-person schools for the remainder of the academic year due to the COVID-19 pandemic. This phenomenon provided a unique opportunity to conduct our natural experimental study. Prior to school closure, baseline data collection (ie, height, weight, and demographics) was completed for 86 youths; 72% (n=62) of these youths were in the control group. Due to school constraints, enrollment for intervention students was slower compared to that for control schools. Students who enrolled in the intervention stayed after school to complete enrollment and baseline testing. During this time, no structured programming had begun in intervention schools. Due to the low intervention enrollment and low dose of the intervention that was delivered, all participants (control and intervention groups) were eligible for inclusion in our analysis.

Instrumentation and Procedures

Each youth was provided with a Garmin Vivofit 4 (Garmin Ltd) to objectively measure PA from February to April 2020. Although it is critical to account for nonwear time in research that involves using consumer activity monitors, there is a lack of consensus on the best approaches for detecting nonwear time. Approaches vary by device manufacturer (eg, Garmin Ltd vs Fitbit LLC) and device model (eg, heart rate is sometimes used but is not measured by the Vivofit 4). Although the most common approaches have been to include all days regardless of wear time (ie, no detection of nonwear) and define valid days based on a minimum step count threshold [14], we used a more rigorous approach in this study, similar to what has been used in some Fitbit-based research [15]. Groups of ≥3 epochs (15 minutes each) with a value of 0 for maximum motion intensity were considered nonwear time. Valid wear days were defined as days for which a participant had ≥8 hours of wear time between 9 AM and 9 PM and ≥500 steps. For each participant, daily data were aggregated at the week level, with a requirement of ≥1 valid day for the week to be included in the analyses. We selected the requirement of ≥1 valid day due to the stringent criteria used for a valid day; however, the mean number of valid days per week was 5.24 (SD 2.21). Weighted weekly values for steps per day and MVPA minutes per day were calculated as follows:

$$([\text{mean of weekdays} \times 5] + [\text{mean of weekend days} \times 2]) \div 7$$

When a participant did not wear the device for ≥1 weekday and ≥1 weekend day in a given week, the weekly value was calculated as a mean of all valid wear days for the week. MVPA was measured by using the Garmin device's automated activity detector. The device automatically measures active minutes when a user runs for at least 1 minute or walks for at least 10 consecutive minutes.

Participants with at least 1 week's worth of data in the 4 weeks prior to school closure and at least 1 week's worth of data in the 4 weeks after school closure were included in the data analyses. The mean numbers of pre–school closure and post–school closure weeks with valid participant data were 2.65 (SD 1.11) and 3.12 (SD 1.17), respectively. This inclusion criterion allowed us to examine multiple time points of PA behavior while also allowing for a larger sample size. After removing participants who did not meet the inclusion criteria, we had 17 participants with valid data. The school closure forced a change in syncing practices; research staff went from syncing youths' Garmin devices weekly at schools to instructing students to sync their Garmin devices to a personal device (ie, a smartphone or tablet) at home. Many of the students did not respond to the research team's efforts to train students on the new syncing practices, which limited the number of participants who had valid data post–school closure to 17 participants. Of these 17 participants, 16 were in the control group.

Ethics Approval

All study procedures were approved by the University of Missouri-Kansas City Institutional Review Board (2017528).

Data Analysis

Descriptive statistics were used to analyze demographic variables. Demographic differences between youth who were included in and excluded from the analyses were assessed by using chi-square tests. Differences in the number of steps per day and MVPA minutes per week from pre–school closure (4-week period) to post–school closure (4-week period) were assessed using 2 mixed effects models (1 for each PA dependent variable). Our models accounted for the nesting of weeks within participants and were adjusted for the number of valid weekday wear days and weekend wear days in each week. A second pair of mixed effects models, which accounted for the nesting of weeks within participants, was used to investigate differences in the number of steps per day and MVPA minutes per week across the 8 study weeks. For these models, the *study week* variable was entered as a categorical fixed effect in addition to the aforementioned covariates. Estimated sample means and CIs were calculated from the models' results and plotted. The restricted maximum likelihood was used in all models to account for missing data. Significance levels were set at $P<.05$. All analyses were conducted with SPSS (version 25; IBM Corporation).

Results

Demographics

The demographics of the participating youth are presented in Table 1; demographics data are presented separately for youth who were included in and excluded from analyses and are compared for statistical differences. The participants included in the data analysis (n=17) were primarily Hispanic or Latinx (8/17, 47%) and female (10/17, 59%). All participants were in the sixth, seventh, or eighth grade and represented 3 public middle schools. The majority of families (15/17, 88%) reported incomes within low-income limits for the county [16]. No significant differences were reported between those who were included in the analyses and those who were excluded from the analyses.

Table 1. Demographic characteristics of participants who were included in the analyses compared to those of participants who were excluded from the analyses.

Characteristic	Participants included in the analyses (n=17), n (%)	Participants excluded from the analyses (n=69), n (%)	*P* value
Race and ethnicity			.66
Black	7 (41)	22 (32)	
Hispanic or Latinx	8 (47)	33 (48)	
White	2 (12)	9 (13)	
Other or preferred not to respond	0 (0)	5 (7)	
Gender			.78
Male	7 (41)	28 (41)	
Female	10 (59)	39 (57)	
Other or preferred not to respond	0 (0)	2 (3)	
Household monthly income (US $)			.72
≤1000	4 (24)	19 (29)	
1000-2000	4 (24)	23 (35)	
2000-3000	5 (29)	12 (19)	
3000-4000	2 (12)	7 (11)	
≥4000	2 (12)	4 (6)	

PA Findings

Table 2 presents the pre– and post–school closure steps and MVPA data. Participants accumulated a mean of 8003 (SE 369.18) steps per day pre–school closure. This decreased to a mean of 4366 (SE 351.42) steps per day after school closures due to the COVID-19 pandemic, which was a significant decrease ($F_{1,6}=50.17$; $P<.001$). Similarly, MVPA significantly decreased ($F_{1,6}=47.3$; $P<.001$) from pre–school closure (mean 80.18, SE 3.56 minutes/week) to post–school closure (mean 46.13, SE 3.39 minutes/week). Figures 1 and 2 show that the number of steps per day and MVPA minutes per week were fairly consistent across the first 4 study weeks; these decreased during the fifth study week, which coincided with spring break, and remained low during the school closure.

Table 2. Changes in the number of steps and physical activity from pre–school closure to post–school closure (n=17).

Characteristic	Pre–school closure, mean (SE)	Post–school closure, mean (SE)	Percent change	*F* test (*df*)	*P* value
Number of steps per day	8003 (369.18)	4366 (351.42)	−45.4	50.17 (1,6)	<.001
MVPA[a] minutes per week	80.18 (3.56)	46.13 (3.39)	−42.5	47.30 (1,6)	<.001

[a]MVPA: moderate-to-vigorous physical activity.

Figure 1. Mean number of steps per day by study week. Study weeks 1 to 4 depict pre–school closure data, and study weeks 5 to 8 depict post–school closure data. Estimated sample means are presented with error bars representing 95% CIs.

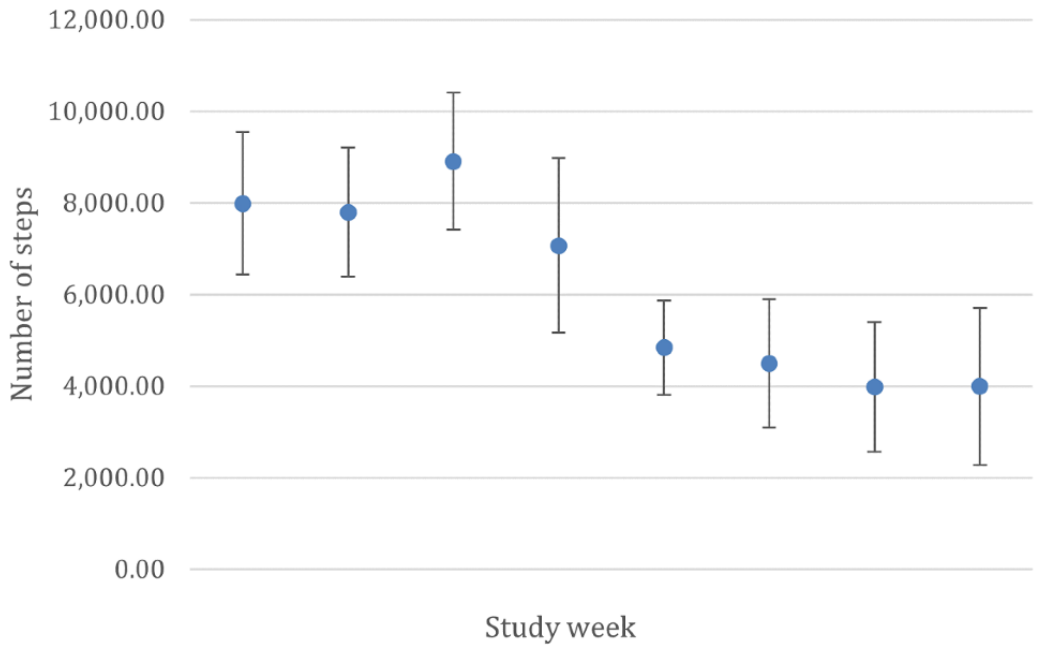
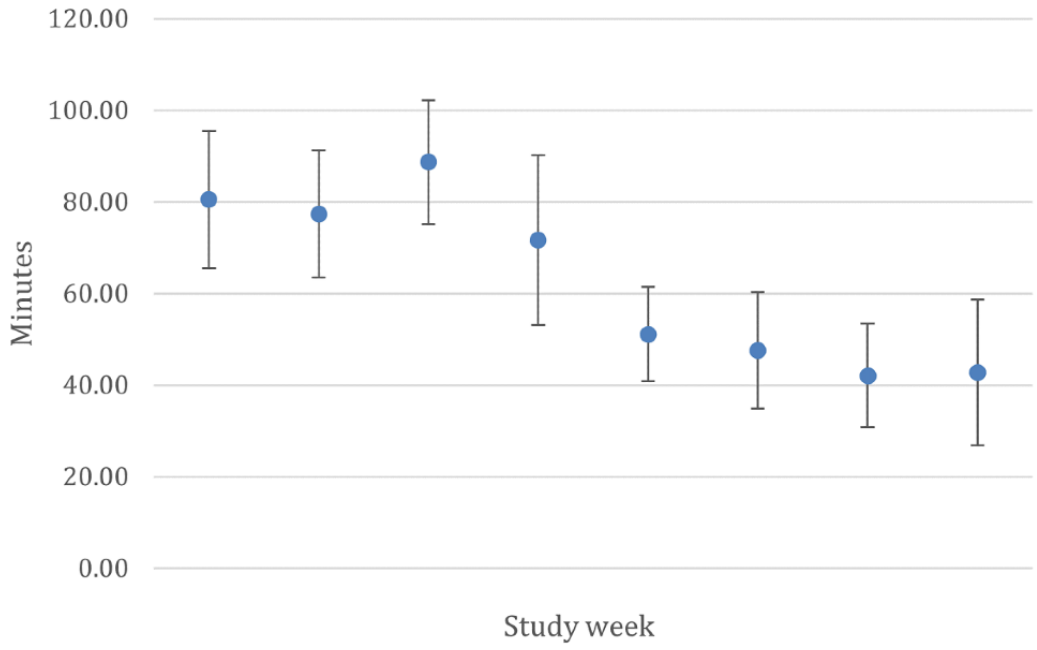


Figure 2. Mean moderate-to-vigorous physical activity minutes per week by study week. Study weeks 1 to 4 depict pre–school closure data, and study weeks 5 to 8 depict post–school closure data. Estimated sample means are presented with error bars representing 95% CIs.



Discussion

Principal Findings

This study aimed to objectively assess the change in youth PA from before to during school closures due to the COVID-19 pandemic. Overall, the sample was small and was comprised of mostly racial and ethnic minority students (15/17, 88%). Similar to findings from a scoping review of other studies conducted in the first year of the COVID-19 pandemic [17], a significant decrease in objectively measured PA was recorded for the participants ($P<.001$). The findings from this study add to the previous literature by providing longitudinal data that spans pre– and post–school closure time points, as the majority of previous studies were cross-sectional and provided no comparison data for PA prior to the pandemic. Moreover, this is the only study, to our knowledge, to use pre– and post–school closure device-based measurements for youth in the United States. The large decrease in PA that we observed in our study may be partially explained by the decreases in PA among racial and ethnic minority groups during school breaks, which are more significant than those among White youth [9]. It appears that the structure and opportunities for movement provided during a web-based school day, at least during the early delivery of web-based schooling, were not sufficient for maintaining PA, as hypothesized in the structured day hypothesis [10].

Childhood obesity and inactivity continue to plague youth in the United States. PA tends to decline during middle school years—a time when recess and physical education requirements often decrease. Additionally, COVID-19 has exacerbated previously identified declines in PA. Schools are still an ideal place for implementing policies and interventions that improve health behaviors because of the significant time spent at school by most youth [2], but new strategies may be needed, particularly when schools are conducting web-based learning. Schools should consider implementing active learning and encouraging movement between classes. Middle school administrators should examine policies regarding physical education requirements and aim to achieve the recommended 225 minutes per week of physical education instruction [18]. Before- and after-school activities are highlighted as key strategies for supplementing youth PA levels [19]. In summary, middle schools need to expand their offerings for increasing PA as students return to in-person learning. This will not only help students achieve prepandemic levels of PA but also help them meet the recommended 60 minutes of PA every day [2].

Although schools have traditionally been a setting for youth to obtain the majority of their recommended PA, the effects of the COVID-19 pandemic suggest that other settings may need to foster a greater proportion of youths' PA. Further, while youth spend more time at home, parents will likely play a more significant role in encouraging PA during the pandemic. However, parents have indicated that they need resources to help them support their child's PA [20]. Web-based, after-school PA programming may be one strategy for increasing PA. Such programming should be tailored to students in middle school, where the activities are fun, involve friends, and include some competition [21]. Lastly, a variety of outdoor activities should be encouraged (eg, nature walks, bike rides, games, etc).

Strengths and Limitations

This study has several strengths. One is its natural quasi-experimental design. Additionally, this study is strengthened by its use of objective measures of PA and offers longitudinal time points that demonstrate the change in PA behavior from before to during the school closures resulting from the COVID-19 pandemic. By using objective measures of PA, participant recall biases were eliminated. Racial and ethnic minority groups are often left out of PA research; this study is strengthened by the participation rates of these groups.

This study also has limitations. The sample for this study was small, and the proportion of participants included in the analyses was also small. There were several days with missing data, which required us to compute weekly means for the number of steps taken. Additionally, we were forced to change the syncing procedures for the Garmin accelerometers due to the school closure. Before the school closure, the research team synced participants' accelerometers at school weekly. After the school closure, we needed youth to register their accelerometers to a personal device, which posed significant issues for consistent data collection, as reflected by our lower number of valid weeks post–school closure. Lastly, social distancing and other precautionary measures that were enforced upon the youth may have impacted other opportunities for PA. Further research with larger sample sizes is needed to confirm our results. Many schools continue to offer web-based learning, and they should be studied to determine if the low PA trends have held consistent.

Conclusions

This study revealed a significant decrease in PA among middle school student participants after the COVID-19–related school closures. As schools remain web-based or continue to have periods of web-based learning, it should be a priority for schools to incorporate regular PA within the school day. Schools and partnering organizations should provide extracurricular PA opportunities, even if they are provided on the web or through other noncontact formats.

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Authors' Contributions

AG conceptualized the study, wrote the manuscript, and performed the literature review. JSL conceptualized the study, analyzed the data, and contributed to manuscript writing. KE collected the data and contributed to manuscript writing. CS collected the data and contributed to manuscript editing. RPS oversaw the research efforts. JC analyzed the data and contributed to manuscript writing.

Conflicts of Interest

None declared.

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Abbreviations

MVPA: moderate-to-vigorous physical activity
PA: physical activity

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Corrigenda and Addenda

Correction: An Alternative to the Light Touch Digital Health Remote Study: The Stress and Recovery in Frontline COVID-19 Health Care Workers Study

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In “An Alternative to the Light Touch Digital Health Remote Study: The Stress and Recovery in Frontline COVID-19 Health Care Workers Study” (JMIR Form Res 2021;5(12):e32165), the authors noted one error.

In the originally published article, author Shazia Rangwala's name was inadvertently not included in the list of authors. They have been added as the 7th author and with the first affiliation. The list of authors and affiliations now appears as follows:

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The correction will appear in the online version of the paper on the JMIR Publications website on April 18, 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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