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Original Paper

Plausibility of Using a Checklist With YouTube to Facilitate the Discovery of Acute Low Back Pain Self-Management Content: Exploratory Study

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Abstract

Background: Access to guideline-consistent effective care for acute low back pain (ALBP) is generally regarded as limited. Researchers have recognized the potential of YouTube as a clinical and patient education resource that may improve access to appropriate care. However, the heterogeneity of evaluation approaches and variable quality of health information have generally limited the potential of YouTube as a self-management intervention.

Objective: This study aims to increase the understanding of ALBP content available on YouTube in 2020 and to establish the plausibility of using a simple checklist to facilitate the discovery of YouTube content consistent with current guidelines. We examined the following 4 research questions: how was the data set defined, what are the metadata characteristics of the videos in the data set, what is the information quality of ALBP YouTube videos, and what are the characteristics of the YouTube data set based on an ALBP self-management checklist?

Methods: This was an exploratory, qualitative infodemiology study. We identified videos in our data set through YouTube search based on popular ALBP-relevant search terms identified through Google Trends for YouTube. We accessed YouTube metadata using the YouTube data tools developed by the University of Amsterdam. We used a modified Brief DISCERN checklist to examine the information quality. We developed a checklist based on the 2018 Lancet Low Back Pain guidelines to examine self-management content.

Results: We analyzed a data set of 202 YouTube videos authored by chiropractors, physicians, physiotherapists, and instructors of yoga and other disciplines. We identified clear differences in the ALBP videos in our data set based on the authors' disciplines. We found that the videos authored by each discipline strongly featured a specific intervention domain, that is, education, treatment, or exercise. We also found that videos authored by physicians were consistently coded with the highest ALBP self-management content scores than all other disciplines.

Conclusions: The results returned by YouTube in response to a search for back pain–related content were highly variable. We suggest that a simple checklist may facilitate the discovery of guideline-concordant ALBP self-management content on YouTube. Further research may identify the clinical contexts in which the use of an ALBP checklist with YouTube is feasible.

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KEYWORDS

YouTube; low back pain; lower back pain; self-management; social media; infodemiology; infodemic; quality of health information

Introduction

Background

This exploratory study aims to increase the understanding of the acute low back pain (ALBP) content available on YouTube (Google Inc) in 2020 and to establish the plausibility of using a simple checklist to facilitate the discovery of YouTube content consistent with current guidelines. Low back pain exerts a high economic and social burden across the globe. The 2018 Global Burden of Disease study suggested that low back pain was the leading cause of years lived with disability in most countries [1].

This paper focuses on ALBP. ALBP is commonly described as a new onset or exacerbation incident lasting less than 12 weeks and including sciatica [2,3]. Most people with ALBP have rapid improvements in pain and disability within several weeks. In most cases, the cause of low back pain cannot be identified, and most low back pain is therefore described as nonspecific [4,5]. However, pain and disability persist for a proportion of people. Up to 80% of people with ALBP may experience recurrence within 12 months [6,7]. The estimates of recovery from an episode of low back pain over 12 months range between 54% and 90% [8,9]. Differing definitions of recovery also complicate the epidemiology of ALBP. Stanton et al [10] described the heterogeneity of case definitions of acute exacerbations of preexisting back pain as further contributing to the diverse understanding of the scale and outcomes of ALBP.

Access to Guideline-Consistent ALBP Care

Access to guideline-consistent effective care for ALBP is generally regarded as limited in the scientific literature. We have described access to ALBP care based on a framework developed by Aday and Anderson [11]. Aday and Anderson's 4 dimensions of access are characteristics of the health delivery system, utilization of health services, characteristics of the population at risk, and consumer satisfaction. These are described below.

Characteristics of the Health Delivery System and Utilization of Services

In 2018, the Lancet Low Back Pain Series Working Group suggested that usual care for back pain was generally unnecessary [12]. The authors defined usual care as incorporating complex pain medications, spinal imaging, spinal injections, hospitalization, and surgical procedures. Among the factors identified as contributing to health system–related access distortions are financial incentives for low value care; clinician attitudes [13,14]; and poor adherence to guidelines by emergency departments [15], family physicians [14,16], and allied health providers [17,18].

Patient Characteristics

The social determinants of health are associated with reduced access to health services [19]. Researchers have also described lower socioeconomic status as a predisposing factor for low back pain [20].

Patient Satisfaction

Researchers have suggested that imaging, extensive testing, and other nonguideline-based investigations and interventions are largely driven by patient demand [21]. Systematic reviews suggest that ALBP patient satisfaction is generally associated with physical examination, diagnosis and prognosis, exclusion of serious pathology, pain relief, and functional improvements [22]. Furthermore, failure by clinicians to provide expected nonguideline-based care may reduce satisfaction and adherence to clinician-prescribed self-management recommendations [23].

In summary, access to effective ALBP care is a complex challenge for patients, clinicians, and policy makers.

Self-Management and Self-Care

Most people manage low back pain with little assistance from health care providers. Estimates of the number of individuals that manage back pain independently, or with occasional formal health care, range from 50% to 70% [24,25]. In scientific literature, the terms *self-management* and *self-care* are often used interchangeably. Self-management is generally regarded as a clinician-guided collaborative intervention that enhances an individual's capacity to monitor and manage their own physical and emotional responses and maintain their quality of life [26,27]. The related term self-care generally refers to actions and decisions taken independent of health providers [28]. Importantly, self-management and self-care are not passive processes. Rather, these processes involve active patient decision making, including symptom monitoring, goal setting, information search and interpretation, and self-efficacy [29,30]. In the case of ALBP, psychosocial status, including fear avoidance, self-efficacy [31,32], and catastrophizing [33], may contribute to the transition from an acute to a chronic condition. Therefore, access to psychosocial support is a consideration in ALBP self-management interventions.

Digital Health Interventions

Digital health interventions (DHIs) may improve access to guideline-consistent ALBP care by facilitating self-management decision making. DHIs include all interventions delivered via digital technologies that facilitate health behavior change [34]. This includes web search, social media, symptom checkers, apps, and telehealth. The reported access benefits of DHIs include reduced health system costs, patient waiting, travel time, and expenses [35] and improved patient-provider communication [36], health outcomes [37], scalability, and safety [38].

By 2020, searching the internet was regarded as a routine dimension of individual health self-management. However, access to web-based health information remained more limited among older and low-income people [39]. Researchers have noted further potential problems associated with the feasibility of implementing DHIs at scale. These feasibility problems include acceptability and demand, usability, real-world implementation, and integration with existing practices [40]. In the case of DHIs for ALBP, a 2017 systematic review found no evidence of positive clinical outcomes or cost-effectiveness [41].

Researchers have suggested that increased patient access to health information represents a profound change in the relationship between patients and providers [42]. Digitally enabled independent self-care by patients has not been universally welcomed by health providers [43,44]. Researchers have reported a consistent pattern of health care provider unease when managing patients informed by internet information.

Importance of YouTube

YouTube is one of the world's most popular websites. In 2020, YouTube was the second most visited website [45] and the second most popular social media network globally [46]. YouTube is commonly used as a source of instructional advice. In 2018, Pew Research reported that 86% of adults in the United States used YouTube for "figuring out how to do things they haven't done before" [47]. It is the instructional use of YouTube that is relevant to this study.

Approaches Used to Analyze YouTube Clinical Videos

YouTube has been widely researched as a source of health information. Although researchers have generally described the potential of YouTube as a clinical and patient education resource, they have also noted the heterogeneity of evaluation approaches and variable quality of clinical information. We identified 3 broad research approaches for evaluating YouTube health videos. These approaches are (1) metadata characteristics, (2) information quality review, and (3) expert clinician review. In practice, most YouTube research has incorporated two or more of these approaches.

First, researchers have described the metadata characteristics of YouTube videos exclusive of the content. A systematic review by Sampson et al [48] described that the most common video characteristics included in studies were the number of views, video length, likes, date posted, and language of the video. Similarly, a 2018 systematic review found number of views, video duration, and likes and dislikes to be the top 3 characteristics reported in evaluations of YouTube [49]. Other researchers [50] have suggested that view counts were the second most frequently cited concept in assessing quality on YouTube.

Second, reviews have reviewed the information quality of videos using validated instruments. These instruments are generic health information quality assessment tools, and they commonly describe the credibility of sources and information contained within publications. Commonly used instruments for evaluating the quality of health information incorporated in YouTube videos include DISCERN [51], Brief DISCERN [52], Patient Education Materials Assessment Tool [53], Health on the Net Foundation Code of Conduct [54], Flesch-Kincaid reading level [55], and guidelines from the *Journal of the American Medical Association* [56].

A third approach involves the evaluation of video content by expert clinicians. Expert clinicians have generally described the potential of YouTube as a self-management resource in positive terms [57]. Similarly, clinician reviewers have consistently noted concerns regarding the discovery of accurate clinical content. Clinician reviewers noted specific concerns about the selection of appropriate search terms [58], including the influences of algorithms [59], and video popularity (views) [60,61] as particular challenges in discovering accurate content.

In summary, the evaluation of YouTube videos is an underdeveloped area. Although there are several approaches to evaluating YouTube content, these are all time consuming, relatively complex, and thus unsuitable for shared care discussions in a clinical setting. Similarly, many patients turn to the internet for self-management advice, although they lack simple cues to identify the content that is consistent with current clinical guidelines.

Methods

Overview

This study was conducted to increase the understanding of YouTube information about ALBP in advance of potential feasibility and clinical studies. This exploratory study aims to (1) increase the understanding of the ALBP content available on YouTube in 2020 and (2) establish the plausibility of using a simple checklist to facilitate the discovery of YouTube content consistent with current ALBP guidelines. We defined plausibility as "a scenario is one that fits prior knowledge well, with many different sources of corroboration, without complexity of explanation, and with minimal conjecture" [62].

We examined the following 4 research questions: how was the data set defined?, what are the metadata characteristics of the videos in the data set?, what is the information quality of ALBP YouTube videos?, and what are the characteristics of the YouTube data set based on an ALBP self-management checklist?

This study incorporates 3 approaches to evaluate YouTube health content. These approaches are (1) analysis of metadata characteristics, (2) analysis of information quality, and (3) expert clinician review. In this study, we extended these approaches by classifying YouTube content based on author's professional discipline and substituted a simple checklist for clinician expertise to analyze ALBP self-management content.

We used 2 simple checklists to analyze the YouTube content within a defined data set. Checklists have been widely used in medicine to reduce costs and improve health outcomes [63]. Coding of all items in the data set was conducted by the 2 authors of this study. Intercoder reliability for all coding results was reviewed using Krippendorf alpha [64] (Multimedia Appendix 1).

This is an infodemiology study. Eysenbach described infodemiology as "the science of distribution and determinants of information" [65]. Infodemiology studies have primarily examined public health and policy issues [66]. In contrast, this study examined patterns of YouTube clinical information, with the ultimate aim of developing a novel clinical intervention for the self-management of ALBP.

RQ1: How Was the Data Set Defined?

Step 1: Selection of Appropriate Search Terms

Search is the most common approach for finding content on YouTube [67]. We identified the search terms "back pain" and

"lower back pain" as popular relevant YouTube search terms using Google Trends for YouTube [68] in Australia and the United States over the 5-year period 2015 to 2020. The third term "back pain exercises" was selected for both popularity and self-management relevance (Multimedia Appendix 2). These search terms were aimed at identifying ALBP content likely to be viewed by YouTube audiences in March 2020. However, no raw search volumes are available in Google Trends for YouTube. This means that a direct comparison of search volumes at the population scale is not possible. Furthermore, back pain epidemiology is imprecise, and the term "back exercises" is not relevant to ALBP epidemiology. Therefore, we used another high-burden disease, diabetes, as a search volume comparator in YouTube. Searches for diabetes and back pain on YouTube were comparable in Australia and the United States for the period between 2015 and 2020.

Step 2: Characteristics of Raw Data Set

We downloaded the metadata for the 300 top-rated English language videos across the 6 search categories in our raw data set in March 2020. The search term categories are described in Table 1. We used the video list module from the YouTube Data Tools (YTDT) developed by the University of Amsterdam to extract these metadata as individual comma separated values (CSV) format files for each of the 6 search categories [69]. The YTDT extract data directly from the YouTube application programming interface and make them available for download as a CSV file. The fields contained in the metadata include the number of views of each video at the specified date, length, internet address, publisher, and date of publication.

We aimed to account for YouTube Search personalization and algorithmic selection in our data set. By default, YouTube displays search results based on relevance. However, YouTube algorithms also modify search results with reference to personalized search history [70] and most viewed videos [71]. To account for relevance and popularity, we separately downloaded the YTDT metadata for the top 50 *most relevant* videos for each of the 3 search terms "back pain," "lower back pain," and "back exercises." We repeated this for the top 50 *most viewed* videos for each of the 3 search terms. Our raw data set thus consisted of 300 English language videos. These videos were divided across 6 separate search term categories, with 50 videos in each category. (See Table 1 and Multimedia Appendix 3).

Table 1. Percentage of videos from each discipline by search term, views, and relevance in raw data set.

Discipline	Lower back pain relevance, n (%)	Lower back views, n (%)	Back pain relevance, n (%)	Back pain views, n (%)	Back exercises relevance, n (%)	Back exercises views, n (%)
Chiropractic	6 (12)	7 (14)	6 (12)	16 (32)	5 (10)	2 (4)
Fitness	3 (6)	8 (16)	1 (2)	7 (14)	26 (52)	30 (60)
Medicine	11 (22)	4 (8)	12 (24)	3 (6)	1 (2)	1 (2)
Physiotherapy	21 (42)	11 (22)	25 (50)	7 (14)	18 (36)	13 (26)
Yoga	0 (0)	9 (18)	0 (0)	10 (20)	0 (0)	2 (4)
Other	9 (18)	11 (22)	6 (12)	7 (14)	0 (0)	2 (4)

Step 3: Validation of the Raw Data Set

By default, YTDT returns the US search results. The authors of this study were located in Australia. We were uncertain about how YouTube geographic and personalization algorithms influenced YTDT or YouTube search results in the location of the study. We therefore validated the YTDT results against the results from YouTube from Sydney, Australia, and from New York, United States. To do this, we first removed the personalization and geographic identifiers from our YouTube website search results. To remove personalization and geographic identifiers, we used a Chromebook with factory reset, Chrome browser with no sign in, and virtual private network (VPN) to link first to New York and second to Sydney. We separately recorded the results for the top 50 *most relevant* filtered videos for each of the 3 search terms "back pain," "lower back pain," and "back exercises." We repeated this for the top 50 *most viewed* videos for each of the 3 search terms. We then compared the YTDT raw data results with the New York and Sydney YouTube website results.

Step 4: Cleansing the Raw Data Set to Produce the Final Data Set

We identified multiple identical videos repeated across the 300 videos across the 6 separate categories in the YTDT raw data set. After removing the duplicates, we retained 202 unique videos across the 6 search categories. These 202 unique videos were pooled to form the final data set.

RQ2: What are the Metadata Characteristics of the Videos in the Final Data Set?

We examined the metadata characteristics of each video in the final data set. First, we coded the 202 unique videos in the final data set according to the author's stated disciplinary affiliation. We used the following 6 disciplinary categories: chiropractor, fitness, medical doctor, physiotherapist, yoga, and other (including osteopaths and massage therapists; Table 1 and Multimedia Appendix 4). Researchers have identified relationships between author's disciplines and user assessments of source credibility. The assessment of web-based source credibility is generally based on rapid evaluation of multiple content features, including visual design [72], trustworthiness and expertise of the source [73], and social cues such as likes and comments [74]. Source credibility is a dimension of user

engagement with video content and thus relevant to this study. Second, we coded each video according to the 3 content categories: education, real-time exercise, or real-time treatment. These categories were derived from the videos in the data set. Third, we incorporated YTDT data, including length of video, number of views, and YouTube channel name. Through this approach, we were able to describe the characteristics of the final data set by the author's professional discipline.

RQ3. What is the Information Quality of ALBP YouTube Videos?

We used a modified Brief DISCERN instrument to assess the information quality of the final data set for this study. The full DISCERN instrument has been widely used in YouTube research [75]. The 6-question Brief DISCERN was designed to be a simpler version of the full DISCERN for patient and clinician use [76]. The Brief DISCERN has been used to evaluate the quality of web-based health content [77]. However, we were not able to identify previous peer-reviewed research using the Brief DISCERN for YouTube analysis.

To analyze information quality, we first modified the Brief DISCERN instrument. We added an ALBP self-management–specific codebook to the original 6 items in the Brief DISCERN instrument (Multimedia Appendix 5). Second, we coded each video in the final data set using our modified Brief DISCERN instrument. Each video was coded as *yes* or *no* only. Third, we organized results by authors' disciplines. Thus, we used the unvalidated modified Brief DISCERN to analyze the information quality of videos in the final data set by the authors' discipline.

RQ4: What are the Characteristics of the YouTube Data Set Based on an ALBP Self-Management Checklist?

We analyzed the final data set based on the checklist of ALBP self-management strategies that we developed for this study. We included checklist items that an individual patient may reasonably be expected to independently implement as part of a self-management intervention for ALBP. In contrast to generic information quality YouTube evaluation tools such as DISCERN, this checklist incorporates specific ALBP self-management guideline-consistent items.

First, we developed a codebook for analyzing the data set using the ALBP checklist. The ALBP checklist was based on self-management items described in the Lancet 2018 ALBP guidelines [12] (Multimedia Appendix 6). This includes maintaining physical activity, education, identification of red flags, analgesia, and reassurance. Second, we coded each video in the data set using the ALBP self-management checklist. Third, we analyzed the ALBP checklist results by authors' disciplines. In summary, by examining the characteristics, information quality, and self-management content, we aimed to determine whether it was plausible that a checklist for YouTube video assessment may facilitate self-management of ALBP.

Results

Overview

We identified clear differences based on the author's discipline in the ALBP videos in our data set. We found that the videos authored by each discipline strongly featured a specific intervention domain such as education, treatment, or exercise. Using a checklist, we found that the videos authored by physicians were consistently coded with the highest ALBP self-management content scores relative to all other disciplines. We suggest that a checklist may facilitate the discovery of guideline-consistent ALBP YouTube content.

RQ1: How Was the Data Set Defined?

We compared the YTDT results with the Australian and US website results to determine the validity of the YTDT raw data set. We found that the US raw data set obtained via YTDT matched with the Australian and US YouTube website results obtained via anonymous sign in and VPN through Chromebook from New York and Sydney. After the removal of duplicates, we identified 202 unique videos. These 202 videos became our final data set (Multimedia Appendix 8). The final data set represented popular videos likely to be displayed to YouTube searchers for information on back pain in Australia and the United States in March 2020.

RQ2: What are the Metadata Characteristics of the Videos in the Data Set?

We had several notable findings from our analysis of the characteristics of the final data set. Videos published by mainstream health providers (physicians and physiotherapists) were more common in results filtered by *search relevance* than in *most viewed* categories (Table 1 and Multimedia Appendix 4). However, overall, ALBP videos published by other providers (chiropractors, fitness, yoga, and other categories) were viewed more often than mainstream health provider videos (Textbox 1 and Multimedia Appendix 7). Overall, chiropractic videos were the most viewed discipline in our final data set. We found that each discipline predominantly produced videos in a specific domain. For example, medical authors primarily published education videos, whereas chiropractors published primarily real-time treatment videos (Table 2 and Multimedia Appendix 8). The most viewed video in our data set featured real-time chiropractic treatment (Multimedia Appendix 9). This video scored poorly on the modified Brief DISCERN and ALBP checklists. User comments suggested that this video was commonly viewed for the purposes of sexual gratification. In summary, we identified clear differences in the ALBP videos in our data set based on the author's discipline. The disciplinary background of the ALBP video author appears to be a noteworthy consideration in selecting guideline-consistent YouTube videos appropriate for facilitating the self-management of ALBP.

Textbox 1. Video views by discipline (mean [SD]).

Chiropractic

- 5,946,902 (sample SD 11,566,170)

Fitness

- 2,161,920 (sample SD 1,638,935)

Medicine

- 2,731,637 (sample SD 3,770,147)

Physiotherapy

- 1,526,882 (sample SD 2,527,643

Yoga

- 4,822,096 (sample SD 2,868,535)

Other

- 6,465,767 (sample SD 9,298,051)

Table 2. Intervention domain by discipline (final data set).

Intervention domain	Number of videos	Education, n (%)	Exercise, n (%)	Treatment, n (%)
Chiropractic	27	2 (7)	6 (22)	19 (70)
Fitness	54	1 (2)	53 (98)	0 (0)
Medicine	20	20 (100)	0 (0)	0 (0)
Physiotherapy	66	5 (8)	60 (91)	1 (2)
Yoga	11	0 (0)	11 (100)	0 (0)
Other	24	1 (4)	5 (22)	18 (78)

RQ3. What is the Information Quality of ALBP YouTube Videos?

We used a modified Brief DISCERN checklist to examine the information quality of ALBP videos in the data set. We examined the information quality for each discipline separately (ie chiropractic, fitness, medicine, physiotherapy, yoga, and *other* categories). The number of videos in the final data set varied by discipline. We therefore displayed information quality results by each modified Brief DISCERN item as a percentage of the number of *yes* responses to that item (Table 3 and Multimedia Appendix 10). For example, in the medicine discipline, 75% (n=15) of videos were coded yes in response to Question 3 of the modified Brief DISCERN. Question 3 refers to videos featuring a biologically plausible mainstream explanation of the mechanism of treatment. In the case of the *medicine* category, 75% (n=15) of the videos were coded *yes* for providing a biologically plausible mainstream explanation of the mechanism of treatment action.

Table 3. Results of modified Brief DISCERN coding.

Intervention domain	Information sources, n (%)	When was the information published, n (%)	How it works? n (%)	Benefits, n (%)	Risks, n (%)	Overall quality of life, n (%)
Chiropractic	0 (0)	0 (0)	2 (6)	29 (94)	1 (3)	7 (23)
Fitness	1 (2)	11 (2)	0 (0)	15 (28)	1 (2)	8 (15)
Medicine	1 (5)	2 (10)	15 (75)	18 (90)	6 (30)	16 (80)
Physiotherapy	3 (5)	2 (3)	9 (14)	44 (67)	3 (5)	17 (26)
Yoga	0 (0)	0 (0)	0 (0)	11 (100)	0 (0)	11 (100)
Other	1 (4)	0 (0)	3 (13)	12 (52)	2 (8)	7 (30)

Overall, we found that videos categorized as *medicine* were consistently coded with higher scores than all other disciplines. These higher scores indicated that medically authored videos had the highest information quality. In contrast, videos from *fitness* and *other* disciplines were consistently coded with the lowest information quality scores.

RQ4: What are the Characteristics of the YouTube Data Set Based on an ALBP Self-Management Checklist?

We used the ALBP self-management checklist to examine the content for each discipline in the final data set. Overall, we found that medically authored videos were coded with consistently higher scores for self-management content than all other disciplines (Table 4 and Multimedia Appendix 11). Chiropractic and fitness videos were consistently coded with the lowest scores for ALBP self-management. Overall, we found that the ALBP self-management checklist may be more sensitive than the modified Brief DISCERN instrument in assisting researchers in identifying differences in self-management content among disciplines and among individual videos.

In summary, we identified clear differences in the ALBP videos in our data set based on the author's discipline. The author's discipline appeared to be a determinant of the number of views, information quality, and ALBP self-management content of the videos in the data set.

Table 4. Results of acute low back pain checklist coding.

Intervention domains	Acute, n (%)	Activities of daily living, n (%)	Analgesia, n (%)	Red flag, n (%)	Affect, n (%)	Appropriate prognosis, n (%)
Chiropractic	9 (29)	10 (32)	9 (29)	4 (13)	13 (42)	5 (16)
Fitness	18 (33)	4 (7)	1 (2)	9 (17)	19 (35)	4 (7)
Medicine	19 (95)	16 (80)	15 (75)	13 (65)	19 (95)	19 (95)
Physiotherapy	52 (79)	18 (27)	19 (29)	32 (48)	42 (64)	19 (29)
Yoga	11 (100)	5 (45)	8 (73)	0.00	11 (100)	11 (100)
Other	14 (61)	5 (22)	7 (30)	3 (13)	20 (87)	5 (22)

Discussion

Principal Findings

We identified considerable variability in the guideline concordance of ALBP self-management content on YouTube. We found that the video author's discipline is an indicator of the provision of guideline-consistent information. We suggest that the access to guideline-consistent ALBP content may be improved by referring to the author's discipline. Furthermore, we suggest that a checklist used with YouTube videos may facilitate the discovery of guideline-consistent ALBP self-management content. We have described the implications of our findings under the following categories: access and discovery, discipline-specific discovery, and self-management.

Access and Discovery

YouTube is a widely available and popular channel for health information. YouTube is free, multilingual, and easy to navigate, without commercial or professional gatekeepers. It is a visual medium demanding low literacy [78]. YouTube is a popular source of instructional advice [47]. Therefore, researchers have described the positive potential of YouTube as a patient resource [57]. YouTube has the potential to improve access to guideline-consistent self-management advice, consistent with patient preferences.

This study suggests that, in practice, the discovery of guideline-consistent ALBP self-management content on YouTube is a health access challenge. YouTube is not primarily a source of self-management health advice. It is a commercial platform directed at increasing viewing time [79]. To increase viewing time, YouTube constantly recommends different videos based on an individual's prior search history and personalized search algorithms.

Researchers and media have suggested that YouTube algorithms promote misinformation, including health misinformation [80,81]. During 2020, widespread concerns about social media dissemination of misinformation on COVID-19 led to YouTube both actively monitoring and restricting pandemic-related content [82]. However, the exceptional information environment present during the pandemic is unlikely to be replicated for all health conditions or for ALBP.

Health researchers have proposed several approaches for improving patient access to guideline-consistent YouTube self-management content. These approaches include encouraging health organizations and clinicians to increase their engagement with YouTube content [83], the use of celebrities in videos [61], shared clinical decision making based on YouTube content [84], algorithmic interventions [81,85], and direct government intervention [86]. On the basis of this study, condition-specific checklists may offer a potential approach to improve access to guideline-consistent ALBP self-management content.

Discipline-Specific Discovery

The YouTube video author's discipline may have implications for health access and content discovery. We identified consistent differences in information quality and ALBP self-management content between disciplines represented in our data set (Table 4). We believe that this may have implications for the discovery and use of ALBP content. The patient's perceptions of author's discipline may be reinforced by web-based source credibility effects [83,87]. For example, medical videos about ALBP may be regarded as more authoritative than chiropractic videos. The YouTube author's discipline may thus cue patients to specific ALBP self-management content. Although we did not assess the effects of source credibility, we believe that this dimension of YouTube health content warrants further investigation.

Author's discipline is a predictor of the content of an individual video. We found that 100% (N=20) of the medical videos were

coded as primarily educational content, 70% of the chiropractic videos were real-time treatments, and 90% of physiotherapist-authored videos consisted primarily of exercise content (Table 2). This suggests that author's discipline may also be used to guide clinicians when considering the selection of guideline-consistent educational and exercise content for ALBP self-management interventions.

Self-Management and Shared Care

The variability of YouTube health content is generally described as having negative implications for the self-management and self-care of health conditions. Within peer-reviewed health literature, inaccurate content and poor-quality information sources are often described as misleading to YouTube viewers. However, self-management and self-care are not passive patient processes [29,30]. Researchers have suggested that these processes involve active patient decision making, incorporating active information search and interpretation, symptom monitoring, goal setting, and self-efficacy.

Engagement with YouTube videos should not be considered a passive or uncritical process. In the case of health content specifically, viewers may be motivated to exert additional cognitive effort during decision making [88,89]. The additional individual cognitive effort may be characterized as the *Ikea effect* [90]. The Ikea effect suggests that individuals' task engagement and self-efficacy may be enhanced through personalization and discovery. Similar guided discovery effects have been noted in educational research [91]. In the case of ALBP, clinician guidance of video discovery based on patient preferences may facilitate effective self-management.

Simple checklists may improve clinician engagement with internet-informed patients. Clinician engagement with internet-informed patients is frequently described as poor [43,44]. Clinician engagement with individual patients over video content may enhance adherence to self-management recommendations. The reported benefits of clinician-guided use of YouTube for self-management include reinforcement of emotional support and clinician advice [92], preclinical screening [93,94], and as a substitute for clinician advice in instances of poor communication during clinical interactions [36]. An ALBP-specific checklist may cue patients to specific domains in advance of health care encounters and provide the foundation for more positive shared care engagements focused around ALBP internet content. Under these conditions, clinicians may choose to actively recommend web-based content rather than defensively respond to patient questions.

In summary, we suggest that the discovery of an appropriate YouTube video for ALBP self-management is highly variable. This is consistent with the existing literature on YouTube health content. However, the use of an ALBP checklist by clinicians may plausibly facilitate access to guideline-consistent ALBP self-management content. For clinicians, an ALBP checklist may also facilitate engagement with internet-informed patients.

Limitations

We identified several limitations in this study.

Limitations of YouTube Geolocation Data

This research was conducted in Australia. We used US YouTube data to investigate English-language YouTube viewing behavior based on global viewing statistics. Country-specific YouTube views data for individual videos are not available in the public domain. Similarly, Google Trends YouTube data are not directly comparable across countries as it is normalized and displayed as percentages only [95]. These YouTube limitations restrict the potential matching with epidemiological, health insurance, waiting times, policy, and other population data sources. However, studies within a specific geographic location that focus on the use of YouTube for self-management of health conditions could incorporate these dimensions into study designs and results.

Limited Examination of Metadata

The YTDT metadata tool contains multiple metadata fields describing each video, including all available comments. In this study, we used only the URL, channel name, and video length. We believe video recommendations within YouTube merit investigation for evaluating video popularity and engagement, consistent with research conducted by Zhou et al [96]. Analysis of YouTube comments has been identified as a rich source of data. Analysis of comments and other metadata was beyond the scope of this study.

Scope of YouTube Content

The analysis in this paper was based exclusively on existing publicly available YouTube content. In addition to YouTube, there are multiple commercial ALBP apps and video content available on proprietary distribution channels. The analysis of health provider commercial and proprietary content was outside the scope of this study.

Digital Divide as an Access Consideration

We did not examine differential access to YouTube based on age, income, or ethnicity. Future research examining the feasibility of YouTube in clinical settings should examine access to YouTube by older and low-income people.

Further Research

Further research is needed to establish the feasibility of checklists and YouTube content discovery for self-management of ALBP in specific clinical contexts. We propose 2 directions for future research to extend this exploratory research into clinical practice. First, a future research program could refine the questions of feasibility, including cost-effectiveness and clinical utility. We suggest that the next stage of research on the use of YouTube for self-management of ALBP could focus on establishing feasibility in a specific clinical context, such as low acuity low back pain interventions by paramedics. Second, during 2020, COVID-19 accelerated the demand and supply for telehealth across the globe [97]. This has also accelerated the experimentation with novel clinical approaches. In light of the rapid uptake of telehealth during 2020, further research into the feasibility of incorporating YouTube with telehealth self-management may be warranted.

Conclusions

Individuals are increasingly using YouTube to self-diagnose and self-manage health conditions, including ALBP. However, the results returned by YouTube in response to searches for back pain content were highly variable. This exploratory study aims to increase the understanding of the ALBP content available on YouTube in 2020 and to establish the plausibility of using a simple checklist to facilitate the discovery of YouTube content that is consistent with current management guidelines. We suggest that a simple checklist may facilitate the discovery of guideline-consistent ALBP self-management content on YouTube. Further research may identify the clinical contexts in which the use of an ALBP checklist with YouTube is feasible.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Krippendorf alpha intercoder reliability.
[PDF File (Adobe PDF File), 41 KB - formative_v4i11e23366_app1.pdf]

Multimedia Appendix 2
Google Trends YouTube. Relevant terms.
[PDF File (Adobe PDF File), 216 KB - formative_v4i11e23366_app2.pdf]

Multimedia Appendix 3
Percentage of videos from each discipline by search term, views, and relevance in raw data set.
[PNG File , 117 KB - formative_v4i11e23366_app3.png]

Multimedia Appendix 4
Video views by discipline (mean).Final data set.
[PNG File , 105 KB - formative_v4i11e23366_app4.png]

Multimedia Appendix 5
Intervention domain by discipline. Final data set.
[PNG File , 122 KB - formative_v4i11e23366_app5.png]

Multimedia Appendix 6
Modified Brief Discern code book.
[PDF File (Adobe PDF File), 56 KB - formative_v4i11e23366_app6.pdf]

Multimedia Appendix 7
ALBP checklist code book.
[PDF File (Adobe PDF File), 62 KB - formative_v4i11e23366_app7.pdf]

Multimedia Appendix 8
Final data set.
[PDF File (Adobe PDF File), 114 KB - formative_v4i11e23366_app8.pdf]

Multimedia Appendix 9
Most viewed video in final data set.
[PDF File (Adobe PDF File), 40 KB - formative_v4i11e23366_app9.pdf]

Multimedia Appendix 10
Results of modified Brief Discern coding.
[PNG File , 40 KB - formative_v4i11e23366_app10.png]

Multimedia Appendix 11
Results of ALBP checklist coding.
[PNG File , 62 KB - formative_v4i11e23366_app11.png]

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Abbreviations

ALBP: acute low back pain
CSV: comma separated values
DHI: digital health intervention
RQ: research question
VPN: virtual private network
YTDT: YouTube data tools

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Original Paper

Partnering With Massage Therapists to Communicate Information on Reducing the Risk of Skin Cancer Among Clients: Longitudinal Study

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Abstract

Background: Skin cancer affects millions of Americans and is an important focus of disease prevention efforts. Partnering with non–health care practitioners such as massage therapists (MTs) can reduce the risk of skin cancer. MTs see clients' skin on a regular basis, which can allow MTs to initiate "helping conversations" (ie, brief behavioral interventions aimed at reducing the risk of skin cancer).

Objective: The purpose of this study was to evaluate (1) the feasibility of recruiting, enrolling, and retaining Arizona MTs in an online electronic training (e-training) and (2) the preliminary efficacy of e-training on knowledge, attitudes/beliefs, and practice of risk reduction for skin cancer. We explored MTs' ability to assess suspicious skin lesions.

Methods: We adapted the existing educational content on skin cancer for applicability to MTs and strategies from previous research on helping conversations. We assessed the feasibility of providing such e-training, using Research Electronic Data Capture (REDCap) tools for data capture. We assessed the preliminary efficacy using established self-report surveys at baseline, immediately post training, and at 3 and 6 months post training.

Results: A total of 95 participants enrolled in the study, of which 77% (73/95) completed the assessments at 6 months (overall attrition=23%). Project satisfaction and e-training acceptability were high. Knowledge, personal behaviors (skin self-examination, clinical skin examination, sun protection frequency), and practice attitudes (appropriateness and comfort with client-focused communication) of risk reduction for skin cancer improved significantly and were sustained throughout the study.

Conclusions: The e-training was feasible and could be delivered online successfully to MTs. Participants were highly satisfied with and accepting of the e-training. As such, e-training has potential as an intervention in larger trials with MTs for reducing the risk of skin cancer.

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KEYWORDS

cancer prevention; skin cancer; e-training; electronic intervention; massage therapists

Introduction

Skin cancer, the most common cancer in the United States, poses a serious public health burden. Over 5.4 million nonmelanoma skin cancers are treated annually [1]. The incidence of melanoma, the most fatal form of skin cancer, increases by about 3% each year among persons aged >50 years [2]. Skin cancer costs exceed billions of dollars annually [3].

Fortunately, the skin cancer burden can be abated through primary prevention and early detection.

Protecting the skin from ultraviolet radiation reduces the risk of skin cancer [4,5]. Recommended primary prevention behaviors are as follows: avoid prolonged sun exposure during peak intensity, cover the skin with tightly woven protective clothing (eg, long sleeves/pants, wide-brimmed hats, and sunglasses), seek shade, apply/reapply sunscreen, and avoid all kinds of intentional tanning [6]. Early skin cancer detection decreases potential morbidity, mortality, and cost [2,3] and can be carried out with viewable skin assessment (VSA) by health professionals or with skin self-examination (SSE) by consumers. Skin lesions can be assessed using several approaches, one of which is the common asymmetry, border, color, diameter, evolving (ABCDE) rule [7].

One approach for delivering risk-reducing information on skin cancer is a structured "helping conversation," a person-centered communication technique that emphasizes on active listening and motivational communication to encourage healthy behavior change [8]. A helping conversation consists of 4 steps: awareness, understanding, helping, and relating [9]. Helping conversations are context-specific and thus cost-effective and time efficient [8]; they have been used for other preventive behaviors [8,10] but not in the context of risk reduction for skin cancer.

The *Surgeon General's Call to Action to Prevent Skin Cancer* [6] endorses community partnerships for reducing the risk of skin cancer. Community partners who can implement helping conversations about reducing the risk of skin cancer include massage therapists (MTs). Compared to primary care providers or dermatologists, MTs are more likely to have repeated and longer appointments that are oriented toward health promotion [11-13], thereby providing greater opportunities for helping conversations. MTs uniquely access most of a client's skin, allowing VSA. Approximately 385,000 MTs and MT students nationwide, provided with training, have the potential to engage in helping conversations [14].

Some MTs receive education on skin cancer during primary training (60%) and continuing education (25%) [15]; however, the content, duration, and source of this education vary. The few existing skin cancer–focused in-person workshops and 1 online course do not include training for client-focused communication on reducing the risk of skin cancer [15]. There is a need to assess the feasibility of providing such training to MTs, particularly considering the popular press stories of their involvement in early detection [15-17].

Our goal was to develop and evaluate the feasibility of delivering online e-training on reducing the risk of skin cancer, to MTs within the context of a helping conversation. Specific aims of this study were as follows:

1. Assess e-training feasibility, namely, facilitators and barriers to recruitment and enrollment, intervention completion and acceptability, and client acceptability of helping conversations.
2. Analyze the preliminary efficacy of e-training preliminary efficacy in terms of knowledge, personal/practice-based attitudes/beliefs, and practice factors of risk reduction for skin cancer, from baseline to immediately post training and 3 and 6 months post training.
3. Explore the assessment of suspicious versus nonsuspicious skin lesions.

Methods

The University of Arizona Institutional Review Board approved this study. Data collection was performed between July 1, 2018, and April 1, 2020. Data analysis was completed on April 27, 2020. The study had 3 phases. In phase 1, we developed e-training content, assessments, and technology. In phase 2, we conducted a feasibility study (recruitment, screening, and enrollment; e-training implementation; and assessment of the main variables at 4 time points). In phase 3, we conducted data analysis and interpretation. We have previously published the protocol for this study [9], which is briefly summarized below.

Conceptual Framework

Social cognitive theory (SCT) posits that individuals learn and maintain new behaviors through reciprocal interaction of person, environment, and behavior [18]. This study was guided by 4 SCT constructs: (1) reciprocal interaction of MTs, their external social contexts, and behavioral responses to the e-training; (2) behavioral capability to have a helping conversation; (3) observational learning from e-training vignettes; and (4) self-efficacy for mastery of knowledge and practice changes.

Study Population

We initially recruited a single cohort of MTs through professional networking, social media posts (on Facebook), flyer postings at MT practices, peer referral, massage school listservs, and online newsletter postings. Eligibility criteria were as follows: age ≥21 years, licensed in Arizona, practicing for at least 3 years, averaging at least 5 clients per week, and internet access. Eligible MTs provided informed consent prior to enrollment. Participants received US $200 for the 6 months of participation and continuing education credit units.

Sample Size

Sample size estimations were based on prior studies of skin cancer training for medical students [19] and our research on helping conversations about tobacco cessation with MTs [10]. A repeated measures power analysis for proportions (effect size 16% at pretest and 51% at posttest) indicated that 40 MTs would be needed (α=.05; β=.9). The reported attrition from online trainings ranged from 20% to 80% [20,21]. Enrolling 80 MTs would allow for attrition and reasonable estimation of sample size and recruitment and attrition in a future trial [19]. Power analyses were conducted using PASS software (version 12) [22].

Intervention

The e-training was built on previously developed skin cancer prevention e-training [23] and established competencies of helping conversations [8]. Participants sequentially completed 6 asynchronous, self-paced modules: introduction, awareness, understanding, helping, relating, and closing. After the modules, they completed 5 simulations of MT-client encounters, reflecting

helping conversations that could occur during a 60-minute, full-body massage.

Measures

Using Research Electronic Data Capture (REDCap) tools hosted at the University of Arizona [24,25], we collected data at 4 time points: baseline (at enrollment), 1 week post training, 3 months post training, and 6 months post training. REDCap is a secure, web-based software platform for supporting data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and exporting, (3) automated export procedures for seamless data download to common statistical packages, and (4) procedures for data integration and interoperability with external sources.

To assess e-training feasibility, we maintained detailed recruitment and enrollment records, coding how each potential participant learned of the study. This allowed us to determine the participant yield from each strategy. We used REDCap reporting capabilities to assess e-training completion rates.

Participants responded to 8 e-training satisfaction items (5-point scale, completely unsatisfied=1 to completely satisfied=5). To assess acceptability of the helping conversations of participating MTs, clients completed a 10-item anonymous survey accessible via a quick response (QR) code embedded in the flyers posted at the participating MTs' practices. If a helping conversation occurred, then the client selected topics mentioned by the MT, along with their recommendations (5-point scale, strongly disagree=1 to strongly agree=5). Clients received a US $5 gift card for participating.

To assess the preliminary efficacy of e-training, we measured general knowledge on skin cancer with 16 multiple-choice items adapted from previous research (scored as correct or incorrect) [26] and 1 item measuring knowledge of the ABCDE rule (scored as correct or incorrect). We measured self-efficacy using a 10-item general self-efficacy scale [27] (4-point scale, not at all true=1 to exactly true=4; total score is calculated by finding the sum of all items and ranges between 10 and 40 with a higher score indicating more self-efficacy). Personal beliefs and attitudes were measured with 1 item for assessing participants' perceived probability of getting skin cancer in the future (scored from 0%-100%), 5 items for appropriateness of including information about reducing the risk of skin cancer in client interactions, and 3 items about their own comfort with and confidence during those interactions (5-point scale, strongly disagree=1 to strongly agree=5).

We measured participants' personal behaviors of skin cancer risk reduction with 5 items pertaining to the frequency of sun protection behaviors (5-point scale, never=1 to always=5) and 1 item each for tanning booth visitation (5-point scale, in the past month=1 to never=5), SSE (5-point scale, never=1 to more than once a month=5), VSA (5-point scale, never=1 to more than once a month=5), and clinical skin examination (5-point scale, never=1 to more than once monthly=5).

Using a 29-item questionnaire on case-based image assessment adapted from a medical continuing education training [28], we measured participants' ability to assess skin lesions. Participants viewed photos of skin lesions accompanied by brief case descriptions, scoring each image as suspicious or not suspicious (scored as correct or incorrect).

We invited participants based in Tucson, Arizona, (n=10) to an in-person posttraining debriefing. We asked them about their overall e-training experience (key takeaways, application in practice, and confidence regarding helping conversations). We asked whether they had noticed any suspicious lesions on a client's skin during study participation and how we could improve the e-training. Study personnel took detailed notes and compiled the comments.

Statistical Analysis

We assessed all data for missing and outlier values, deleting missing values listwise and double-checking and verifying outlier data. To describe demographic variables, we computed frequencies and means. We also computed individual composite scores, which summed the average answer value for each item of each of the assessment questionnaires: self-efficacy, personal beliefs and attitudes, and frequency of sun protection behavior.

We scored general skin cancer knowledge questions as percentages of correct or incorrect answers and computed mean scores for questions with continuous answers, such as perceived probability of getting skin cancer. We computed the percentages of correct and incorrect answers for image assessments. Using repeated measures analysis of variance, we evaluated longitudinal differences in composite scores for each of the measures; percentage of correct answers; and continuous variables at baseline, immediately post training, and at 3 and 6 months post training. We used Intercooled Stata, version 15 (Stata Corp), and applied a significance level of .05 for all statistical tests.

Results

A total of 95 participants enrolled in the study: 77% (73/95) completed all assessments at 6 months. The final sample had a mean age of 46 years; was predominantly female (93%), non-Hispanic or Latino (89%), and White (83%); worked part-time; and saw <11 new or returning clients per week (Table 1). There were no major differences in the demographic characteristics between participants who completed the e-training and those who completed the training and all assessments.

Table 1. Demographic characteristics of the sample (N=73).

Characteristics	Values
Age in years, mean (SD)	46 (12)
Hours worked per week, mean (SD)	23 (10)
Number of new clients per week, mean (SD)	9 (9)
Number of returning clients per week, mean (SD)	11 (7)
Gender, n (%)	
Male	5 (7)
Female	68 (93)
Ethnicity, n (%)	
Hispanic or Latino	8 (11)
Non-Hispanic or Latino	64 (89)
Prefer not to answer	0 (0)
Race, n (%)	
American Indian or Alaskan Native	4 (6)
Asian	3 (4)
Black or African American	4 (6)
Native Hawaiian or other Pacific Island	1 (1)
White	60 (83)
Prefer not to answer	0 (0)
Personal history of skin cancer = yes, n (%)	7 (9)
Family history of skin cancer = yes, n (%)	40 (55)

During recruitment, 225 MTs requested study information. Out those, 170 (68%) underwent eligibility screening, and 95 (42%) were enrolled (see Figure 1 for recruitment yield). Overall attrition following enrollment was 23% (Figure 1). Participant acceptability of the e-training and study procedures are shown in Table 2.

A total of 57 clients reported visits with 9 participating MTs (who did not vary in demographics from the overall sample). Clients reported 55 helping conversations, primarily focusing on skin cancer prevention. Conversations mentioned the topics of sunscreen (91%), protective clothing (76%), and wide-brimmed hats (74%). Clients agreed that MTs appropriately initiated the helping conversation (mean 4.41, SD 0.92). Clients were accepting of questions by their MT about sun safety and sun protection behaviors (mean 4.09, SD 1.35), SSE behaviors (mean 3.78, SD 1.65), suggestions regarding skin cancer prevention (mean 4.35, SD 0.99), and shared information about skin cancer prevention (mean 4.45, SD 0.97). Clients were less accepting of queries about marks on their skin (mean 2.30, SD 2.33) and referral to a dermatologist (mean 2.92, SD 2.26).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

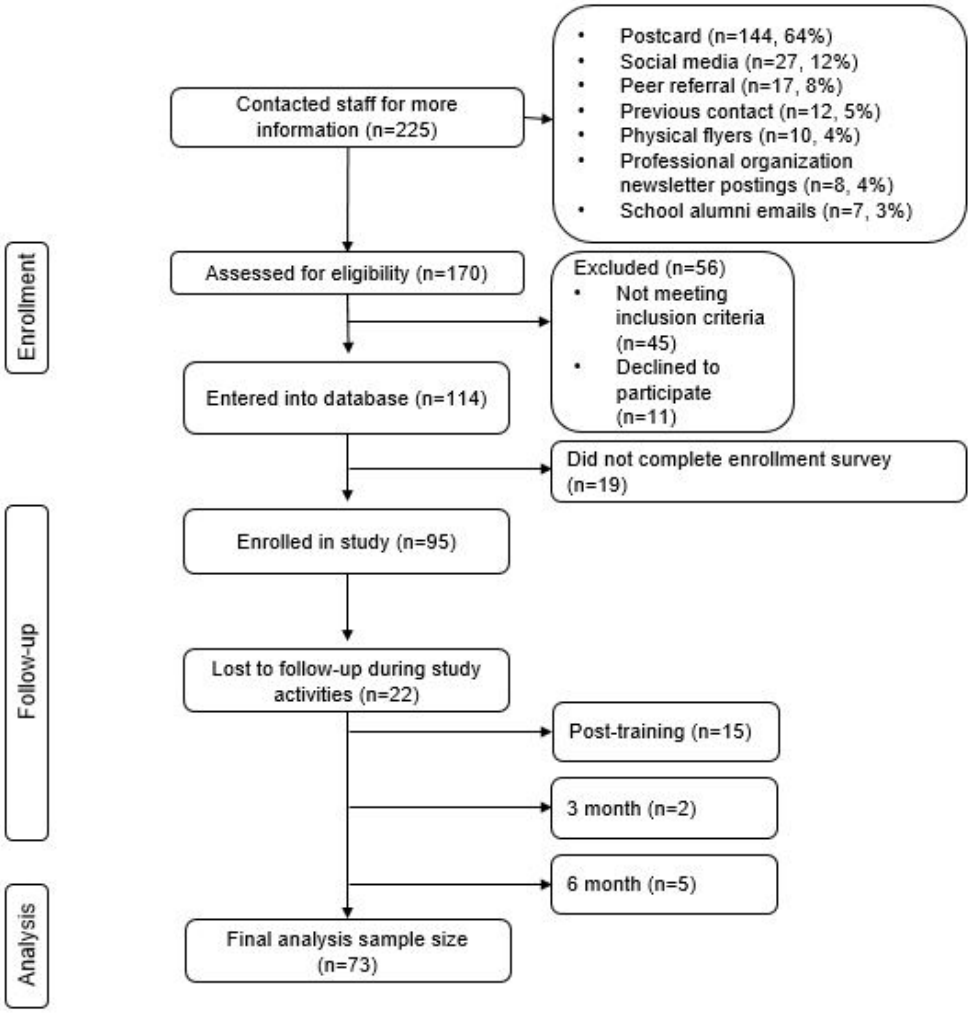

Table 2. Project satisfaction and attitudes toward training (N=73).

Criteria	Values, mean (SD)
Project satisfaction (1=completely unsatisfied; 5=completely satisfied) (N=73)	
Overall, how satisfied were you with participation in this project?	4.4886 (0.99)
How would you rate the quality of the information you received as part of this project?	4.4953 (0.62)
How would you rate the value of this project based on the amount of time you participated?	4.5022 (0.84)
How responsive were study staff to your questions or concerns about the project?	4.5092 (0.69)
How likely are you to continue using the skin cancer risk reduction knowledge you learned?	4.5024 (0.52)
How likely are you to continue to use the helping conversation skills you learned?	4.4955 (0.67)
How likely is it that you would recommend this training to a colleague?	4.5024 (0.90)
Overall, how satisfied were you with the training?	4.47 (0.65)
Scale mean	4.51 (0.01)
Attitudes toward training (1=strongly disagree; 5=strongly agree) (N=81)	
I would take this training only if continuing education units were offered.	2.7 (1.12)
The time commitment required for the training was realistic.	4.31 (0.75)
The training met my personal expectations.	4.12 (0.84)
I would take this training without receiving an incentive.	3.73 (0.99)
I learned more than I knew before about skin cancer risk reduction.	4.14 (0.96)
I trusted the information I received from the training.	4.49 (0.74)
The content of the training was useful for my daily life.	4.43 (0.78)
The training helped build my self-confidence.	3.9 (0.96)
I would recommend this training to others.	4.38 (0.81)

During the debriefing session, participants stated that the e-training component of the helping conversation was the easiest to remember. Helping conversations were new knowledge to most participants, encouraging communication skills that were not emphasized during their MT education. A common theme was posttraining confidence in discussing skin cancer risk reduction. Participants also found that their existing clients were more accepting of conversations than new clients. The most common conversation topics were prevention-oriented, such as reducing sun exposure; these conversations often started with variations of the example phrases provided in the e-training (eg, "what do you do to protect yourself from the sun?"). Moreover, 2 MTs reported mentioning suspicious lesions to clients, which were later diagnosed as skin cancers by a dermatologist.

Preliminary efficacy results for knowledge, personal and practice beliefs, and behaviors are shown in Table 3 along with the exploratory findings for the case-based image assessment. During the in-person debriefing session, participants commented that they would have preferred more examples of suspicious skin lesions and correct answers to each case. Participants felt there was no harm in labeling every image as suspicious or eliciting concern to avoid missing any important findings.

Table 3. Knowledge, personal beliefs/attitudes, and practice attitudes.

Criteria	Composite scores of correct answers				*P* value[a]
	Baseline	Posttest 1	Posttest 2	Posttest 3	
Knowledge					
General skin cancer knowledge	0.57	0.74	0.71	0.71	<.001
ABCDE[b] knowledge	0.64	0.68	0.68	0.83	.002
Case-based image assessment	0.74	0.72	0.72	0.72	.04
Personal beliefs/attitudes					
Prevention beliefs	3.79	3.92	3.63	3.59	<.001
Prevention behavior: SSE[c]	2.97	3.23	3.42	3.53	<.001
Prevention behaviors: clinical skin examination	1.99	2.08	2.27	2.33	<.001
Frequency of sun protection behavior	3.73	3.82	3.84	3.84	.03
General self-efficacy	34.54	34.08	33.95	34.45	.19
Perceived potential risk of skin cancer (on the scale of 1 to 100)	44.54	43.29	39.46	40.91	.10
Practice attitudes					
Appropriateness of client interactions	3.97	4.33	4.22	4.33	<.001
Confidence in client interactions	4.11	4.48	4.44	4.46	<.001
Confidence in protecting one's own skin	3.43	3.52	3.53	3.55	.18
Confidence in assessing one's own skin	3.34	3.5	3.48	3.51	.08

[a]Statistical significance (P<.05) for repeated measures analysis of variance.

[b]ABCDE: asymmetry, border, color, diameter, evolving.

[c]SSE: skin self-examination.

Discussion

Feasibility

The key finding was that the e-training was feasible and could be delivered online successfully. Similar to our pilot study [9], participants were highly satisfied with and accepting of the e-training. Clients were also satisfied with their MTs discussing skin cancer–prevention topics.

The main challenge was recruitment. Previous studies of MTs recruited participants attending massage therapy conferences [15,29]. To the best of our knowledge, this study was the first to recruit MTs for research from statewide independent, group, and national chain practices. Our initial multipronged recruitment efforts resulted in a surge of interested MTs that lasted 2 months. Contacts then lagged until we contacted the Arizona Chapter of the American Massage Therapy Association, purchased their mailing list, and mailed recruitment postcards to members as a secondary strategy. Contrary to previously reported observation of higher success with using social media versus direct mail to recruit hard-to-reach populations [30], the mailed postcard was the most effective recruitment strategy in our study. We did not ask participants why this strategy was successful but surmised that they preferred a direct outreach approach with targeted mailings [31] or did not tend to engage in social media.

Despite recruitment challenges, participants tended to stay in the study. According to the debriefing comments, once they completed the e-training, incentives such as continuing education credit and their own desire to add to the body of knowledge of their profession maintained their participation. This thinking reflected surveyed attitudes toward the e-training, with participants indicating that they would take the training without incentives and continuing education credit. This form of altruism is not unusual in community-based research, where participants desire to have a connection to science and their profession [32]. However, we would recommend incentives for future studies of this scope.

Collecting client survey responses was another challenge. MT participants received flyers that provided access to the client survey for posting in their practices; however, we had limited knowledge of whether they posted those flyers. We concur with others that flyers have limited utility [33]. At the 3- and 6-month evaluations, we asked MTs to remind clients about the survey, which appeared to improve the client survey response.

Preliminary Efficacy

The key finding was that participants' knowledge, personal behaviors (SSE, clinical skin examination, and frequency of sun protection), and practice attitudes (appropriateness and comfort with client-focused communication) of risk reduction for skin cancer improved and were sustained throughout the duration of the study. Despite these positive findings, there are some persistent issues.

Improved skin cancer knowledge is consistent with findings of previous education interventions for skin cancer provided to

MTs or cosmetologists [29,34]. Although knowledge improved, it improved to a barely "passing score," which reflected the passing score (70%) required for the Massage & Bodywork Licensing Examination (MBLEx) [35]. The most common incorrect knowledge answers selected at 6 months were the strongest risk factor for melanoma, indices important for reducing exposure to ultraviolet radiation, and recommended sunscreen ingredients. We are considering adding "boosters" to the revised e-training to further improve knowledge that is critical to helping conversations.

Attitudes favorably increased over the duration of the intervention except for self-efficacy and perceived risk of skin cancer. The general self-efficacy scale reflects a belief that an individual is capable of performing novel or difficult tasks and coping with adversity [27]. Self-efficacy scores did not significantly change over the 3 data collection points. Although participants had positive general self-efficacy, they were neutral in their confidence for protecting and assessing their own skin. They were more comfortable discussing skin cancer risk reduction with their clients, which reflects findings from other studies [15]. A situation-specific self-efficacy measure may be more useful in characterizing MTs' self-confidence, particularly that of helping conversations. A perceived risk of skin cancer is most commonly considered a stable belief; however, it could change under specific circumstances, such as a personal skin cancer diagnosis [36].

Exploratory Aim: Case-Based Image Assessment

We explored whether participants could assess a suspicious versus nonsuspicious skin lesion using the ABCDE rule. Although participants' understanding of the rule improved over time, mean correct scores on the case-based image assessment at all time points fell in the range of 72%-74%. Trotter et al [29] had a similar finding in their image assessment using just 4 images. Participants in our study tended to correctly score "ugly duckling" (unsightly) lesions and incorrectly score nonsuspicious lesions. This pattern has been reported in other studies of case-based image assessments [29]. The drop in scores following the training may be attributable to MTs' opinions mentioned during the debriefing session, where they would "rather be safe than sorry" and were likely to select all images as suspicious and warranting referral. Throughout the study, MTs shared their desire for more images of skin cancers as well as the correct answers to the image assessment. Although the latter was not feasible as per the study design, future e-training content will use a larger image bank that will enable us to alternate image choices during data collection and provide immediate feedback.

Additional Limitations

There is some missing data in our analysis due to our failure to initially force item responses and initially develop asynchronous/chained survey invitations when designing the online instruments. We added questions (MT practice type and asking for more specific training feedback) shortly after the enrollment began, further resulting in missing data from the previous version. In total, 3 participants failed to fully complete a total of 7 surveys between them. Our Arizona-specific sample also limits generalizability to MTs in other geographic areas. The heterogeneity of MT practice models (eg, sole proprietor, employee, partner, and independent contractor) made it challenging to recruit participants and collect data for client surveys. Noninclusion of a control group limits the strength of our findings and will be incorporated in future research.

Conclusions

Our results demonstrated that it is possible to engage practicing MTs in a skin cancer education study and that MTs will complete e-training. We also demonstrated that although MTs completed 2-hour-long, case-based e-training, it was not sufficient to significantly increase their self-efficacy in initiating helping conversations about skin cancer with clients or their ability to recognize images of skin cancers. The e-training increased their knowledge about skin cancer prevention and early detection.

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Conflicts of Interest

None declared.

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Abbreviations

ABCDE: asymmetry, border, color, diameter, evolving
e-training: electronic training
MBLEx: Massage & Bodywork Licensing Examination
MT: massaging therapist
QR: quick response
SCT: social cognitive theory
SSE: skin self-examination
VSA: viewable skin assessment

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Original Paper

A Behavioral Change Smartphone App and Program (ToDo-CR) to Decrease Sedentary Behavior in Cardiac Rehabilitation Participants: Prospective Feasibility Cohort Study

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Abstract

Background: Cardiac rehabilitation participants are encouraged to meet physical activity guidelines to reduce the risk of repeat cardiac events. However, previous studies have found that physical activity levels are low and sedentary behavior is high, both during and after cardiac rehabilitation. There is potential for smartphone apps to be effective in reducing sedentary behavior, although among the few studies that have investigated smartphone apps in cardiac rehabilitation, none targeted sedentary behavior.

Objective: This study aims to evaluate the feasibility of a behavioral smartphone app (Vire) and a web-based behavior change program (ToDo-CR) to decrease sedentary behavior in cardiac rehabilitation participants.

Methods: Using a single-center, pre-post design, participants were recruited by nursing staff on admission to cardiac rehabilitation. All eligible participants installed the Vire app, were given a Fitbit Flex, and received the 6-week ToDo-CR program while attending cardiac rehabilitation. The ToDo-CR program uses personalized analytics to interpret important behavioral aspects (physical activity, variety, and social opportunity) and real-time information for generating and suggesting context-specific actionable microbehavioral alternatives (Do's). Do's were delivered via the app, with participants receiving 14 to 19 Do's during the 6-week intervention period. Outcome measures were collected at 0, 6, and 16 weeks. The assessors were not blinded. Feasibility outcomes included recruitment and follow-up rates, resource requirements, app usability (Unified Theory of Acceptance and Use of Technology 2 [UTAUT2] questionnaire), and objectively measured daily minutes of sedentary behavior (ActiGraph) for sample size estimation. Secondary outcomes included functional aerobic capacity (6-min walk test), quality of life (MacNew Heart Disease Health-Related Quality of Life Questionnaire), anxiety and depression (Hospital Anxiety and Depression Scale questionnaire), BMI, waist circumference, waist-to-hip ratio, and blood pressure.

Results: Between January and May 2019, 20 participants were recruited consecutively. One-third of people who commenced cardiac rehabilitation were eligible to participate. Other than declining to take part in the study (15/40, 38%), not having a smartphone was a major reason for exclusion (11/40, 28%). Those excluded without a smartphone were significantly older than participants with a smartphone (mean difference 20 [SD 5] years; $P<.001$). Participants were, on average, aged 54 (SD 13) years, mostly male (17/20, 85%), and working (12/20, 67%). At 6 weeks, 95% (19/20) of participants were assessed, and 60% (12/20) of participants were assessed at 16 weeks. Participants were relatively satisfied with the usability of the app (UTAUT2 questionnaire). Overall, participants spent 11 to 12 hours per day sitting. There was a medium effect size (Cohen $d=0.54$) for the reduction in sedentary behavior (minutes per day) over 16 weeks.

Conclusions: The use of a behavioral smartphone app to decrease sitting time appears to be feasible in cardiac rehabilitation. A larger randomized controlled trial is warranted to determine the effectiveness of the app.

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KEYWORDS

mHealth; eHealth; sedentary behavior; cardiac rehabilitation; mobile phone

Introduction

In 2017, ischemic heart disease resulted in 8.93 million deaths worldwide and was the leading cause of years of life lost, which is a measure of premature death [1]. Physical inactivity and sedentary behavior are independent risk factors for cardiovascular disease, including ischemic heart disease, and all-cause mortality in both healthy and cardiovascular disease populations [2,3]. People with cardiovascular disease who watched television for 4 or more hours per day, a marker of sedentary behavior, were found to have a 52% increase in all-cause mortality compared with those who watched television for less than 2 hours per day [4]. Cardiac rehabilitation, a secondary prevention program, aims to reduce the risk of repeat cardiac events by targeting modifiable risk factors for ischemic heart disease, such as physical inactivity, smoking, and diet [5-7]. Despite strong scientific evidence for exercise-based cardiac rehabilitation decreasing morbidity and mortality in patients with heart disease, studies have found that physical activity levels are low in cardiac rehabilitation participants and sedentary behavior is high, approximately 8 to 11 hours a day [8-11].

The development of smartphone apps has been extensive in recent years, with many targeting healthy behaviors, including encouraging physical activity, offering health and exercise monitoring, motivation, and education [12,13]. At present, there is limited evidence regarding the effectiveness of smartphone apps in improving physical activity and sedentary behavior in healthy and heart disease populations [14-17]. The available evidence suggests that there is some potential for smartphone apps to be effective in increasing physical activity and decreasing sedentary behavior, with small effect sizes found [15,16]. This area is currently receiving increased attention in cardiovascular disease research [12,18].

In Australia, the country where this study was conducted, from 2016 to 2017, 91% of households accessed the internet via smartphones [19]. To investigate the use of mobile technology in cardiac rehabilitation, 282 Australian cardiac rehabilitation participants were surveyed from 9 hospitals and community sites in metropolitan and rural settings [18]. Approximately 65% of the people attending cardiac rehabilitation reported having a smartphone, with those aged <56 years being the biggest users of mobile apps (70%). Internationally, in Ireland and Belgium, 310 cardiac rehabilitation participants (mean age 62 years) were surveyed, and it was found that 97% of the patients had a mobile phone and 91% used the internet [20]. A total of 68% of the patients were interested in receiving cardiac rehabilitation support via a mobile phone. Despite the high use of mobile phones in cardiac rehabilitation, few studies have investigated the efficacy of smartphone apps, excluding text messaging–only interventions, in this population [16].

One such study compared cardiac rehabilitation delivered via a smartphone app with traditional center-based cardiac rehabilitation and addressed a number of risk factors [21]. They found that there is potential for cardiac rehabilitation to be delivered via a smartphone app (intervention group) as an alternative to traditional programs. However, despite reporting that 89% of the intervention group (smartphone app group) recorded daily physical activity, they failed to directly report on physical activity levels in either group or whether this had changed over time. In contrast, another study investigated a personal health assistant delivered via the web and smartphone-based platforms in addition to cardiac rehabilitation and encouraged the adoption of healthy lifestyle behaviors, including physical activity [22]. Cardiac rehabilitation participants at the beginning of cardiac rehabilitation and after 3 months of attending cardiac rehabilitation were divided into intervention and control groups (nonrandomized, 4 groups). Compared with the control groups, the personal health assistant group had significantly decreased weight (P=.03) and blood pressure (P=.01), with no difference in self-reported physical activity (P=.24). Notably, both intervention groups showed significant reductions in rehospitalizations and emergency department visits during the study period compared with the cardiac rehabilitation–only groups (P<.05). Another study, using a randomized multicenter design, evaluated a smartphone-based interactive tool for heart attack participants attending secondary prevention programs to assess whether it had an impact on lifestyle changes, including physical activity, and drug adherence [23]. The app included personalized feedback messages, using a traffic light model to describe the participant's status on whether or not they were adhering to the medical recommendations, according to the data they entered. At 6 months, there was greater drug adherence in the app group, but there was no difference in self-reported lifestyle modifications, including physical activity.

With high levels of sedentary behavior reported in cardiac rehabilitation participants and low levels of physical activity, new initiatives are needed to improve the effectiveness of cardiac rehabilitation programs to address these behaviors. In addition, interventions aiming to decrease sedentary behavior appear to be more effective if they focus on sedentary behavior and not physical activity or a combination of both, and this should be taken into consideration [24]. There is some evidence that smartphone apps are able to modify risk factors for heart disease in cardiac rehabilitation populations [21-23] and interventions using computer, mobile, and wearable technologies can be effective in reducing sedentary behavior in healthy populations, but the evidence is limited [25]. No studies have

investigated the use of a smartphone app to reduce sedentary behavior in cardiac rehabilitation participants. Therefore, the main aim of this study is to conduct a feasibility study as a precursor for a larger randomized controlled study to determine whether the behavioral smartphone app (Vire) and web-based behavior change program (ToDo-CR) targeting sedentary behavior are feasible in cardiac rehabilitation participants [26]. Specifically, the aims are as follows:

1. To evaluate the feasibility of the smartphone app (Vire) and web-based behavior change program (ToDo-CR) in cardiac rehabilitation, including recruitment, response and follow-up rates, and the usability of the app.
2. To estimate the sample size for a larger randomized controlled trial based on the SD of the main outcome measure (sedentary behavior) [27].

Methods

Design

This feasibility study was a single-center, pre-post design study conducted over 16 weeks at the Canberra Hospital (Australia) cardiac rehabilitation program (Australian New Zealand Clinical Trials Registry: ACTRN 12617001429347). Participants were assessed on admission to cardiac rehabilitation, at the end of the 6 week program, and at 16 weeks after admission to the program. The phase 2 cardiac rehabilitation program is multidisciplinary, time limited (12 sessions; 2 per week for 6 weeks), conducted in groups, hospital based, and has educational and supervised exercise components (1 hour education and 1 hour exercise). Ethics approval was received on February 14, 2018, from the Australian Capital Territory Health Human Research Ethics Committee (ETH.10.17.230). Study information, including the project aim; data storage; and details regarding participant involvement, confidentiality, and anonymity, were provided to participants at the beginning of the study. All participants provided written informed consent after reading this information.

Recruitment

Cardiac rehabilitation staff recruited consecutive participants who commenced cardiac rehabilitation between January and May 2019. Eligible participants were those aged ≥18 years, currently enrolled in the cardiac rehabilitation program, and who had a smartphone. Participants were included if they had stable coronary heart disease (CHD) and were receiving optimal medical treatment with or without a revascularization procedure, that is, coronary artery bypass graft surgery, percutaneous coronary intervention (PCI), or myocardial infarction. Participants were excluded if they had a primary diagnosis of atrial fibrillation, New York Heart Association class II-IV symptoms of heart failure, uncontrolled arrhythmias, severe chronic obstructive pulmonary disease, uncontrolled hypertension, symptomatic peripheral artery disease, unstable angina, or uncontrolled diabetes; if they were unable to perform a submaximal walking test or unable to wear an accelerometer because of disability, for example, if they were confined to a wheelchair; and if they did not have adequate English language and cognitive skills. Participants were also excluded if they had a prepaid phone plan (limited data availability) or if the smartphone's operating system was not compatible with all apps.

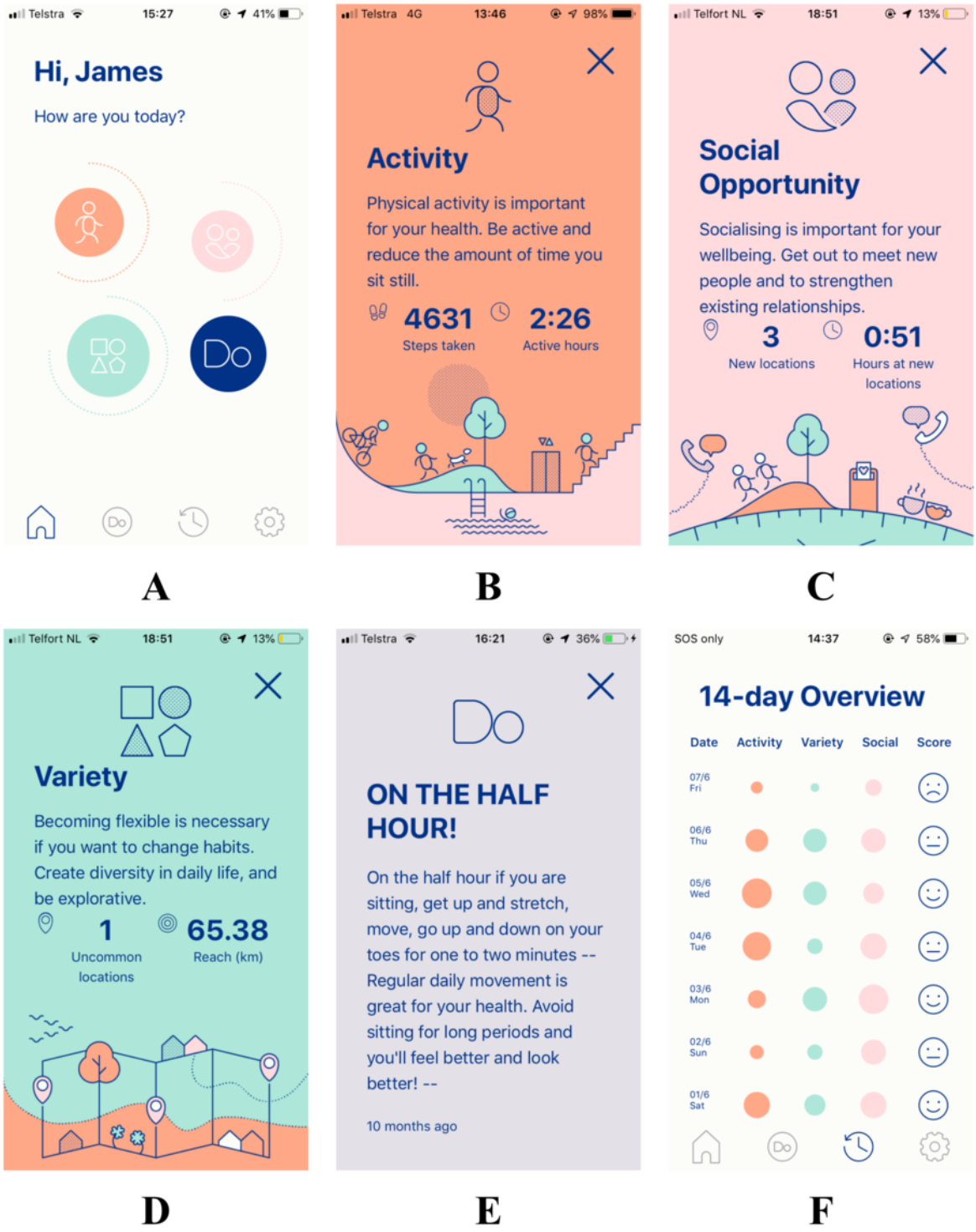
Intervention

On the first day of attendance at the cardiac rehabilitation program, eligible participants were given a wrist-worn Fitbit Flex that could be worn for 24 hours and written information on how to install the Vire and Fitbit apps on their smartphones. To access the Vire app, participants needed to use a study-specific log-in code. Participants were requested to wear the Fitbit Flex for the 16-week study period and were able to keep the Fitbit Flex on completion of the study.

ToDo is a cloud-based behavior change program delivered through a smartphone app (Vire) created by Onmi in collaboration with Do Something Different Limited [28,29]. The Vire app has been progressively developed over the course of several projects together with end users and health care professionals [28]. A previous version of Vire used a co-design method called Experiential Design Landscapes [30]. This version of the Vire app had similar features for listing, opening, and completing context-specific actionable microbehavioral alternatives (Do's) and was further refined using the Klikker methodology [31]. The Klikker methodology aims to unite the designer, developers, and end users in the initial phases of development by using modern web technologies, readily available and interchangeable design, and analytics software. Klikker combines the collection of quantitative user behavior and qualitative feedback from end users on their own devices to support the design process for researchers and designers. The Vire app used in ToDo-CR is created through another iteration of design and development, keeping in mind some basic principles of persuasive design. This version is substantially simplified based on user feedback. It reduces cognitive load by reducing the amount of information presented at once. The app is more appealing, information is decluttered, and visual consistency and hierarchy have been improved. The navigation is slightly simplified by limiting options to 4 options and prioritizes the dynamic home screen in an attempt to conserve attention and engagement. The Vire app is available in both the iOS and Android versions.

The ToDo program aims to improve an individual's behavioral flexibility, learning new behaviors so they have more choice over how they react to different situations [32]. The program suggests microbehavioral alternatives (Do's) that gradually change people's habits, with some evidence that these small behavioral changes, which may not directly target the habit of interest, effect health outcomes such as decreases in weight [28,32]. The original program has been adapted by the research team to target sedentary behavior, based on Australian physical activity and cardiac rehabilitation guidelines to create ToDo-CR, a 6-week behavior change program (Figure 1) [5,33]. By combining technology, evidence-based guidelines, and behavior change techniques such as action planning and feedback [34], the ToDo-CR program aims to increase the participants' self-efficacy and behavioral flexibility and decrease their sitting time.

Figure 1. User interface of the app.



The ToDo-CR program is personalized and consists of different types of Do's delivered through the smartphone app via push notifications: Core Do's and Data-Driven Do's. The Do's are small actionable and achievable goals based on the individual's data. They provide prompts on how to achieve the goal and opportunities to practice new behaviors (Figure 1E). Core Do's address the individual's existing habits that often prevent healthy changes. Data are used from the answers to a questionnaire completed in the app at the start of the program asking questions about risk factors and desired behaviors, for example, "how often do you spend most evenings watching TV or in front of a screen?", determining the Core Do's that are distributed. Data-Driven Do's address the individuals' everyday context that traps them in habitual behavior by combining data from the Fitbit Flex (activity data) and the Vire app (GPS) to create a comprehensive digital profile of the individual. Real-time analysis algorithms use the GPS and activity data to calculate scores in 3 main variables: physical activity, social opportunity,

and variety, and providing feedback to participants, allowing self-monitoring, and aiming to increase their self-efficacy (Figure 1A-D). Physical activity measures steps per day and the amount of time spent being active (Figure 1B). Social opportunity uses GPS coordinates to extract the number of new places visited and the amount of time spent in these places, and by combining these 2 parameters to estimate the chances of meeting people, the program encourages participants to change their social environment (Figure 1C). Variety uses GPS coordinates as well as activity data, including uncommon places visited, the distance traveled, the routes taken, and the order and time at which places are visited, thus analyzing how much the individual's day differs from an average day and encouraging participants to change their physical environment (Figure 1D). For all variables, a baseline assessment is conducted for 1 week at the start of the program to understand a person's routine and activity capabilities. The baseline computation includes an assessment of the minimum and maximum values recorded during the week. The parameters are then linearly rescaled in a 0 to 10 range using the information collected in the baseline assessment (minimum and maximum value). The *0* value is assigned to the daily values that are equal or below the minimum, and the value *10* is assigned to the daily values that are equal or exceed the maximum value registered during the baseline period. The scores for each variable are made relative to each participant, and the 0 to 10 range represents different levels of activity. Therefore, individuals are only prompted to make relative improvements, not to reach absolute levels. Scores for each variable are represented by the size of the circle on the home page (Figure 1A) and in the 14-day overview (Figure 1F). The larger the circle, the higher the score, indicating a greater change from the individual's baseline measures.

The Data-Driven Do's within the ToDo-CR program are dispatched based on these measurable variables or habits. Before sending any Data-Driven Do's, the program checks intraday data to ensure that the analysis represents the day sufficiently, that is, data must represent more than 60% of the total available data to be considered precise enough to dispatch a Do. The system logs were continuously monitored using automated methods and manually for errors. When the participants' scores were low on 3 consecutive days, an individualized, context-specific Data-Driven Do was sent to stimulate the participant to improve their score and behavior, and it provided an opportunity for participants to mark the Do as completed (Figure 1E). Participants received feedback on their daily variable scores within the 14-day overview by receiving sad, neutral, or smiley faces to reward them for changes in their behavior and allowed them to track observed trends (Figure 1F). In total, there were 89 different Do's, small actionable and achievable behavioral goals, which could be dispatched to individuals depending on their individualized data, a combination of Core Do's and Data-Driven Do's. One-third (30/89, 38%) of the Do's targeted decreasing sedentary behavior and increasing physical activity. The maximum number of Do's received by participants per week was 3, with participants receiving 14 to 19 individualized Do's during the 6-week intervention period. Some of the Do's contained hyperlinks to other resources, such as the Australian Heart Foundation website [35]. During the study period, 5 updates were performed to improve location tracking and the functionality of the app. The content of the Do's and analysis of the behavioral variables did not change during the study period. Participants had access to the Vire app for the entire 16 weeks.

Outcome Measures

All assessments were conducted at the hospital and were carried out by a cardiac rehabilitation nurse, exercise physiologist, or physiotherapist, who were not blinded. The main feasibility outcome measures were the number of eligible participants, follow-up rates and response rates to questionnaires, and the usability of the app (the Unified Theory of Acceptance and Use of Technology 2 [UTAUT2] questionnaire) [27]. Objectively measured sedentary behavior was used to estimate the sample size for a larger randomized controlled trial. Other outcome measures included objectively measured moderate-to-vigorous physical activity (MVPA), BMI, waist-to-hip ratio, blood pressure, exercise capacity (6-min walk test, 6MWT), quality of life (MacNew Heart Disease Health-Related Quality of Life Questionnaire, MacNew), anxiety and depression (Hospital Anxiety and Depression Scale, HADS), and clinical and demographic information.

Smartphone App Usability and Adherence

The UTAUT2 questionnaire was used to assess the usability of the Vire app and ToDo-CR program at 6 and 16 weeks [36]. The UTAUT2 was developed as a comprehensive integrated model for better understanding consumer acceptance of a new technology or system and has been used in adults with multiple chronic conditions [37]. UTAUT2 is a 23-item self-reporting questionnaire consisting of 7-point Likert-scale items. The items assess the following constructs: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, habit, and behavioral intention. Behavioral intention is expected to have a significant influence on the use of the smartphone app [38]. In addition, the completion of Do's as marked by the participant was used as an indicator of adherence to the program.

Sedentary Behavior and Physical Activity

A triaxial commercial accelerometer (ActiGraph, ActiSleep) was used to objectively assess sedentary behavior and physical activity. Participants were asked to wear the monitor on their right hip during waking hours for 7 consecutive days and not to wear the accelerometer in water. All data were sampled and downloaded as raw data (30 Hz) and converted to 15-second epochs (time interval) and then to counts per minute (cpm) using the ActiLife software [9,10]. Data were screened, excluding data if less than 10 hours per day wear time (nonwear defined as >60 consecutive minutes where there is zero activity, with no allowance of epochs with counts above zero) and less than 4 days of valid data [9,10,39]. If there were more than 7 days of valid data, all valid days were used to calculate the average [10]. The Sasaki vector magnitude cutpoints were used to determine the time spent in light (150-2689 cpm) and MVPA (≥2690 cpm) [9,10,39,40]. To measure the sedentary behavior, the vector magnitude cutpoint was used (<150 cpm) [9,10,39,41]. Estimating daily time spent in physical activity and sedentary behavior was calculated by dividing the total time

spent (in minutes) in each threshold by the number of valid days. In addition, daily time spent in sedentary behavior was expressed as a percentage of the total daily wear time. Sedentary behavior bout data used a minimum length of 10 min, with no drop time, recording the number of sedentary bouts per day [9]. The average sedentary bout length and number of sedentary breaks were also recorded.

Anthropometric Characteristics and Blood Pressure

Height (m), weight (kg), and BMI (kg/m^2) were recorded using a calibrated set of scales and a stadiometer. Waist and hip circumference were measured in centimeters using a tape measure. Blood pressure levels were obtained using a standardized sphygmomanometer on the right arm of seated subjects.

Exercise Capacity

The 6MWT is a commonly used objective measure of functional exercise capacity in cardiac rehabilitation [42]. The distance an individual was able to walk along a flat 25 to 30 m walkway over a 6-min period was recorded. The test is a self-paced, submaximal test of exercise capacity and has been found to have moderate to high reliability and validity [42].

Health-Related Quality of Life

The MacNew was used for the assessment of heart disease–specific health-related quality of life. The MacNew is self-administered and consists of 27 items that fall into 3 domains (physical limitations, 13 items; emotional function, 14 items; and social function, 13 items). The maximum possible score in any domain is 7 (high health-related quality of life), and the minimum possible score in any domain is 1 (poor health-related quality of life). The time frame for the MacNew is the previous 2 weeks, and it has good reliability and validity internationally [43].

Anxiety and Depression

The HADS was used to assess anxiety and depression [44]. This questionnaire is a 14-item self-reporting questionnaire comprising 4-point Likert-scale items covering the occurrence of symptoms of anxiety and depression over the 2 weeks before taking the questionnaire. Each item on the questionnaire is scored from 0 to 3, so that a person can score between 0 (best outcome) and 21 (worst outcome) for either anxiety or depression. The HADS has demonstrated excellent discriminant validity, construct validity, test-retest reliability, and internal consistency in adults with cardiovascular disease [45].

Demographic and Clinical Questionnaire

Participants were assessed on their sociodemographic variables (ie, gender, age, education level, relationship status, and current employment status) and clinical predictor variables (ie, smoking status and other medical conditions).

Statistical Analysis

As this is a feasibility study, a formal sample size calculation was not completed [27]. The aim was to recruit a minimum of 20 participants. All participants who completed the baseline assessment and attended at least one cardiac rehabilitation session were included in the sample. Intention-to-treat analysis was performed. For missing data at follow-up, the last value was brought forward. Descriptive analyses were completed. The normality of the data was assessed using the Kolmogorov-Smirnov test. For data that were normally distributed, repeated-measures analysis of variance was used to test for differences within the cohort. If variables were not normally distributed, the Friedman test was used. For accelerometer data, differences in wear time were controlled for by using individual mean wear time (within-subject effects). The significance level was set at $P<.05$. All data were analyzed using SPSS, version 25.

Results

Recruitment and Response Rates

A total of 20 participants were consecutively recruited for this feasibility study (Figure 2). One-third (21/61, 34%) of the people with CHD who commenced cardiac rehabilitation over the 4-month recruitment period were eligible to participate in this study. Other than declining to take part in the study (15/40, 38%), not having a smartphone was a major reason for exclusion (11/40, 28%). Those excluded without a smartphone were significantly older than participants with a smartphone ($P<.001$). Participants were, on average, aged 54 years, mostly male, in a relationship, and working (Table 1). Most participants had undergone a PCI, were nonsmokers, and did not have type 2 diabetes or other chronic diseases, and half of them were tertiary educated. A total of 85% (17/20) of participants attended all cardiac rehabilitation sessions during the 6-week cardiac rehabilitation program. At follow-up, 95% (19/20) of participants were assessed at 6 weeks, and 60% (12/20) of participants were assessed at 16 weeks (Figure 2). A quarter (5/20, 25%) of the participants were unable to be contacted at 16 weeks. Moreover, 2 participants had unplanned cardiovascular disease hospital admissions and were unable to complete their final assessment at 16 weeks.

Figure 2. Flow of participants through the ToDo-CR feasibility study. CVD: cardiovascular disease; ITT: intention-to-treat.

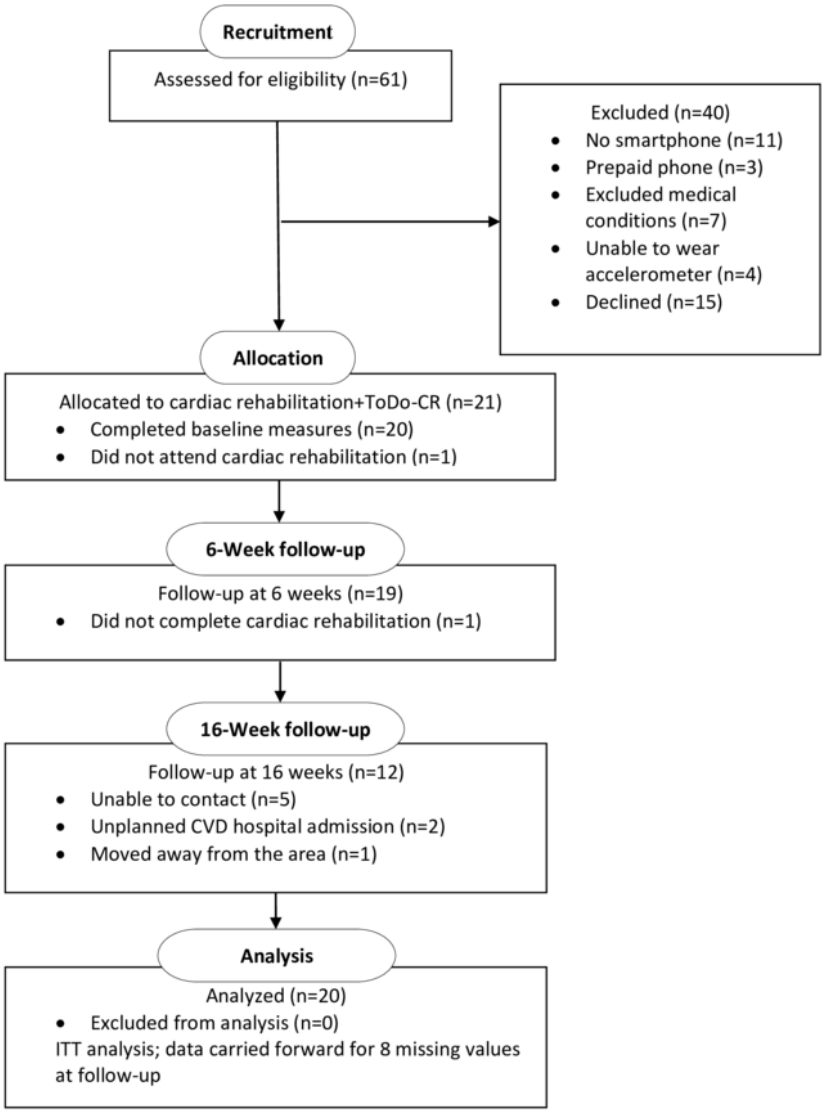


Table 1. Characteristics of participants at baseline (N=20).

Characteristics	Values
Age, years, mean (SD)	54 (13)
Gender, male, n (%)	17 (85)
Country born, Australia, n (%)	11 (61)
Paid work, full or part time, n (%)	12 (67)
Education level, tertiary, n (%)	9 (53)
Relationship status, partner, n (%)	14 (78)
Diagnosis, n (%)	
Coronary heart disease	2 (10)
Percutaneous coronary intervention	16 (80)
Myocardial infarction	1 (5)
Coronary artery bypass graft	1 (5)
Other chronic disease (no), n (%)	12 (67)
Current smoker (no), n (%)	16 (89)
Type 2 diabetes (no), n (%)	15 (83)

App Usability and Adherence

Participants were relatively satisfied with the usability of the app at 6 weeks, with median scores in all constructs greater than 4, except for *habit* (Table 2). However, satisfaction with the app declined at 16 weeks after the Do's ceased at 6 weeks. There were significant positive correlations ($P<.05$) between all UTAUT2 constructs and *behavioral intention to use* the app except for *effort expectancy* at 6 weeks. This indicates that the ease of use of the app may not be a factor in the intention to use the smartphone app. At 16 weeks, only *performance expectancy* ($r=0.70$; $P=.02$) and *habit* ($r=0.80$; $P=.003$) had significant correlations with *behavioral intention*, indicating that participants believe that the smartphone app will help them to make changes in their behavior, and the use of the smartphone app has become a habit that influences their intention to use smartphone apps in the future. In terms of adherence, 73.7% (252/342) of the Do's sent to participants during the 6-week intervention period were marked as completed.

Table 2. Smartphone app usability (the Unified Theory of Acceptance and Use of Technology 2 questionnaire constructs) at 6 and 16 weeks.

Construct (7-point Likert scale[a])	6 weeks (n=15), median (IQR)	16 weeks (n=12), median (IQR)
Performance expectancy	4.25 (2.5-5.25)	1.75 (1-2.94)
Effort expectancy	4.5 (3.75-5.75)	3.5 (3-4.25)
Social influence	4 (3.5-4.17)	2 (1-4)
Facilitating conditions	4.88 (4.19-6.06)	4.75 (3.75-6.25)
Hedonistic motivation	4.17 (3.83-5)	1.5 (1-3.25)
Habit	3.75 (2-4.25)	1 (1-3)
Behavioral intention	4 (2.33-6)	1 (1-4.33)

[a]Likert scale: 1=strongly disagree; 4=neutral; and 7=strongly agree.

Resource Requirements

All participants installed the app, were given a Fitbit, and received the 6-week ToDo-CR program. Participants required more support than expected to install the app, to link the app to the Fitbit app, and to troubleshoot any issues with the app and Fitbit. The Vire app required updating in the initial stages of the study, which caused some issues. Consequently, written material was developed to support this, and a frequently asked questions button was added to the app. The research assistant also called all participants within the first week of commencing the study to determine if they were having any issues with the app and provided advice and support accordingly. In addition, during recruitment, some nursing staff were unsure about introducing the app to potential participants and checking whether or not the smartphones of potential participants had suitable operating systems to be eligible for this study. Simplified written material and instructions on downloading the Fitbit app were developed to aid nursing staff and to ensure that the recruitment process was as efficient as possible to decrease the impact it had on their clinical services.

Sedentary Behavior and Other Health Outcomes

Overall, participants spent 11 to 12 hours per day sitting (Table 3). The effect size for the reduction in sedentary behavior (minutes per day) was medium (Cohen $d=0.54$) and small for percentage of the day spent in sedentary behavior (Cohen $d=0.25$) at 16 weeks. Using a two-sided significance of $P<.05$ and power of 80%, 110 participants (55 in each group) would be needed to detect a difference in sedentary behavior (minutes per day) of this magnitude between groups, calculated using G*Power version 3.1.9.4. Allowing for a 40% dropout based on this study, 184 participants would need to be recruited (92 in each group) for a randomized controlled trial.

There were statistically significant changes in other health outcomes. There was a significant improvement in functional fitness (6MWT; $P<.001$; Table 4) and quality of life in all domains (MacNew; Table 4). There was also a significant decrease in systolic blood pressure at 6 weeks, which then increased from 6 weeks to 16 weeks ($P<.05$; Table 4).

Table 3. Sedentary behavior and physical activity characteristics at baseline, 6 weeks, and 16 weeks.

ActiGraph	Baseline, mean (SD)	6 weeks, mean (SD)	16 weeks, mean (SD)
SB[a] (minutes per day)	747 (224)	774 (209)	640 (165)
Percentage of SB per day (SB per wear time)	68.2 (9.9)	68.8 (9)	65.7 (9.8)
Duration of SB bouts per day (min)	23 (5.7)	24 (4.8)	22 (4.5)
Number of SB bouts per day	16 (6.5)	17 (7.1)	14 (5.9)
Number of SB breaks per day	15 (6.5)	16 (7.1)	13 (5.9)
MVPA[b] (minutes per day)	74 (23)	78 (27)	77 (31)
Light physical activity (minutes per day)	257 (78)	261 (78)	253 (84)
VM[c] (counts per day)	519,365 (127,852)	548,689 (153,920)	535,794 (42,204)
Steps per day	7873 (2073)	8477 (2493)	8028 (2478)
Wear time (minutes per day)	1078 (210)	1113 (208)	970 (179)

[a]SB: sedentary behavior.

[b]MVPA: moderate-to-vigorous physical activity.

[c]VM: vector magnitude.

Table 4. Comparison of baseline, 6-week, and 16-week measures.

Outcome	Baseline	6 weeks	16 weeks
Waist circumference (cm), mean (SD)	101 (14)	101 (15)	100 (14)
Waist-to-hip ratio, mean (SD)	0.97 (0.07)	0.96 (0.07)	0.95 (0.08)
BMI (kg/m^2), mean (SD)	29 (4)	29.1 (4)	28.9 (4.5)
Systolic blood pressure (mm Hg), mean (SD)	119 (12)	113 (11)[a]	118 (13)[b,c]
Diastolic blood pressure (mm Hg), mean (SD)	71 (8)	69 (9)	69 (7)
MacNew[d] global, mean (SD)	5.3 (0.74)	5.9 (0.75)[e]	5.9 (0.79)[f]
MacNew physical, mean (SD)	5.2 (0.72)	5.9 (0.75)[g]	6 (0.73)[f]
MacNew social, mean (SD)	5.3 (0.97)	6 (0.97)[g]	6.2 (0.92)[f]
MacNew emotional, mean (SD)	5.5 (0.87)	5.9 (0.86)[a]	5.9 (0.94)[b]
HADS[g,h] anxiety, mean (SD)	4.6 (3.3)	4.3 (4.2)	3.6 (3.3)
HADS depression, median (IQR)	1.5 (1-5.75)	1 (0.25-4.5)	1 (1-5.25)
6-min walk test distance (m), mean (SD)	506 (83)	581 (75)[g]	640 (84)[f,i]

[a]Paired *t* test: baseline to 6 weeks, $P<.05$.

[b]Repeated measures analysis of variance, $P<.05$.

[c]Paired *t* test: 6 weeks to 16 weeks, $P<.05$.

[d]MacNew: MacNew Heart Disease Health-Related Quality of Life Questionnaire.

[e]Paired *t* test: baseline to 6 weeks, $P<.05$.

[f]Repeated measures analysis of variance, $P<.001$.

[g]Paired *t* test: baseline to 6 weeks, $P<.001$.

[h]HADS: Hospital Anxiety and Depression Scale questionnaire.

[i]Paired *t* test: 6 weeks to 16 weeks, $P<.001$.

Discussion

Principal Findings

The use of a behavioral smartphone app (Vire) and a web-based behavior change program (ToDo-CR) to decrease sitting time appears feasible in cardiac rehabilitation and may reduce sedentary behavior over time. To our knowledge, this is the first study to report the effects of a behavioral smartphone app and a web-based behavior change program on objectively measured sedentary behavior in cardiac rehabilitation. However, consideration must be given to the number of participants who did not have a smartphone within cardiac rehabilitation. In

addition, a smartphone app–based intervention may be more suited to younger cardiac rehabilitation participants. Despite this, even those with a smartphone required support with downloading the app and using the Fitbit, indicating additional support (written materials and telephone support) may be required when implementing a smartphone app–based intervention within this population.

Comparison With Prior Work

Of the limited studies that have evaluated smartphone app–based interventions in cardiac rehabilitation, descriptions of participant recruitment rates and reasons for study exclusion are limited [21-23]. Varnfield et al [21] reported that 85.6% (715/835) of cardiac rehabilitation patients assessed for the smartphone intervention were ineligible to participate in the study, with not meeting the inclusion criteria cited as the main reason for exclusion (280/715, 39.2%). One of the exclusion criteria was not being able to operate a smartphone for the purposes of the trial; however, the number of patients related to these criteria was not reported. In this study, the number of patients with smartphones was not relevant as all participants were provided with smartphones. More recently, Beatty et al [46] developed a smartphone app to be used in cardiac rehabilitation and reported on its usability. A total of 41 cardiac rehabilitation participants were approached for the app trial and only 2 were excluded because they did not have a smartphone (5%); this was a much lower rate than that found in this study (11/61, 18%).

Regardless of this, the majority of cardiac rehabilitation participants assessed did own a smartphone, as reported in other studies within cardiac rehabilitation settings, and those with a smartphone were significantly younger than participants without a smartphone [18,20,47]. Unsurprisingly, this is a younger cohort compared with previous studies in cardiac rehabilitation [11]. However, this may be the cohort of participants with CHD that need to be targeted with alternative interventions for lifestyle modifications, such as smartphone apps. Despite the steady decline in CHD death rates over the last 40 years in Australia, in more recent years, this decline has slowed in younger age groups (age range 35-64 years), indicating that an increased focus on primary and secondary prevention of heart disease is needed in these age groups [48].

There is some evidence that mobile health (mHealth) technologies, including smartphone apps, can reduce self-reported and objectively measured sedentary behavior levels in healthy populations compared with control groups, although the effect size is small (standardized mean difference −0.26; 95% CI 0.53 to 0.00) [15,49]. The reduction in sedentary behavior effect size reported in the systematic review [49] is of a similar magnitude to that found in this cohort study (Cohen *d*=0.25-0.54). The only study that objectively measured sedentary behavior (ActiGraph accelerometer) in the systematic review found that following a 12-week mHealth intervention for weight reduction, which included a smartphone app, there was a nonsignificant reduction in sedentary behavior in both the intervention and control groups [49]. Despite that specific study being conducted in a different population (university staff and students), there is some indication that mHealth interventions, including smartphone apps, can reduce objectively measured sedentary behavior, suggesting that further investigation of this type of intervention in various populations is warranted. Our study indicates that in cardiac rehabilitation participants, a sample size of 184 participants is necessary for a randomized controlled trial to detect a difference in sedentary behavior (minutes per day) between groups using a smartphone app as the intervention. Furthermore, adequate support (written material and telephone support) is indicated in this population for this type of intervention, which may be as a result of high levels of anxiety and kinesiophobia (fear of movement) in cardiac rehabilitation participants [50,51].

According to these preliminary findings, it is unclear if the 6-week ToDo-CR program was long enough to achieve a sustained change in behavior. According to social cognitive theory, for an increase in physical activity to be adopted and maintained, it must be sustained for at least 6 months [52]. It has been reported that many smartphone apps are not based on behavioral theories and use limited behavior change techniques, particularly for sedentary behavior [13,53]. The ToDo-CR program uses a number of behavior change techniques, including action planning (Do's), prompting via advice on ways to achieve small actionable goals, opportunities to practice new behaviors, encouraging participants to change their physical and social environments (variety and social opportunity scores), providing feedback on their behavior for self-monitoring over the course of a day or 14 days, and providing rewards with smiley faces if their behavior positively changes from their baseline assessment. By sending behavioral prompts (Do's), the ToDo-CR program aims to change behavioral habits by disrupting the habits that are common in our daily lives, potentially increasing behavioral or cognitive flexibility, and subsequently changing habits associated with an unhealthy lifestyle [28,32]. It has been suggested that cognitive flexibility is a key mechanism in the reduction of unwanted habits, such as sedentary behavior, and cognitive flexibility can be improved with suitable interventions, resulting in a reduction of habitual sedentary behavior [54]. Thus, this program is based on a behavior change framework and uses behavior change techniques, although a longer program may be necessary to result in changes in sedentary behavior, and further investigation of the potential behavior change mechanism is required.

Limitations

This study has several strengths, including the use of a personalized smartphone behavior change program based on real-time data analysis and clinical guidelines, the objective measurement of sedentary behavior, and the collection of data to inform a large-scale randomized controlled trial. This study also has several weaknesses. As this was a feasibility study, the sample size was small, and the results should be interpreted with caution. This was also a single-center study where the majority of participants were men, limiting the generalizability of the results within cardiac rehabilitation settings. The ability to detect a significant change in sedentary behavior may have been limited by the small sample size. The attrition rate was high at 16 weeks, although this is commonly reported in app studies targeting the management of disease risk factors and long-term conditions [16]. Further investigation of app

engagement using back-end data would have been useful to determine if there was a relationship between app engagement and changes in sedentary behavior. There is some evidence that inexperienced app users may not use all the features of the app and therefore may not receive the proposed benefit from the behavior change smartphone app [55]. In addition, using the last value carried forward for the intention-to-treat analysis may not have been the most appropriate approach to use in this type of research [56]. Finally, as this was a single-cohort study, the detected small to medium effect sizes in reducing sedentary behavior over 16 weeks may not have been related to the ToDo-CR behavior change program and may have resulted from the cardiac rehabilitation program or measurement reactivity [57].

Conclusions

The behavioral smartphone app (Vire) and web-based behavior change program (ToDo-CR) appear to be feasible and acceptable in cardiac rehabilitation and may be useful to decrease sedentary behavior in this population. Further research is indicated with larger sample sizes, a control group, possibly an extended behavior change program, and longer follow-up to determine whether the behavioral smartphone app and web-based behavior change program decrease sitting time in cardiac rehabilitation participants.

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Conflicts of Interest

NF, RD, MM, and TM declare that they have no conflicts of interest. SVB is the Manager and Designer for Onmi [29], the Vire app, and the ToDo behavior change program developer.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1695 KB - formative_v4i11e17359_app1.pdf]

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Abbreviations

6MWT: 6-min walk test
CHD: coronary heart disease
cpm: counts per minute
HADS: Hospital Anxiety and Depression Scale questionnaire
MacNew: MacNew Heart Disease Health-Related Quality of Life Questionnaire
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
PCI: percutaneous coronary intervention
UTAUT2: Unified Theory of Acceptance and Use of Technology 2

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Original Paper

Co-Designing a Web-Based Decision Aid Tool for Employees Disclosure of Mental Health Conditions: A Participatory Study Design Using Employee and Organizational Preferences

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Abstract

Background: Decisions of whether to disclose mental health conditions are extremely personal and require the consideration of multiple factors associated with the disclosure process (eg, weighing the risks and benefits). Decision aid tools help people make these complex decisions. Such an aid needs to be confidential, easily accessible, and easy to use with the potential to access the tool on multiple occasions. Web programs are well suited to meet these requirements and, if properly developed, can provide feasible, accessible, affordable, and effective workplace interventions.

Objective: This study aims to gain insights from potential end users, in this case both employees and organizations, into what type of components including language, style, and content would avoid potential stigma and ensure that elements of clear value for users would be built into a web-based decision aid tool that aims to assist employees in making decisions about the disclosure of their mental health condition at work.

Methods: A participatory design approach was used to allow developers, researchers, experts, and end users to collaborate in co-designing the tool. During the user research phase of the development of the web-based tool, a participatory design workshop approach was selected as a part of a larger study of focus groups. Australian employees and managers in rural, suburban, and urban locations participated in an exploratory qualitative study involving participatory workshops designed to elicit their perspectives and preferences for a decision aid tool.

Results: A total of 2 workshops were conducted with 13 participants. The majority were from a transport company (9/13, 69%), male (8/13, 62%), and employed full time (11/13, 85%). Six employees had previous experience disclosing their own mental health condition, and 7 were in a supervisory role and had previously been disclosed to. In any co-design development, there are certain trade-offs that need to be made between the views of experts, developers, end users, and the available budget. In this specific instance of a very delicate, personal decision, the end users provided valuable design insights into key areas such as language, and they were very antipathetic to a key feature, the avatar, which was thought to be desirable by experts and developers. Findings including aspects of the tool where all stakeholders were in agreement, aspects where some stakeholders disagreed and adaptations were implemented, where disagreements could not be implemented because of financial constraints, and misalignment between stakeholders and how to decide on a balance were shared.

Conclusions: The co-design with a lived experience approach is useful for contributing much to the design, language, and features. The key in this study was balancing the needs of the workers and the potential impact for the managers and organizations, while ensuring legislation and regulation requirements were upheld.

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KEYWORDS

employee disclosure; decision aid tool; mental health; web-based

Introduction

Disclosure of a mental health condition is a necessary first step to help seeking in the workplace [1] as employers are not legally obliged to provide individual support before disclosure [2]. A lack of disclosure limits opportunities to access workplace support that could allow employees to maintain performance in their role or successfully return to work [3]. Once a condition is disclosed, employees may be theoretically protected under the relevant legislation and antidiscrimination laws.

For people in employment, deciding to disclose a mental health condition is often complex and requires thoughtful decision making to ensure personal, legal, and employment risks are best managed. The majority of employees with a mental health condition favor nondisclosure as their preferred option [3]. A global survey of employees with major depressive disorder showed that 71% preferred to conceal their condition from others in the workplace and almost half of those (47%) feared they would lose their job if they disclosed [4].

Decisions on whether to disclose are highly personal and require the consideration of multiple factors associated with a disclosure process, for example, weighing the risks and benefits [5]. The capacity to make decisions may be more complex in this population as those with depression and anxiety show impaired decision-making behavior [6,7]. While research does not yet provide clear-cut guidelines for disclosure, facilitators and barriers involved in the disclosure decision-making process in workplaces have been evaluated [8]. The decision to disclose mental ill health according to those who had disclosed in the past and those who, as managers, had received disclosures appears to be determined primarily by consideration of barriers to disclosure and fear of negative consequences rather than any perceived facilitators or benefits [9]. Despite recent progress toward increasing knowledge of public stigma and discrimination [10], they remain to be a significant issue. Discrimination toward those with a mental health condition is a common problem in the workplace globally [11].

In addition to the consequences of disclosing, there are a number of components in the disclosure decision-making process. Employees must decide *who* the best person to disclose to is, for example, a supervisor or manager, *what* information about their condition they will disclose, and *when* to do so. These decisions rest solely with the employee and/or their close supports and clinicians, but many have little help in the decision-making process.

Decision aid tools offer a means to help people manage these complexities. Such tools have commonly been used in decision making regarding medical treatment options [12]. A systematic review showed that decision aids for people facing treatment decisions produced less decisional conflict and led them to have a more active role in the decision-making process [13]. In an organizational mental health context, a paper-based decision aid tool for people with a severe mental illness in secondary care services reduced disclosure decisional conflict and improved individual empowerment when seeking employment [14]. This tool, CORAL (Conceal or ReveAL), developed and evaluated by Henderson et al [14] was the first intervention to support decision making about disclosure in the employment context. In collaboration with Henderson [14] from the CORAL study, we developed a decision aid tool READY (Reducing dEcisionAl conflict, a Decision aid tool for emploYees). The labels of the original modules in CORAL were used to form a framework for READY. The authors developed the content of the tool based around (1) relevant legislation and regulation specific to Australia, (2) delivery to those with any mental health condition when they are still at work, and (3) language for low mental health literacy. The prototype was then presented to a larger expert group of clinicians, researchers, mental health professionals, peer support workers, and work health and safety and vocational officers.

When designing a disclosure decision aid, a tool needs to incorporate counterfactual and potentially positive aspects that, from our focus groups, do not appear to be considered in decisions about disclosing mental health issues in the workplace [9]. Such an aid needs to be confidential, easily accessible, and easy to use, with the potential to access the tool on multiple occasions. Web programs are well suited to meet these requirements and, if developed properly, can provide feasible, accessible, affordable, and effective workplace interventions [15,16]. In addition, they provide around-the-clock access [17] as employees might consider their options outside of their normal work hours.

As with all digital interventions, a tool can only be effective if it engages its intended audience [18], which means that considering end users' needs and preferences during the design process is crucial. Participatory design methods allow researchers to co-design interventions with potential end users by eliciting user perspectives, preferences, and ideas [19]. This approach is used to ensure that these interventions are more likely to be engaging and effective for the intended audience [19-21].

In this study, results are presented from the user research phase (co-design) of the development of a web-based tool that aims to assist employees in making decisions about the disclosure of their mental health condition at work. A participatory design workshop approach was selected. The aim of this study is to gain insights from potential end users into what type of

components, including language, style, and content, would avoid potential stigma and to ensure that elements of clear value for users would be built into the decision aid tool to fundamentally increase uptake and ongoing engagement.

Methods

Study Setting

Participatory workshops were conducted as part of a large Australian-based research collaboration (Well@work) with 15 industry partners, all of whom were invited at an annual meeting to participate; 2 industry partners agreed to participate.

Sample/Recruitment

Participants were recruited from a First Responder Association and a transport company in New South Wales, Australia. Recruitment was conducted via internal organizations inviting those employees who had already formally disclosed their mental health condition and any supervisors who had received disclosures. Within these organizations, 23 employees and supervisors were selected by the human resources team within their organization and were invited through an email sent out via their workplace administration to attend the workshops. The research team had no contact with the participants until the day the study was conducted. Ethical approval was obtained from the University of Sydney Human Research Ethics Committee (project no. 2016/766).

Participants were identified as belonging to 1 of 2 categories: (1) those who had disclosed their mental health conditions in the workplace, that is, *disclosure group* and (2) those who supervised employees within their organization and therefore received disclosures, that is, *authority group*.

Procedures

After obtaining written informed consent, each participant was asked about their role within their organization and whether or not they wished to disclose their mental illness as part of the workshops. Overall, 2 activity-based workshops were conducted in July and August 2017.

The facilitator (ES) was guided by a user experience specialist (DP), an experienced workplace qualitative researcher. The facilitator (ES), author (DP), and the principal investigator (NG) constructed the discussion guide (Multimedia Appendix 1) using semistructured topic guides and activities. An activity-based participatory design approach was adopted for the workshops with flexibility to ensure that the facilitator could follow-up on any important remarks or seek clarification of understanding. This qualitative strategy allowed access to a variety of perspectives and experiences and maximized the ability to develop an effective, appropriate intervention by being able to open dialogue and expand on responses when clarification was needed.

Prototype Development

A prototype was developed based on previous literature on a paper-based decision aid tool [14] and in consultation with a group of workplace disclosure experts. The experts assisted in defining the core concepts, requirements, and features to adapt the tool. The expert group consisted of clinicians, researchers, mental health professionals, peer support workers, and work health and safety and vocational officers.

After consultation with the expert group, the prototype consisted of 7 interactive modules:

1. Pros and cons of disclosure: a list of possible advantages and obstacles was suggested. This module explained that users were to drag and drop the examples that were relevant to them into either the prosor the cons box.
2. Disclosure needs at work: focusing on what employees may need at work to do their job well and stay healthy. This module gave several examples of needs based on the expert's opinions on accommodations that were typically required by those with mental health conditions at work. Users were asked to select how important the example needsare at work to them on a scale of unimportant to very important.
3. Disclosure values at work: this module provided examples of values that may influence disclosure decision making. Users were provided with 2 opposite options and to slide a scale to the option that best suits their values. An example is "I value… Being open and honest versus keeping private."
4. When is the best time to disclose: this provided employees advantages and obstacles for each of the following options: in a one-on-one meeting, in a chat at work, in the pub or social event, in my review, after I have a good bond with my supervisor or coworkers or never.
5. Who have they disclosed to in the past: this section provided participants with a space to reflect on their previous experiences by selecting who they may have told, for example, a spouse and the selection of whether the experience was positive or negative.
6. Who is the best person to disclose to: this provides employees with advantages and obstacles to methods of disclosure and/or nondisclosure with the following options: keep it a secret, only tell trusted people, tell anyone, tell everyone, and tell no one.
7. Summary of making the decision (based on the individual options selected in each module) presented to each user.

Each of the first 6 modules allowed space for users to enter their own options for consideration.

We decided to develop a prototype before the participatory design as we wanted to ensure a safe tool was developed. It was first and foremost important to develop the tool based on aspects that have been evaluated and shown to be effective in the previous CORAL paper-based tool. As every country has specific requirements, we developed the content specific for use in Australia.

Participatory Design Process

The workshops followed the design of Peters et al [19], including individual, whole group, and small group participatory design activities with the main facilitator (ES).

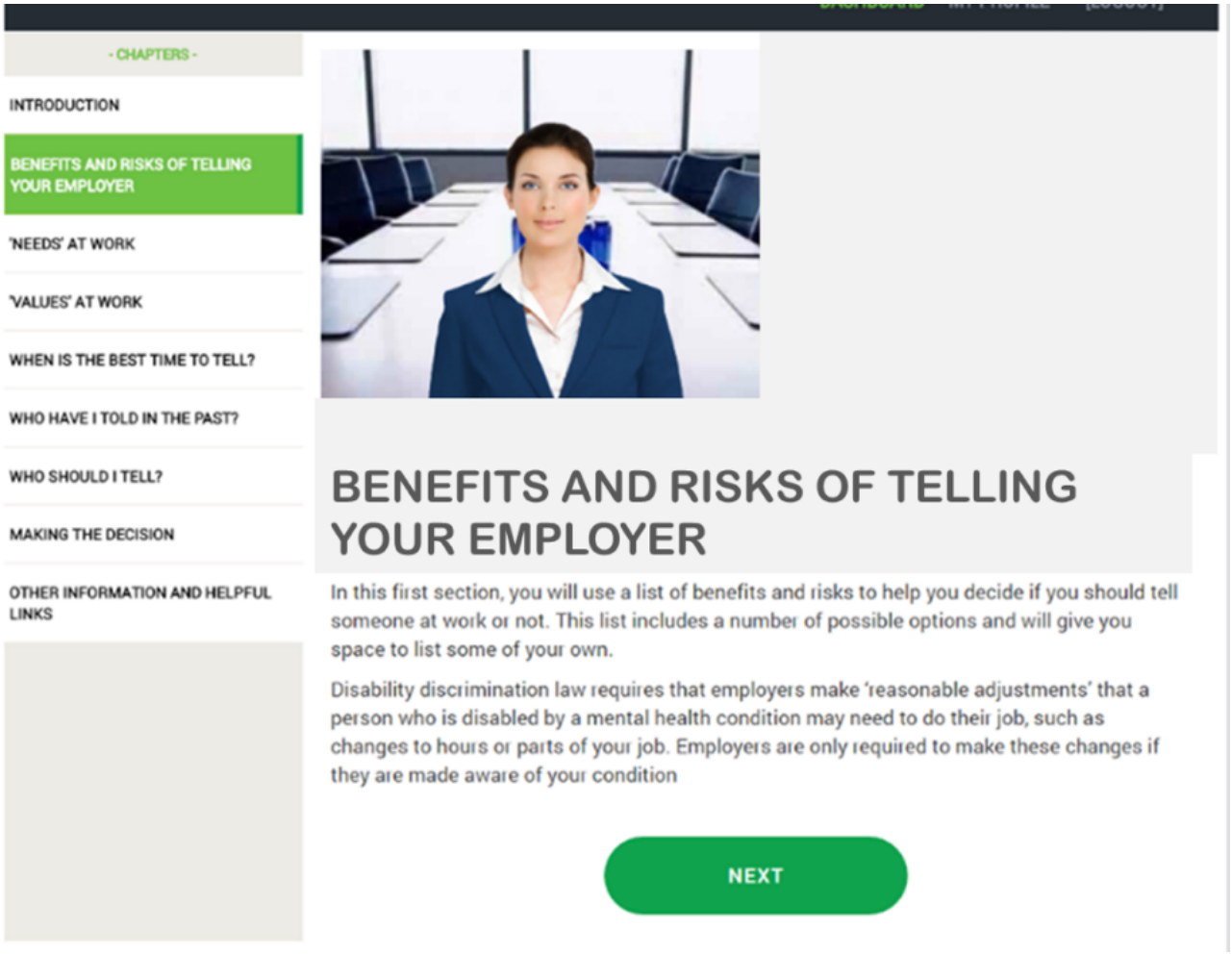
Participatory design was used as it involves users in the design process, focusing on user-centered orientation to draw out user perspectives, preferences, and ideas for the co-design of

technologies. Participatory design is increasingly being used as a means of empowering end users by involving them in development [20,21]. Furthermore, participatory methods provide a means to create a democratic and destigmatized space in which to discuss complex topics such as the disclosure of mental health concerns.

These activities included individual reflection and collaborative ideation. The facilitator guided the participants to create ideas for desirable prototype functionality and characteristics. Participants were provided with both interactive and paper versions of the prototype. These consisted of the proposed content of the decision aid tool and its modular design. Participants generated ideas for desirable functionalities and website characteristics and provided feedback on draft screen designs for a prototype. The structure of the groups is provided in Multimedia Appendix 1.

Participants in the groups were also shown a video example of a virtual avatar (an example is shown in Figure 1). This avatar was designed to read sections from within the tool to the participants. Many commercial platforms such as SitePal have been designed for and evaluated within health research and are often used as virtual coaches [22]. We decided to use SitePal because the avatar's appearance, voice, and even accent were customizable by the developer and allowed users to select their preferred avatar features. This avatar uses the artificial intelligent markup language (AIML) introduced by Wallace [23]. AIML is known to possess *the most human computer*–like features with facial expressions of emotion and nonverbal interaction exhibited by the avatar. Furthermore, it has the ability to handle dialogue flows and closed-ended questions.

Figure 1. Example of avatar used in workshops as a prototype.



Data Collection

Data were collected through audio recordings and resulting *artifacts* created by participants demonstrating their ideas and comments as well as paper-based forms, sticky notes, and field notes. The workshops were conducted at organizational sites and lasted approximately 90 min.

Semistructured topic guides and activities were designed to assess the process and content of the proposed web-based decision aid tool. The sessions were audio recorded and transcribed verbatim, and the accuracy was verified. The transcriptions were deidentified, and each participant was given a participant identification number as a pseudonym to protect anonymity. Only the lead researcher (ES) had access to the participants' identification. After the workshops, the facilitator (ES) and principal investigator (NG) met to review the techniques used in facilitation as a debrief. Transcripts were analyzed as soon as possible after each interview. After the 2

groups, participants were corroborating ideas about the design of the tool.

Data Analysis

Two researchers (the first author and a trained qualitative researcher) independently coded workshop transcriptions using NVivo 11 (QSR International). The investigators used the framework analysis method by Ritchie et al [24] to analyze the data [25]. This method allows for the structured identification of commonalities and differences in qualitative data and helps to draw descriptive and explanatory conclusions clustered around common themes. It is especially useful when multiple researchers are coding the same data set by providing an open, critical, and flexible approach to allow for a rigorous step-by-step qualitative analysis [26]. This method uses 5 stages; the first stage, familiarization, began when investigators started transcribing the data. A thematic framework was then identified by 2 investigators, and each transcript was coded separately. The coding involved an iterative process as the codes were refined, whereas discrepancies were resolved by a third investigator (NG). Next, key themes of direct quotes were indexed to demonstrate the richness of the themes. Subthemes within these key themes provided a more in-depth understanding. In the fourth stage, themes were charted so that the key and subthemes could be easily identified, and data may easily be traced back to its original source.

Thematic analysis focused on categorizing data to inform the development of features and content of their preferred website. Initial coding involved attaching labels to text segments to identify themes related to the research questions, that is, what type of components, including language, style, and content, would avoid potential stigma and ensure elements of clear value for users. The analysis progressed iteratively with independent re-reading of transcripts and re-examining themes against the raw data to further refine the themes and identify subthemes. Discrepancies in coding were regularly discussed and resolved with both coders and with the senior researcher (NG).

Results

Participants

The 2 workshops were attended by 13 of the 23 potential participants invited (57% response rate). The majority were from the transport company (9/13, 69%), were male (8/13, 62%), and had full-time employment (11/13, 85%; Table 1). Of the total, 6 employees had previous experience disclosing their own mental health condition (employees: E1-E6), and 7 were in a supervisory role and had previously received disclosures (supervisors: S1-S7). Each workshop contained a mix of individuals from the authority and disclosed groups. With such a small group, we wanted to ensure that the participants were not identifiable, so minimal demographic information was collected. This was an important requirement from both participating workplaces.

Table 1. Demographic information for participants.

Category	Values, n (%)
Worksite	
First responder association	4 (31)
Transport company	9 (69)
Gender	
Male	8 (62)
Female	5 (38)
Employment status	
Part time	2 (15)
Full time	11 (85)
Category	
Disclosure	6 (46)
Authority	7 (54)

Main Themes and Insights

The workshops resulted in 2 overarching themes: content and features.

The *content* theme included the following 4 subthemes:

1. Overall usefulness of the tool.
2. Information on disclosure options.
3. Language preferences, including acceptable mental health terms.
4. Style preferences, including the length of the intervention.

The *features* theme included the following 2 subthemes:

1. Desirable features.
2. Undesirable features.

Content

Overall Usefulness of the Tool

Overall, the participants felt positive about the tool. They found the content and purpose of the tool to be useful and suggested that there would be a benefit for those who were struggling with

their mental health but were not sure where to start asking for help:

> *Self-explanatory, it makes sense.* [Employee 1]
>
> *This would help those struggling.* [Employee 3]
>
> *I thought it was quite good actually. I really thought the questions were good, from my point of view. There's enough of a broad area covered that they will work.* [Employee 4]
>
> *The positive aspect is that it shows that there are lots of avenues that you can take and just because you're not going to tell one person doesn't mean you can't tell anybody, provided your workplace doesn't have an issue with confidentiality or obligations. It sends a positive message to them.* [Employee 6]

Information Around Disclosure Options

One of the key themes identified was how the tool should present information on *specific disclosure options* within the workplace. There were 3 modules that were discussed under this theme.

1. "When is the best time to tell?" This provided employees advantages and obstacles for each of the following options: in a one-on-one meeting, in a chat at work, in the pub or social event, in my review, after I have a good bond with my boss or coworkers or never.
2. "Who have you told in the past?" This section provided participants with a space to reflect on their previous experiences.
3. "Who should you tell?" This provided employees advantages and obstacles for methods of disclosure and/or nondisclosure following options: keep it a secret, only tell trusted people, tell anyone, tell everyone, and tell no one.

Both groups had concerns about guidelines in the prototype suggesting disclosing during a *specially arranged meeting*, which was provided as an option in the *when is the best time to tell* module. This was thought to imply that the meeting may not be confidential:

> *I'd probably lose "specially arranged" but that's just me or in a meeting, sounds too formal and might not be confidential.* [Employee 2]
>
> *I would change the wording from "formally arranged meeting" to "one-on-one meeting". Just sounds more confidential.* [Employee 3]

As a result of this feedback, the phrase *one-on-one meeting* replaced *formal and specially arranged meeting*.

There were some concerns regarding the information guidelines. Some participants expressed concerns that the options suggested for reasonable accommodations might only be suitable for those working a typical 9 to 5 job in an office setting and not applicable to those working shift hours or out-of-office roles:

> *All needs mentioned seem to fit with those working nine-to-five jobs. I don't know if these would fit with, for example, shift workers.* [Supervisor 5]
>
> *This doesn't seem to address people who don't ever work in the office.* [Supervisor 1]
>
> *Some people might need a complete change in job, not just modifications to their current job.* [Employee 4]

To address these concerns, some options that would suit nontypical working hours were discussed in the workshop. Some examples of options for the *needs* for adjustments, individuals, roles, and developers implemented were "to be able to meet with my boss and co-workers more often" and "to have more flexible hours."

Language Preferences

Many preferences were expressed for the language to be used in the tool, particularly around words in the prototype that seemed to hold negative connotations. Specifically, both groups reported that the words *disclosure*, *cons*, *risks*, and *disabled* should not be used as they may portray that a mental health condition is *wrong* or *blame worthy*:

> *Obstacles may hold less of a negative connotation; cons feel like they have done something wrong.* [Employee 1]
>
> *Using the word "disclosure" tends to have a negative connotation it's like I've got to put something on paper, and I've got to disclose something bad or wrong. "Reach out", or "help" might be better.* [Employee 1]
>
> *"Affected" is probably a better word to use than "disabled" as people might not see themselves as disabled.* [Employee 2]

As a result, the term "obstacles and advantages" was replaced with "pros and cons" and "disclosure" was replaced with "telling or tell."

The first responder group noted that certain words may have a specific meaning or be more commonly recognized within their industry. For instance, they preferred the word(s) "understanding or empathy" over "sympathy" and "education" over "teaching":

> *Some language naturally skews away from, for instance, something like "sympathy about my mental health condition" wouldn't be used. They don't want sympathy. I think it should be "understanding about my" maybe "empathy" or "supportive approach to" or "understanding" or "support about my. . . ."* [Supervisor 2]
>
> *Potentially the same with "teaching others is not important" maybe something like "it's not a priority" or education about mental illness is probably a better word than teaching for the leaders in the organization.* [Supervisor 4]

These suggestions were implemented into the tool: "sympathy" was replaced with "understanding" or "empathy" and "teaching" was replaced with "education" or "training."

Acceptable Terms Around Mental Ill Health

Several common terms were used to describe mental health conditions by the participants.

The authority group commonly used *mental health space, mentally not feeling well, mental health case,* and *mental health issues.*

The disclosure group used *mental health "basket," mental state, mental problem, mental health issues, and mental illness.*

There was 1 common term between the 2 groups and that was *mental health issues*. As a result, the tool adapted language to suit the use of this commonly used phrase and was implemented when referring to concerns surrounding poor mental health.

To understand the common slang used for symptoms related to mental health conditions, the coding team noted colloquial words and phrases that were commonly used. The following were used throughout both workshops: *struggling/struggle, not coping, cup is filled up, suffer/suffering, hit the fan, send over the edge, trigger(s)/triggered, strain, stressed, and weak(ness).*

Although there was no appropriate place in the tool for each of the commonly used slang, the following terms were implemented where appropriate: *struggle and stressed.*

A similar approach was used to identify the common words for the clinical services available for addressing mental health conditions and their related symptoms. Participants referred to the following often: *psych services, employee assistance program (EAP), counselling/counselor/psychologist, workers comp, therapy, get support, and support person/group.* The tool implemented a *get support* section in which links to find *psychologist* and *counseling* were added.

Participants made helpful suggestions that within the text for each section of the prototype, it may be important to reassure users that there is no right or wrong answer at any point. This was added to each instruction section for all modules in the tool:

> *Advise in the starting captions that there's no right or wrong answers to make sure answers are honest.* [Employee 5]

Style Preferences

Length of Intervention

Overall, participants felt that the prototype intervention was the right length, easy to use and understand, and helpful and that it would be of use to those who would be considering disclosure. Participants felt that the tool would educate employees about disclosure options:

> *It's a good length and doesn't take too long* [Employee 4]
>
> *I think this isn't too long for people who aren't feeling well, I would've liked as much information as possible.* [Employee 5]
>
> *I think it would generally cover every occupation. There's not too much.* [Employee 4]

Features

Desirable Website Features

There were several desirable features and characteristics that were requested consistently throughout both groups that were clustered into 4 themes: (1) measuring mental health symptoms, (2) resources, (3) disclosure and industry specificity, and (4) interactive functions.

Measuring Mental Health Symptoms

Mood Scale

Many participants suggested that having somewhere to log their mood before and after using the tool would be a great way to see how they were feeling as a *check in*:

> *I would like to see a scale of mood to measure at the start to see how I'm feeling when I am ready to disclose.* [Employee 4]
>
> *Something to measure "what has brought you here today", I am feeling down this that.* [Supervisor 2]

Self-Assessment of Symptom Tool

There was strong interest in a mental health assessment tool that measures the current mental health state; the idea was to see if this may provide further knowledge of individual symptoms and help those who have not ever received a diagnosis to understand or validate their symptoms:

> *Needs an assessment scale at the start before it's used.* [Employee 4]
>
> *An assessment tool would be useful to see if what I'm feeling is really a mental illness or not.* [Employee 5]

Feedback of the Current Mental Health Score

A couple of participants felt that after the self-assessment, it may be beneficial for participants to receive feedback about their current mental health state. The idea was that this information could be provided via an email or a pop up. This did not receive any disagreements in either workshop:

> *I think its missing diagnose section. I need to know results from some symptoms if I'm struggling to see if it's really a problem.* [Employee 4]

Resources for Providing Mental Health Support

Option to Send Feedback to a Clinician

Some participants requested a function where feedback could be sent to their own psychologist or possibly even the EAP. One participant suggested a print option so that they could take the results along to a future meeting around disclosure:

> *It would be good to be able to share the results with support people to make sure you're getting the right help or print and give it to someone when you're disclosing as a backup.* [Supervisor 7]

Easy Access to Urgent Help via Pop-Up or Contacts Page

Most participants suggested and/or agreed that links to mental health support organizations both within the workplace and externally were a must, particularly as the website may be accessed outside of work hours and some may be unwell or even suicidal. This was met with strong support from the authority group:

> *Add a section on having a contact person that you know you can get help.* [Supervisor 4]
>
> *A section on either inside their workplace or like beyondblue or something would be good to have to show people who they should contact to where they should go if they aren't feeling great.* [Supervisor 3]
>
> *Add a section on where to get assistance.* [Supervisor 3]

Option to Request Contact From an External Provider

The idea that someone from outside of the workplace should monitor participants' responses and contact them or that participants might have an option to ask for help from a member of the research team was suggested to make sure participants are being helped:

> *I would like to see a 'would you like to be contacted' section mainly for those who score high on mental health because they probably won't get help.* [Employee 3]
>
> *Add a section on having a contact person that can contact and give you help.* [Employee 1]

Characteristics: Disclosure and Industry Specificity

Tailoring for Industry Specificity

The idea of the intervention being tailored to suit each industry was prevalent in both workshops. This idea was repeatedly requested by a majority of participants based on the idea that industries would require specific needs that may not be translatable across all industries:

> *I think it should be based on each industry, as our needs would be different to another organization.* [Employee 2]
>
> *The needs suggested should be workplace specific as not every job has the same needs.* [Supervisor 2]

Interactive Functions

Notifications With Positive Daily Messages or Emails

Participants suggested that sending emails or messages with positive facts or mental health statistics may help participants feel like they have ongoing support:

> *Ongoing help and reminders will make it feel more supportive and helpful.* [Supervisor 3]
>
> *It wouldn't be a bad idea to have push notifications with positive messages or mental health stats.* [Employee 6]
>
> *If they (messages) were short messages people would benefit.* [Employee 5]

"Get Help" Chat Section to Interactively Chat With Someone External

The idea that giving participants someone to interactively chat with was mentioned in both workshops. Participants felt a chat function would allow them to feel like they have ongoing support:

> *At the moment the extent of the resources is go onto the intranet and find the resources and download the PDF and it all feels a bit static that's why a chat type thing would help with getting support or feeling supported.* [Supervisor 2]

Anonymous Community Forum to Share and View Stories of Lived Experiences of Disclosure

The idea of having an anonymous community forum for individuals to share stories had mixed responses. Some participants felt this would be a useful function as long as it was anonymous, not identifiable, and monitored to avoid cases of bullying:

> *As long as a community forum is not identifiable it would be a good tool.* [Supervisor 2]
>
> *I think information about it [mental illness] and sharing stories with each other is a good idea, useful.* [Employee 4]
>
> *The team might to vet who's on there as there's a risk if you're talking to some people who are also depressed it might make people worse.* [Employee 3]

Testimonial Section From Others Who Have Disclosed in the Past

Participants felt as though a testimonial section about the tool would encourage other employees to use the tool, especially if the testimonial was positive and shared a positive outcome:

> *People love hearing about other people's successes so if someone comes back and says, I did the tool and I spoke to my boss and my workplace and everythingwent well.* [Employee 5]

Videos or Scripts of Example Discussion or Guidance About How to Disclose

One participant suggested that giving participants access to scripts or examples of disclosures in short videos may help those disclosing to feel less isolated and more informed:

> *I think information is power and that kind of thing, facts about disclosing might make people feel like they aren'tisolated.* [Supervisor 1]

Disclosure Decision Making

There was strong interest in having the tool provide a *score* or give recommendations. Participants seemed to want to be told what to do in terms of choosing disclosure or nondisclosure. For instance, the tool could advise on which disclosure option to choose based on the answers selected by the participant. Other suggestions proposed that the answers could be summarized at the end of the tool:

> *It would be helpful to have a score or suggestion page to tell people which option is best based on what they have said.* [Employee 1]

Undesirable Website Features

Participants in the groups were shown the video example of a virtual avatar (an example is shown in Figure 1). Participants

were advised that the avatar and the background could be customized to their liking.

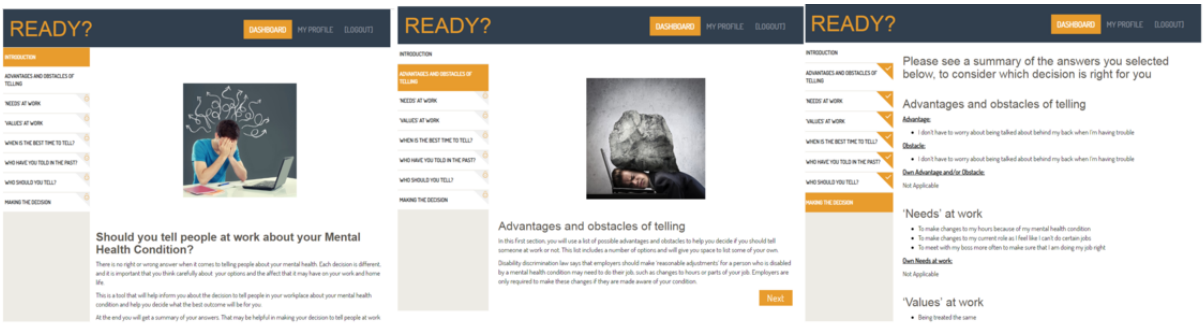
In both groups, a majority of the participants reacted unfavorably to the use of an avatar. In total, 11 participants reported that their main concern was that the cartoon figure may be interpreted negatively, suggesting that the tool may not be taking the condition seriously enough. Another participant suggested that in remote areas, it may become frustrating if the avatar was pausing because of poor internet connection:

> *May be too light-hearted for such a serious problem.* [Employee 5]
>
> *May make people feel like they're not being taken seriously with a cartoon.* [Employee 6]
>
> *may be frustrating if you're in a remote area with no Wi-Fi or not a strong internet connection.* [Employee 6]
>
> *Probably better with the younger crowd you know that interaction if you're given something to read it might just go over their head.* [Employee 1]
>
> *Feel like it's making jokes about mental health or makes it seem child-like.* [Employee 2]

Participants were asked to describe the avatar in a few words, all of which were negative, for example, *creepy, childlike, annoying, not professional*, and *not confidential*.

The final 7 modules discussed in the prototype were approved by the participants as: advantages and obstacles, *needs* at work, *values* at work, when is the best time to tell, who have you told in the past, who should you tell, and making the decision. A visual example of the final version of the tool is provided in Figure 2.

Figure 2. Example of the adapted READY intervention dashboard.



Discussion

Digital and mobile health interventions have become more popular in workplaces because of their accessibility, cost-effectiveness, and confidentiality [16]. The use of digitally delivered decision aids has shown positive results in helping patients make treatment-related decisions [12]. Furthermore, an evaluation of a paper-based decision aid tool for employees showed promising results in assisting in making decisions about mental ill health disclosure options [14]. However, a primary reason why digitally delivered interventions can be poorly implemented is that a tool can only be effective if it engages its intended audience [18]. When developing interventions, developers should consider the end user's needs and preferences. A key aspect of ensuring that the tool is effective is a collaborative co-design design approach.

This study used a participatory design approach to allow all stakeholders, including developers, researchers, experts, and end users, to collaborate in co-designing the tool. This approach was used to ensure that READY, the decision aid tool, was more likely to be engaging and effective for its intended audience. We share our key findings including (1) aspects of the tool where all stakeholders were in agreement, (2) aspects where some stakeholders disagreed and adaptations were implemented, (3) where disagreements could not be implemented because of financial constraints, and (4) where there was misalignment between stakeholders and how to decide on a balance, for instance, how the developers came to decisions about which stakeholders' ideals were implemented and why.

Areas of the Prototype Where All Stakeholders Were in Agreement

Overall, participants felt positively about the prototype put forward. They found the content and purpose of the tool to be useful and all modules necessary. Participants suggested that there would be a benefit for those who were struggling with their mental health but were unsure where to start asking for help. Interestingly, many changes were superficial features such as preferred language, which only required minimal adaptations.

Although participants noted that the tool contained a large amount of written text, they did not consider this something that required changing as they acknowledged that disclosure is a complex area and requires thorough information.

Adaptations That Were Integrated Into the Tool Because of Disagreements With the Prototype

Several changes were made to the language of the tool, for example, *pros and cons* and *risks and benefits* were changed to *obstacles and advantages* to allow for optimal acceptability of the tool. It was important to both groups that the word *disclosure* was not used. This word seemed to carry negative connotations, thus, developers referred to disclosure in the final version as *tell*.

As the intended end users were from Australia, we developed the language in the tool for Australian-specific industries.

Interestingly, participants felt that the language should be *industry specific* as common colloquialisms are used across different industries. For international adaptations of the tool, future research may consider whether the language differs within industries across countries; for example, the slang used in male-dominated industries in Australia may differ from that in the United States.

Several desirable interactive features were added to the final version of the tool, including the addition of mental health feedback scores. The participants were provided with an email regarding their depression and stress levels. This was deemed important as, in our previous qualitative analysis, it was identified that employees who did not have a formal diagnosis had little knowledge of whether their mental health symptoms would meet diagnostic criteria [9].

It was decided that mental health support resources were an important feature of the tool. Mental health resources were added throughout the website. Participants could click on the *get support* tab to obtain phone numbers and links to relevant mental health resources in their area. If participants indicated significant depression or suicidality when answering the mental health screening questions, they were automatically provided with these links and phone numbers and were advised to contact a general practitioner for more information on their mental health.

Desirable Features That Could Not Be Integrated Because of Financial Constraints

The participants suggested some interesting features that could not be included in the scope and budget of this tool that warrant focus in future developments. First, an anonymous community forum provides helpful or positive stories. The research team agreed that it would be important to share success stories around disclosure as all too often we hear about negative injustices and discrimination that occurs as a result of disclosure. The Chief Executive Officer of the lead mental health charity in Australia herself suggested in a national newspaper that employees should not disclose their mental health conditions, “Don’t [disclose], because you might not get that promotion, you might get the sack, there might be repercussions” [27]. However, studies suggest that those who decide to disclose more often than not have positive experiences [28]. Future versions could benefit from a monitored anonymous community forum where other employees may share their success stories or helpful advice. This development team did not have the ability to monitor a community forum under the scope of this project. Second, the suggestion was made about video testimonials again sharing success stories or helpful advice on how and when to disclose. As a result of budget, staffing, and time constraints, the developers were unable to provide this feature; however, it is strongly recommended in future versions as this would be a means of addressing the negative reporting bias.

Areas of Misalignment Between End Users and the Developers, Expert Groups, and Researchers

There were 2 main areas where misalignment appeared between the workers and organizational preferences and the prototype developed by experts. The first was the suggested use of an avatar by the developers. Avatars have previously been used in medical settings. The developers were initially interested in including an avatar into the intervention to assist those with lower literacy levels. Previous studies utilizing avatars to deliver medical information to patients with low literacy indicated that the avatar provided an additional authoritative source for their medical information and a majority preferred receiving the information via the avatar compared with reading the information themselves [29]. An avatar assisted veterans with postdeployment distress in help-seeking decisions. Those randomized to an avatar group exhibited significantly greater likelihood of recognizing their symptoms and seeking help for their mental health concerns compared with a control [30]. However, in this scenario, with such a strong negative response from the worker preference discussions, it was decided not to include the avatar to minimize potential harm as participants suggested that the use of a *cartoon* may be downplaying the seriousness of mental ill health.

The second area of misalignment was the provision of a final score or recommendation on disclosure by the tool. Although workers and some of the expert group wanted a final score of whether or not users should disclose, the developers felt there was no fair or safe manner to provide either a score or a recommendation for several reasons: (1) decision aid tools are not designed to make decisions for the users but aim to increase autonomy and self-determination; (2) it is difficult to ascertain the relative weight of each component as it is unknown what value to place on each selected response. For instance, if 5 small positive reasons for disclosing outweigh one very negative reason, what relative value would “I will get sacked” have compared with “I will feel honest”; (3) a recommendation led to unforeseen consequences. If the tool suggested that the employee should disclose and, as a result of the said disclosure, the employee is fired from their position, there are potential governance and medicolegal consequences that might vary enormously by the employer and occupation, and (4) the tool can only collect information requested. The tool may miss key aspects in certain scenarios, for instance, mandatory reporting requirements in health care.

As an alternative, the final intervention included a summary page on which each of the answers selected were summarized on 1 screen such that participants could see the full picture of their selected values, needs, and facilitators to their disclosure or nondisclosure.

Strengths and Limitations

The participatory design approach supported employees in openly and voluntarily discussing their experience with mental health disclosure. Consistent with Peters et al [19], when participants are given a safe space to discuss mental health disclosures, typically a taboo subject in an occupational setting, they can be highly generative of ideas. Interestingly, the mental health disclosure experiences of employees were discussed openly in the same workshop as the authority group within the same organization, despite these employees reporting only negative experiences and barriers to disclosure [9]. This suggests that employees have an interest in contributing to and improving future disclosure decision making, be it their own or other

employees, above and beyond any potential stigmatizing attitudes.

This study was not without limitations. It should be noted that it is likely to have been influenced by a self-selection bias as those who volunteered to participate are likely to represent those more willing to discuss mental health issues. More importantly, the research team only had information to invite participants from the organizations that had disclosed or been disclosed to. Our study did not include anyone considering disclosure or those who were yet to disclose who would most benefit from the use of this tool.

The study was limited by the involvement of only 2 organizations. Therefore, the participant sample was limited in terms of industries represented and geographical location as all participants were from Australia and from male-dominated industries. As such, responses may not be generalizable to other occupational populations.

Conclusions

In any co-design development, there are certain trade-offs that need to be made between the views of experts, developers, and end users and the available budget [31]. These trade-offs should be carefully considered, although it is important for the uptake, engagement, and usability of the target audience to include input from end users [32]. In this specific instance of a very delicate, personal decision, the end users provided valuable design insight into key areas such as language and were very antipathetic to a key feature, the avatar, which was thought to be desirable by experts and developers. Conversely, the end users only know what they know and they may not be aware of the implications of what they may wish for [33]. In this study, the suggestion of the tool providing a score at the end or advocating disclosure or nondisclosure may have legal ramifications. The co-design with lived experience approach is useful for contributing much to the design, language, and features. The key in this study was balancing the needs of the workers and the potential impacts for the managers and organizations when ensuring legislation and regulation requirements were upheld.

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Authors' Contributions

ES and NG conceptualized the study. ES, NG, IC, DP, and RC contributed to the design, and all authors contributed to the methodology of the study. ES was one of the workshop facilitators. ES, DP, and IC conducted thematic analysis. ES and IC developed the original draft of this manuscript. NG provided overall supervision of this project. All authors contributed to reviewing and editing the draft and final versions of this manuscript.

Conflicts of Interest

ES and the affiliations associated with NG and SH co-own the intellectual property for READY.

Multimedia Appendix 1
Workshop plan and design.
[DOCX File , 17 KB - formative_v4i11e23337_app1.docx]

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Abbreviations

AIML: artificial intelligent markup language
CORAL: Conceal or ReveAL
EAP: employee assistance program
READY: Reducing dEcisionAl conflict, a Decision aid tool for emploYees

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Original Paper

Effectiveness of a Smartphone App (BioBase) for Reducing Anxiety and Increasing Mental Well-Being: Pilot Feasibility and Acceptability Study

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Abstract

Background: The prevalence of workplace-related stress and anxiety is high, resulting in stress-related physical and mental illness. Digital self-guided interventions aimed at key areas of workplace design may be able to provide remote anxiolytic effects.

Objective: The aim of this feasibility study is to assess changes in anxiety and mental well-being after use of the BioBase programme, a mobile phone platform for psycho-educational modules, tools, and real-time feedback of physiological data.

Methods: A 4-week observational study was carried out in 55 healthy adults who were screened for stress with the Depression Anxiety Stress Scale (DASS) Stress subscale. Participants completed anxiety (6-item State-Trait Anxiety Inventory [STAI]) and mental well-being (Warwick-Edinburgh Mental Well-being Scale [WEMWBS]) questionnaires at baseline and at 4 weeks. Feedback questionnaires were administered after 4 weeks.

Results: After 4 weeks of using the programme and controlling for any effect of being paid to take part in the study, STAI significantly decreased (baseline mean 45.52 [SD 13.2]; 4-week mean 39.82 [SD 11.2]; t_{54}=–3.51; P<.001; CI –8.88 to –2.52; Cohen d=0.96) and WEMWBS significantly increased (baseline mean 48.12 [SD 6.4]; 4-week mean 50.4 [SD 6.9]; t_{53}=2.41; P=.019; CI 0.44-4.23; Cohen d=0.66). Further, higher baseline stress was significantly associated with a greater decrease in STAI (t_{53}=–3.41; P=.001; CI –8.10 to –2.10; R^2=0.180) and a greater increase in WEMWBS (t_{52}=2.41; P=.019; CI 0.38-4.11, R^2=0.101). On feedback, participants found the programme easy to use/navigate, with the content being acceptable and relevant to workplace-related stressors; 70% (21/30) of participants would recommend the programme to a friend.

Conclusions: The BioBase programme is a potentially effective intervention in decreasing anxiety and increasing mental well-being, with larger changes in those with higher baseline levels of stress.

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KEYWORDS

health and well-being; health promotion; organizational and leadership support; workplace

Introduction

The workplace can be a major cause of anxiety that leads to depression and burnout [1-4] as well as stress-related illnesses [5,6]. In the UK, 12.8 million working days were lost in 2018-2019 due to mental ill health, equating to 21.1 days lost per year per working individual [7].

Interventions in the workplace may be able to reduce the effects of anxiety or facilitate the recovery of employees with anxiety [1]. Structured and targeted psychological interventions have been found to be more effective than general stress management training [8,9], and those employees experiencing higher levels of anxiety have been shown to benefit most [10]. Smartphone apps offer a practical, scalable, accessible, and cost-effective solution to promoting employee mental health [11-13]. As smartphone use becomes more ubiquitous, a mobile solution to mental health is becoming increasingly more common [13-15].

Many therapist-assisted or guided workplace digital interventions have been shown to be effective in reducing work-related stress [12,16-22]; however, these suffer from the limited availability and high cost of more traditional forms of support, and therefore are rarely available to the entirety of the workforce [9]. Self-guided digital interventions, which overcome some of these barriers for individuals seeking support, have also shown promising results in reducing stress and anxiety [9,23,24].

Engaging, innovative, and effective interventions that address specific workplace-related mental health difficulties are still needed. Integrated technology in self-guided interventions offers several advantages that increase engagement, behavior change, and positive psychological outcomes [25], such as personalized mental health/well-being summaries and insights [1], real-time monitoring of health data from linked biosensors [20,26], and a secure and private means to access confidential support [14,27]. Combined interventions that utilize advanced technology for real-time data feedback plus active therapeutic content may yield a synergistic effect to decrease anxious symptoms, especially in those with higher baseline levels of stress and anxiety [10].

The BioBase programme (by BioBeats Ltd) includes a mobile app, BioBase, used in conjunction with its wrist-worn wearable BioBeam. The programme offers therapeutic content in a modular format in addition to tools such as deep breathing exercises and mood tracking; these data are integrated with passively collected data on activity, heart rate, and sleep duration and quality that are presented to the users via a dashboard view. This information is used to inform individuals off their current well-being, and then to direct the individual to the most appropriate intervention modules. As yet, the effectiveness of this type of self-guided combined intervention has not yet been investigated in working individuals.

The aim of this study is to evaluate the usability, acceptability, feasibility, and preliminary efficacy of BioBase in individuals in full-time employment with varied levels of stress on perceived anxiety and mental well-being. We hypothesize that after 4 weeks of using the programme (1) there will be a significant decrease in anxiety and (2) a significant increase in mental well-being compared to baseline. Further, we hypothesize that (3) higher baseline levels of self-reported stress will be associated with larger decreases in anxiety and increases in well-being. This paper first tests these hypotheses and then describes the participants' reported acceptability, usability, and feasibility, as well as any evoked behavior change.

Methods

BioBase Programme

The BioBase programme consists of the BioBase smartphone app platform that integrates data from its paired wrist-worn wearable. BioBase includes workplace-specific psycho-educational content based on the job demands-resources model [28] and combines elements of mindfulness, cognitive behavioral therapy and behavioral activation theory. The content consists of 42 modules designed around 3 courses based on the UK Health & Safety Executive's (HSE) work stressor dimensions: demands, control, and social support. These courses highlight the importance of lifestyle factors, such as sleep awareness, sleep hygiene, and activity levels, as well as recognizing internal physiological and emotional processes as a trigger for stress. The objective of all the courses is to help the user identify and use effective coping strategies: the demands course aims to reduce the perceived stress due to overwhelming demands, the control course aims to increase a person's perception of control to avoid burnout, and the support course aims to increase social connections and social support. Each course has 14 modules, presented in either text or audio format, taking approximately 3-5 minutes to complete and containing an action or tool to complete in-app or in the workplace. To personalize content based on the individual's needs, individuals first complete a tailored questionnaire (HSE management standards indicator tool) and the modules pertaining to the area with the lowest score are then recommended (Multimedia Appendix 1).

Data on physical activity, sleep quality, and heart rate are collected via its paired wearable device, BioBeam, and fed back to the individual via a dashboard view in order to increase awareness of the individual's current well-being state and to help them learn how physiological patterns are related to their well-being in parallel with the content of the modules.

The app also contains on-demand tools such as an in-built ecological momentary assessment based on the Circumplex Model of Affect [29], allowing individuals to log their mood in the moment, and reflect back on their entries at a later date to gain insights into patterns and themes, and diaphragmatic breathing exercises for stress reduction.

Recruitment

Paid participants were individually recruited from a recruitment agency specializing in user research and usability testing (People for Research UK) alongside unpaid participants recruited through convenience sampling through a local Facebook campaign. Recruitment of small businesses was also conducted by a local small business network.

Participants were eligible to take part if they were aged between 18 and 65, in full-time employment, had access to an Apple iPhone, and were able to read and understand English. Exclusion criteria were a history of clinical diagnosis of a mental health or neurological disorder, pregnancy, or current engagement in counselling or therapy. Ethical approval was granted by the University of Exeter and informed consent was obtained electronically from all participants.

Procedure

The study lasted 4 weeks. Participants were screened for inclusion and exclusion criteria using an online questionnaire. At baseline, online questionnaires were used to collect demographic information on age, gender, education, and employment categories, as well as self-reported stress from the Stress subscale of the 21-item Depression Anxiety Stress Scale (DASS-21) [30]. The stress subscale consists of 7 questions with range 0-21 and relates to the experience of stress symptoms in the previous week. The internal consistency of the scale is good (Cronbach α=.85) and construct validity measured in previous studies is also good [31].

At baseline and at 4 weeks, questionnaires included the 6-item State-Trait Anxiety Inventory (STAI; [32]) and the Warwick-Edinburgh Mental Well-being Scale (WEMWBS; [33]). The 6-item STAI measures state anxiety, with responses ranging from 1 (Not at all) to 4 (Very much). Scaled scores are obtained by multiplying the summed responses to each item by 20 and subsequently dividing the score by 6 (range 20-80). The STAI is widely used and has a good internal consistency (α=.92) [32].

The WEMWBS is a 14-item scale assessing subjective mental well-being. Scoring is obtained by summing each response, ranging from 1 (None of the time) to 5 (All of the time) (range 14-70). WEMWBS has been validated for use in the UK with those aged 16 and above with good internal consistency (α=.91) [33].

Participants were asked to engage naturally with the app, but encouraged to continuously wear the BioBeam, use the BioBase app for around 5 minutes per day for 4 weeks, and complete at least 14 daily 3-5-minute-long modules. Measures of app engagement consisted of number of days in which the app was opened (ie, “active” days), total duration of use, number of modules completed, and total tools completed over the 4 weeks.

An additional feedback questionnaire with multiple-choice questions and free-text answers was distributed at the end of the study along with an optional semistructured interview with the researcher to expand on their responses in the feedback form. Quotes from the free text and interviews were given to illustrate insights into the feasibility, usability, and acceptability of the BioBase programme.

Statistical Analysis

Analysis was performed using R version 3.6.0 (R Foundation Statistical Computing) [34]. To test the first hypothesis of change in STAI and WEMWBS scores between baseline and 4 weeks, variables were first tested for a normal distribution using Shapiro–Wilk tests and linear mixed-effects models (R package: “lmer”) with participants as random effects were fitted to the data.

To test the third hypothesis that baseline DASS stress scores would be associated with greater decreases in STAI and greater increases in WEMWBS, baseline DASS stress scores were first transformed using ordered quantiles to follow a normal distribution (method: OPQ, R package: “bestNormalize”). Linear regression models were used to determine association between baseline DASS stress scores and change in STAI and WEMWBS scores. All analyses used *paid* status as a covariate. *P*-values were considered statistically significant at <.05.

Results

Participants

A total of 70 participants were initially recruited; 4 were excluded due to current engagement in counselling/therapy and 1 was excluded because they were employed part-time. The final sample consisted of 55 participants (25 paid and 30 unpaid) as 10 participants did not complete the exit questionnaires. While paid participants were significantly older, there were no significant differences between paid and unpaid participants in terms of gender distribution; education or employment category; or baseline stress, anxiety, or well-being scores (Table 1).

Table 1. Sample demographics of participants with baseline self-reported stress on DASS (N=55).

Participant demographics	Paid	Unpaid	*t* test (*df*) or chi-square (*df*)	*P* value
Total participants	25 (45)	30 (55)		
Age, mean (SD), years	38.6 (13.3)	31.4 (6.7)	2.45 (54)	.02
Gender			0 (54)[a]	>.99
Female, n (%)	14 (56)	16 (53)		
Male, n (%)	11 (44)	14 (47)		
Education				.35[b]
School (age 16), n (%)	3 (12)	0 (0)		
Sixth form/college (age 18), n (%)	3 (12)	8 (27)		
Some university, n (%)	1 (4)	1 (3)		
2-year degree, n (%)	4 (16)	4 (13)		
4-year degree, n (%)	10 (40)	14 (47)		
More than 4-year degree, n (%)	4 (16)	3 (10)		
Job category[c]				.43[b]
Administrative, n (%)	5 (20)	2 (7)		
Service, n (%)	2 (8)	1 (3)		
Technical, n (%)	1 (4)	4 (14)		
Sales, n (%)	2 (8)	6 (21)		
Professional, n (%)	10 (40)	10 (34)		
Executive, n (%)	5 (20)	6 (21)		
Baseline DASS[d] stress, mean (SD)	13.7 (8.0)	16.7 (9.9)	1.23 (53)	.22
Baseline STAI[e], mean (SD)	43.9 (11.0)	46.9 (14.8)	0.87 (54)	.39
Baseline WEMWBS[f], mean (SD)	48.1 (5.6)	48.2 (7.2)	0.05 (53)	.96

[a]Presented as chi-square (*df*).

[b]Fisher exact test.

[c]N=29 for unpaid.

[d]DASS: Depression Anxiety Stress Scale.

[e]STAI: State-Trait Anxiety Inventory.

[f]WEMWBS: Warwick-Edinburgh Mental Well-being Scale.

Engagement

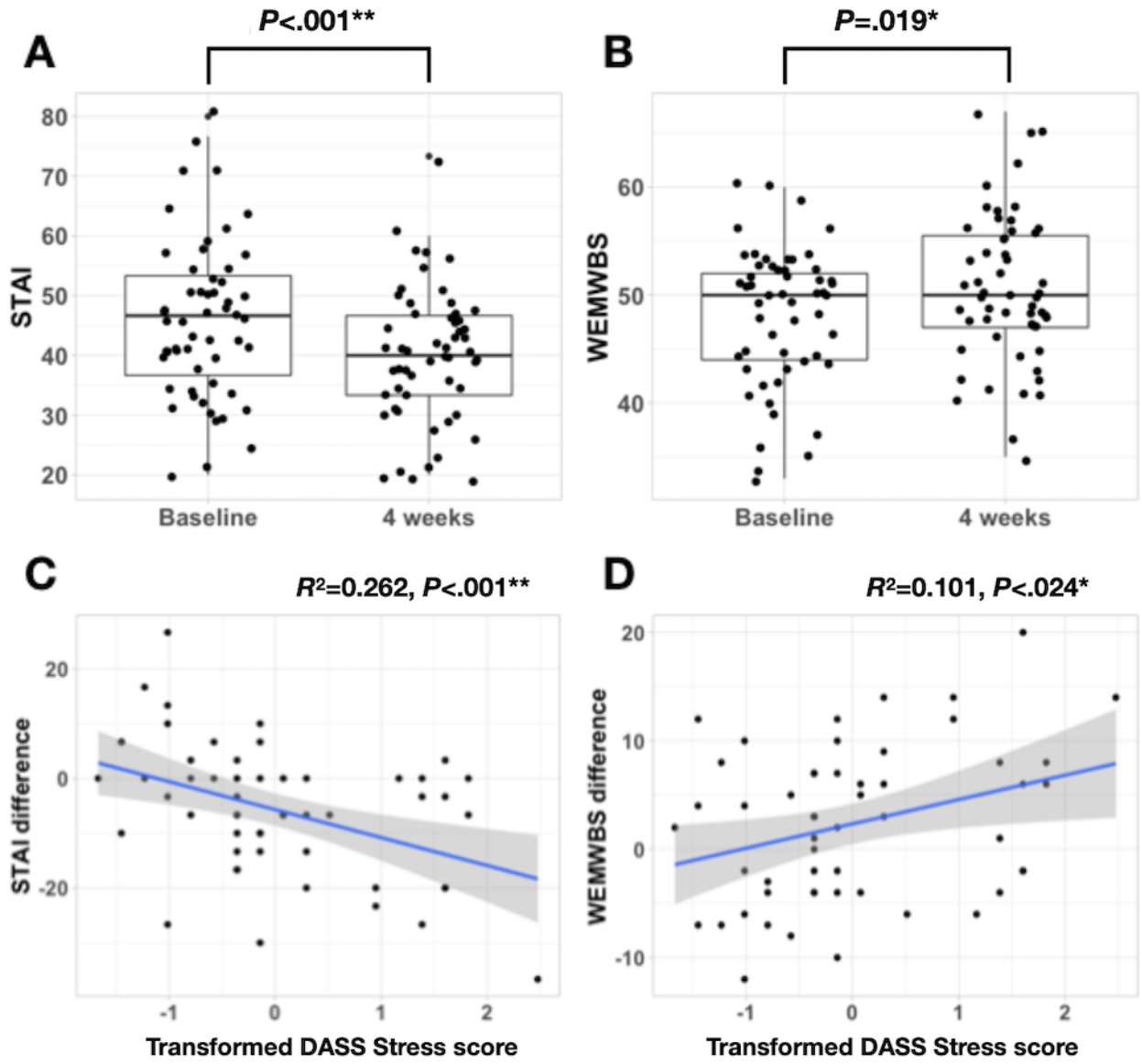
Participants used the app on average 20.9 days (median 22; IQR 7.5) of 4 weeks, completing an average of 28.4 tools (median 25) and completing an average of 8.9 modules (median 7). The mean total duration of use was 164.3 minutes (median 157.0 minutes).

Paid participants used the app on more days (paid: mean days 23.9; unpaid: mean days 18.4; t_{54}=3.39; *P*=.014; Cohen *d*=0.89), completed more tools (paid: average tools 36.8; unpaid: average tools 21.3; t_{54}=3.12; *P*=.003; Cohen *d*=0.86), completed more modules (paid: average modules 13.7; unpaid: average modules 4.9, t_{54}=4.81; *P*<.001; Cohen *d*=1.30), and had a longer total duration of use (paid: 210.2 minutes; unpaid: 125.9 minutes; t_{54}=3.20; *P*=.003; Cohen *d*=0.88) than unpaid participants.

Outcomes

The first 2 hypotheses were supported. After controlling for paid status, linear mixed models revealed that anxiety as measured by STAI significantly decreased (baseline mean 45.52 [SD 13.2]; 4-week mean 39.82 [SD 11.2]; t_{54}=–3.51; *P*<.001; CI –8.88 to –2.52; Cohen *d*=0.96) and mental well-being significantly increased (baseline mean 48.12 [SD 6.4]; 4-week mean 50.4 [SD 6.9]; t_{53}=2.41; *P*=.019; CI 0.44-4.23; Cohen *d*=0.66) after 4 weeks of using the BioBase programme. There were nonsignificant effects of paid status on STAI (t_{54}=1.97; *P*=.054) and WEMWBS (t_{53}=0.28; *P*=.78; Figure 1).

Figure 1. After controlling for paid status, differences in (A) 6-item STAI and (B) WEMWBS after 4 weeks of the BioBase program. Association between transformed DASS Stress scores and difference in (C) STAI and (D) WEMWBS, ***P*<.01, **P*<.05. DASS: Depression Anxiety Stress Scale; STAI: State-Trait Anxiety Inventory; WEMWBS: Warwick-Edinburgh Mental Well-being Scale.



After controlling for paid status, linear regression models revealed that a higher baseline DASS stress significantly predicted a greater decrease in STAI (t_{53}=–3.93; *P*<.001; CI –8.62 to –2.80; R^2=0.262) and significantly predicted a greater increase in WEMWBS (t_{52}=2.32; *P*=.024; CI 0.30-4.12; R^2=0.101; Figure 1).

Participant Feedback

As much as 32 of 55 participants completed a feedback questionnaire with both multiple-choice questions and free-text answers and were given the opportunity to expand their responses in an interview with an experienced researcher (NH). Responses from 2 participants were withdrawn because the participant did not want their responses shared. Table 2 describes responses from 30 participants (18 paid and 12 unpaid) of the multiple-choice questions.

Table 2. Feedback questionnaire results on intervention engagement, usability, and self-reported behavior change.

Theme	Paid (N=18, 60%)	Unpaid (N=12, 40%)	*P* value
Feasibility and usability			<.001[a]
How many times did you usually log in?			
Never, n (%)	0 (0)	0 (0)	
Once a week, n (%)	0 (0)	1 (83)	
Several times a week, n (%)	0 (0)	7 (58)	
Once a day, n (%)	10 (56)	2 (17)	
Several times a day, n (%)	8 (44)	2 (17)	
What time of day did you usually log in?			.50[a]
Morning before work, n (%)	3 (17)	2 (17)	
Morning at work, n (%)	2 (11)	0 (0)	
Lunch time, n (%)	0 (0)	2 (17)	
Afternoon at work, n (%)	1 (6)	1 (8)	
Evening at home, n (%)	12 (67)	7 (58)	
Where did you usually log in?			>.99[a]
Home, n (%)	14 (78)	10 (83)	
Work, n (%)	4 (22)	2 (17)	
Commute, n (%)	0 (0)	0 (0)	
Acceptability			
Would you recommend the BioBase programme to a friend?			.13[a]
Yes, n (%)	15 (83)	6 (50)	
Maybe, n (%)	3 (17)	5 (42)	
No, n (%)	0 (0)	1 (8)	
Would you like to continue using the BioBase programme?			.26[a]
Yes, n (%)	11 (61)	4 (33)	
No, n (%)	7 (39)	8 (67)	
Promoting behavior change			
Have there been any changes to your physical health since starting the BioBase programme?			>.99[a]
Yes, n (%)	6 (33)	3 (25)	
Maybe, n (%)	2 (11)	2 (17)	
No, n (%)	10 (56)	7 (58)	
Have there been any changes to your mental health since starting the BioBase programme?			.06[a]
Yes, n (%)	5 (28)	3 (25)	
Maybe, n (%)	3 (17)	7 (58)	
No, n (%)	9 (50)	2 (17)	
Have there been any changes to your engagement at work since starting the BioBase programme?			.69[a]
Yes, n (%)	6 (33)	3 (25)	
Maybe, n (%)	2 (11)	3 (25)	
No, n (%)	10 (56)	6 (50)	

[a]Fisher exact test.

Participant Feedback: Feasibility and Usability

Participants stated that the app was easy to use and navigate ("really good experience" [unpaid participant]). The wearable was also considered usable ("easy to wear and keeps you informed" [paid participant]), with participants paying particular attention to the battery life ("the battery life of the device is exceptional" [paid participant]).

The BioBase programme was convenient and feasible to use as 73% (22/30) of participants reported checking the app at least once per day ("I think we all checked it when we first got in 'cause we were talking about our sleep and our rubbish sleep, and I guess at lunchtime I'd have a go and then when I'd go home" [unpaid participant]). There was a significant difference between paid and unpaid participants in how often they logged in, with unpaid participants logging in less often (P<.001; Table 2).

There were no differences between paid and unpaid participants in the time of day or location in which they logged in; 80% (24/30) of participants logged in at home and 70% (21/30) in the evening or in their lunch break in the workplace ("Yeah normally at home, I do it on my lunch break as well, when I was at work at times, when was stuck in the queue or something" [paid participant]).

Participant Feedback: Acceptability in the Workplace

The majority of participants responded they would recommend the programme to a friend (70%, 21/30) and 50% (15/30) would have liked to continue with the programme after 4 weeks. There were no differences between paid and unpaid participants in this respect (Table 2).

BioBase was seen as an acceptable solution in the workplace to support employee health ("I think it's definitely needed. I think it's a really great way to track your company satisfaction and well-being and this changes the way people build their HR policies, 100%. I think there are a lot of companies that say they are doing really amazing things, but might not be, and this is a good way to prove it, because you're not like messing around with the data" [unpaid participant]). Participants appreciated the accessible and personal approach ("on demand, private-ish, lots of great education" [unpaid participant]) and the concept of increasing self-awareness ("it provides great exposure to education and techniques for managing and discussing mental health maintenance," "The programme has made me more self-aware...I think the BioBase is excellent for workplace use" [unpaid participant]). Many participants had support and encouragement from their colleagues ("I just used the app mostly at work because I was sort of reminded by everyone here" [unpaid participant], "we would do the breathing things, if one of us was stressed" [unpaid participant]).

Participant Feedback: Promoting Behavior Change

There were no differences between paid and unpaid participants with regard to perceived changes in physical health, mental health, or engagement at work (Table 2). Key themes in the feedback revealed that real-time data helped participants to understand their current state ("BioBase has helped me become more aware of my body and how external factors were affecting me" [paid participant]) and the impact of environmental triggers ("being aware of what triggers stress and being taught and successful ways of managing this. Has been a game changer" [paid participant]).

Learned proactive and preventative mechanisms from the modules and tools helped achieve positive outcomes ("I approach some tasks, particularly procrastination differently sometimes. I am also even more mindful of taking time to unwind." [unpaid participant]; "[I learned] how to breathe properly, coping mechanisms for stress, how to get things into proportion where stress concerned and how to cope with stress by developing interests outside work and relaxing after work" [paid participant]). Specifically, the breathing tool was found to be very useful to achieve on the spot stress reduction ("I like the breathing exercises; this is something I will continue with after the trial. I find them very useful for winding down in the evenings before sleep" [paid participant]).

Changes in sleep habits was seen as a consistent behavior change with multiple participants reporting various new health behaviors ("[I] prepare myself for sleep more deliberately than previously" [unpaid participant], "I'm more conscious of going to bed at a reasonable time" [unpaid participant], "I make the room completely dark 30 mins before going to sleep" [paid participant], "Ensuring I go to bed at a particular time even on the weekend" [paid participant]).

There were also reports of increased social connection ("the tribes concept stuck with me and I intend to invest more in building social groups" [unpaid participant], "I consciously try and arrange social activity to increase my activity [levels, like] playing golf, badminton, swimming" [paid participant]).

Discussion

Principal Results

This study explores the efficacy of BioBase, which to our knowledge is the first self-guided intervention that combines measurement and biofeedback of passively collected physiological data and linked content on physical and mental health. We found significant decreases in anxiety and increases in mental well-being after 4 weeks of using BioBase in a workplace setting. Importantly, this study found that higher baseline stress levels were associated with greater decreases in anxiety and increases in well-being. These results fit into a wider body of literature showing that digital health interventions may improve symptoms of depression, stress, and anxiety in a workplace environment [35-38], with more pronounced benefit in those with elevated stress levels [10,19].

Comparison With Prior Work

Self-guided digital health interventions have been shown to have positive effects on mental health and well-being [23] and can be as effective as face-to-face treatments for anxiety [9,39]. The results from this study show BioBase is also potentially effective. The effect sizes found were d=0.96 for reduction in anxiety and d=0.66 for increase in well-being, which is higher than previous studies using self-guided interventions (d=0.44 for work-related worry [9]; d=0.47 for anxiety [24]).

The BioBase programme was found to be feasible for use in the work environment, due to ease of access on a personal or work phone [25]. Participants found it relevant, acceptable, and that it worked within their time constraints, as it focused on work-related stressors with simple, short tasks that are easily implemented in the working day [9].

From an employer's perspective, self-guided interventions do not require the vast resources needed for either traditional organizational support or therapist- or coach-assisted interventions. In addition, they provide more accessibility than in-house training and reach a larger population with comparable clinical outcomes [40]. Our findings suggest that participants with higher levels of stress had significantly greater reductions in anxiety and increases in well-being, which may help employers deliver a solution for those employees most at risk.

Self-guided interventions have the advantages of allowing the user to go at their own pace and access content that is right for them; however, they rely more on an individual's willingness to take part and often have lower engagement rates or failed adoption [41]. Participants in this study used the app on average 72% of days (20.9/29 days), which is higher than [9,23] or similar to [24] other self-guided digital interventions. It is possible that engagement was higher because the BioBase programme is a unique intervention that provides targeted and relevant content [1] along with integrated technology [25]. The feedback suggests that people appreciated different aspects of the programme based on what content and insights were tailored (ie, feedback on sleep quantity and quality and ability to customize recommended modules).

Limitations

This study was conducted with participants recruited from a workplace setting across a variety of workplaces and job roles; however, it is beyond the scope of this study to separate participants by type of role or organizational conditions. Future studies with larger samples should be carried out to explore these effects.

The current feasibility study did not utilize a control group and therefore was not able to rule out a regression to the mean or a placebo effect of using a digital intervention. Future studies should conduct a randomized controlled trial to add evidence that the anxiolytic effects were more specific than a placebo effect.

Due to the personalized nature of the intervention and the multiple therapeutic touch points in the BioBase programme, it is difficult to conclude which elements of the BioBase programme contributed most to the observed reductions in anxiety and increases in well-being. Further practical investigation is needed into breaking into the "black box" of digital health interventions to understand the main therapeutic effects [42,43].

Acknowledgments

JK and NH collected and analyzed the data and wrote the manuscript. SP analyzed the data and made significant contribution to the manuscript. DM, GB, and DP conceived of the research and made significant contribution to the manuscript.

Conflicts of Interest

DP was the CEO of BioBeats, the provider of the BioBase programme; JK, NH, and SP were employees of BioBeats; GB was a freelancer and was compensated for his work on this research by BioBeats; industry support was provided by BioBeats Group LTD in the form of provision of participant recruitment fees and provision of wearable devices.

Multimedia Appendix 1
Content and theoretical contextualization of the three psychoeducational courses contained in BioBase.
[DOCX File , 22 KB - formative_v4i11e18067_app1.docx]

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Abbreviations

DASS: Depression Anxiety Stress Scale
HSE: Health & Safety Executive
STAI: State-Trait Anxiety Inventory
WEMWBS: Warwick-Edinburgh Mental Well-being Scale

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Original Paper

Diagnosing Chronic Obstructive Airway Disease on a Smartphone Using Patient-Reported Symptoms and Cough Analysis: Diagnostic Accuracy Study

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Abstract

Background: Rapid and accurate diagnosis of chronic obstructive pulmonary disease (COPD) is problematic in acute care settings, particularly in the presence of infective comorbidities.

Objective: The aim of this study was to develop a rapid smartphone-based algorithm for the detection of COPD in the presence or absence of acute respiratory infection and evaluate diagnostic accuracy on an independent validation set.

Methods: Participants aged 40 to 75 years with or without symptoms of respiratory disease who had no chronic respiratory condition apart from COPD, chronic bronchitis, or emphysema were recruited into the study. The algorithm analyzed 5 cough sounds and 4 patient-reported clinical symptoms, providing a diagnosis in less than 1 minute. Clinical diagnoses were determined by a specialist physician using all available case notes, including spirometry where available.

Results: The algorithm demonstrated high positive percent agreement (PPA) and negative percent agreement (NPA) with clinical diagnosis for COPD in the total cohort (N=252; PPA=93.8%, NPA=77.0%, area under the curve [AUC]=0.95), in participants with pneumonia or infective exacerbations of COPD (n=117; PPA=86.7%, NPA=80.5%, AUC=0.93), and in participants without an infective comorbidity (n=135; PPA=100.0%, NPA=74.0%, AUC=0.97). In those who had their COPD confirmed by spirometry (n=229), PPA was 100.0% and NPA was 77.0%, with an AUC of 0.97.

Conclusions: The algorithm demonstrated high agreement with clinical diagnosis and rapidly detected COPD in participants presenting with or without other infective lung illnesses. The algorithm can be installed on a smartphone to provide bedside diagnosis of COPD in acute care settings, inform treatment regimens, and identify those at increased risk of mortality due to seasonal or other respiratory ailments.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12618001521213; http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375939

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KEYWORDS

respiratory; medicine; diagnostic algorithm; telehealth; acute care

Introduction

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of mortality, affecting more than 384 million individuals worldwide [1]. It is characterized by airflow limitation and a progressive decline in lung function [2]. The population prevalence of COPD via spirometry screening is reported to be 9% to 26% in those older than 40 years [3]. It is estimated that 80% of people with COPD are undiagnosed [4], and up to 60% of those with a diagnosis of COPD have been found to be misdiagnosed upon subsequent spirometry [5,6]. Moreover, 30% to 60% of patients who have been diagnosed by a physician as having COPD have not undergone spirometry testing [7]. In a study of 533 patients with COPD, 15% of those with spirometry tests did not show obstruction and 45% did not fulfill quality criteria [8].

COPD should be considered in patients who present with dyspnea, chronic cough, sputum production, or recurrent lower respiratory tract infections and patients who have been exposed to tobacco or air pollution. Airflow limitation, demonstrated by a forced expiratory volume in the first second to forced vital capacity (FEV_1/FVC) ratio of <0.7 on postbronchodilator spirometry, is considered diagnostic of COPD according to criteria stipulated by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [2]. The severity of airflow limitation in COPD can be classified by the degree of reduction in FEV_1 as a percentage of the predicted value [2]. However, spirometry is not routinely used in emergency departments or primary care settings due to inexperience, time constraints, and availability of equipment [9]. Further, the COPD remote patient monitoring equipment (spirometers and oximeters) with the most technological promise and compatibility with daily living are expensive and of limited use [10].

Early and accurate diagnosis of COPD is imperative to ensure initiation of correct treatment, particularly as evidence suggests that the incipient stages represent a period of rapid decline in lung function, during which cessation of smoking and targeted intervention may be of value [11]. Rapid identification and management of COPD is important in acute care settings, as there is a heightened risk of mortality from respiratory infections such as seasonal influenza [12]. SARS-CoV-2 has a reported case fatality rate of 1.4% for patients without comorbid conditions versus 8.0% for those with chronic respiratory conditions [13].

Screening for COPD in primary care settings using spirometry in asymptomatic patients has not been found to be efficient, as high numbers of patients need to be screened to detect any cases [14,15]. Screening questionnaires, such as the COPD diagnostic questionnaire (CDQ), have performed poorly in an asymptomatic cohort in the primary care setting [16]. We propose that the best use of an algorithm for screening is in a scenario in which patients present to a health care facility with symptoms, as this has a higher pretest probability of case detection.

We previously demonstrated high diagnostic agreement of an automated algorithm with clinical diagnoses for pediatric respiratory diseases, including croup, asthma, bronchiolitis, and pneumonia. The algorithm also accurately separated upper from lower respiratory tract conditions [17]. The technology, which has regulatory approval, is similar to that used in speech recognition software and combines lower airway audio data transmitted during cough events and simple patient-reported clinical symptoms to derive the diagnostic probability output [18]. As the lower airway is open to the outside during a cough, sounds are transmitted through the mouth and can be recorded. In this way, it is similar to traditional auscultation; however, much higher bandwidth is achievable using our method, as the chest wall no longer reduces sound transmission. We recorded audio using a standard smartphone, and the built-in diagnostic algorithm provided a rapid result without requiring clinical examination or additional diagnostic tests.

In this paper, we describe the development and evaluate the accuracy of an algorithm for diagnosing COPD in a cohort of mixed respiratory disorders, including acute respiratory infections. The intended use population is patients who present to health settings with suspected respiratory illness.

Methods

Study Population and Setting

Between January 2016 and March 2019, a convenience study sample was obtained by prospectively recruiting participants from the emergency department, low-acuity ambulatory care, and inpatient wards of a large general hospital in Western Australia and from the consulting rooms of a respiratory physician.

This diagnostic accuracy study is part of a more extensive development program (Breathe Easy; Australian New Zealand Clinical Trials Registry ACTRN12618001521213). Patients were approached if they presented to a participating site with signs or symptoms of respiratory disease or to specialist rooms for a lung function test. Patients with no discernible symptoms of respiratory disease were also recruited. Patients were excluded if they were on ventilatory support, had a terminal disease, were medically unstable, had structural upper airway disease, or had a medical contraindication to providing a voluntary cough (eg, severe respiratory distress; eye, chest, or abdominal surgery within 3 months; history of pneumothorax). Patients with uncontrolled heart failure or cardiomyopathy, neuromuscular disease, or lobectomy or pneumonectomy were also excluded. From this cohort, only those aged 40 to 75 years were enrolled in the COPD development program.

Written informed consent was obtained from all participants, and the study was approved by a human research ethics committee (Reference No. 1501). There were no adverse events reported. The study did not interfere with clinical care and all treatment decisions were at the discretion of the treating physician.

Index Test (Software Algorithm)

The development of the mathematical techniques used to derive the algorithm has been described in depth elsewhere [17-20]. Briefly, an independent training cohort (N=564) was used to obtain clinical data and cough samples (from which mathematical features were extracted). In developing the algorithm, selected features were weighted and combined to build various continuous classifier models used to determine the probability of a COPD diagnosis (reference test). The probability output of the algorithm represents the specific, weighted combination of features. Multiple clinical symptoms and audio characteristics were examined and combined, with the goal to minimize the number of inputs and to use patient-reported symptoms rather than clinically determined signs, vital signs, or investigations. Each input added to the overall accuracy and discriminatory clinical ability of the algorithm. The optimal model and corresponding probability decision threshold were selected using a receiver operating characteristic (ROC) curve, with due consideration given to achieving a balance of positive percent agreement (PPA) and negative percent agreement (NPA) [18]. Once the optimal model was developed, it was locked from further development and prospectively tested for accuracy on an independent testing set.

Audio data were obtained from 5 coughs using a smartphone (iPhone 6; Apple Inc) held approximately 50 cm away from the participant at a 45° angle to the direction of the airflow. Recordings were undertaken in standard clinical environments; however, we took care to avoid other people's coughs and voices. The cough recording was obtained within 30 minutes of the physical examination of the patient to ensure the clinical features had not changed. If the participant was unable to provide 5 coughs that were recognized by the cough detection software or if the cough recording became corrupted, the participant was excluded from further analysis.

The following 4 clinical symptoms were selected for inclusion in the tested model: participant age, smoking pack-years, and participant-reported presence of acute cough or fever during this illness. One smoking pack-year was defined as 20 cigarettes or 20 g of tobacco smoked each day over 1 year [21]. Where the clinical symptoms were partially unknown, the algorithm did not return a response.

Reference Test (Clinical Diagnosis or Spirometry)

A full medical assessment was performed on all participants at the time of enrollment, including history and clinical examination. Diagnostic tests were ordered by the treating clinician independently of the study and results were available to researchers.

A specialist physician assigned a clinical diagnosis to each participant based on a review of their medical file, including discharge diagnosis, all outpatient and inpatient notations, and radiology and laboratory results. The same clinical diagnosis definitions (Table 1) were employed in both the testing set (described here) and in the training set used for algorithm development.

Spirometry was performed according to standard methodology [2,22].

Table 1. Clinical diagnosis definitions.

Condition	Definition
COPD[a]	Respiratory symptoms consistent with COPD and history of smoking (>10 pack-years) or environmental exposure AND: • If spirometry performed, then FEV_1/FVC[b] <0.7 on the best test (after bronchodilator) OR • If spirometry not performed, then previous physician diagnosis of COPD
COPD (infectious exacerbation)	ALL OF: • Met COPD case definition (as above) • Worsening symptoms of SOB[c] or cough • Signs and symptoms of acute respiratory tract infection
Acute LRTI[d]	New lower respiratory tract symptoms (SOB, cough, chest pain <1 week) and acute fever AND: • For pneumonia: new consolidation on CXR[e] or CT[f] OR • For LRTI: infiltrate but no consolidation on CXR or CXR not performed
No lower airway disease	No lung disease and spirometry results within normal parameters (FEV_1/FVC >0.7 on best test)

[a]COPD: chronic obstructive pulmonary disease.

[b]FEV_1/FVC: forced expiratory volume in the first second to forced vital capacity.

[c]SOB: shortness of breath.

[d]LRTI: lower respiratory tract infection.

[e]CXR: chest x-ray.

[f]CT: computed tomography.

Analysis Population

Diagnostic accuracy tests were performed for 4 groups using an independent test set of participants. The same inclusion and exclusion criteria were used for both training and test sets (Table 2).

After a clinical diagnosis was assigned to all participants, the database was locked and the software algorithm was run by an independent researcher to ensure blinding was maintained. Each participant's cough sound data and clinical diagnosis were only used once in the prospective test.

Table 2. Analysis groups.

Group name	Role	Participants included and excluded
Group 1: COPD[a] total cohort[b]	To determine the presence or absence of COPD	Included participants with: 1. COPD with and without acute lower respiratory tract infections (pneumonia and LRTI[c]) 2. Chronic bronchitis, emphysema, or chronic asthma (with and without acute lower respiratory tract infections, such as pneumonia and LRTI) 3. No underlying COPD with acute lower respiratory tract infections (pneumonia and LRTI) 4. No lower airway disease Excluded participants with physician-diagnosed episodic asthma who were experiencing an isolated acute exacerbation or physician-diagnosed restrictive lung disease
Group 2A: COPD with infectious comorbidity	To determine the presence or absence of COPD when participants with COPD also have an acute LRTI	All of group 1, excluding participants with COPD without LRTI
Group 2B: COPD without infectious comorbidity	To determine the presence or absence of COPD when participants with COPD do not have an acute LRTI	All of group 1, excluding participants with COPD with LRTI
Group 3: COPD confirmed by spirometry	To determine the presence or absence of spirometry-confirmed COPD	Of group 1, excluding those whose COPD was not confirmed by spirometry

[a]COPD: chronic obstructive pulmonary disease.

[b]From the total cohort (group 1), groups 2A, 2B, and 3 were derived.

[c]LRTI: lower respiratory tract infection.

Statistical Analysis

Power calculations were derived as follows. Based on an expected positive and negative percent agreement greater than 85% from the training program, to obtain a superiority end point of 75% (lower bound 95% confidence interval of maximum width within 0.10), a minimum of 48 cases were required.

PPA is defined as the percentage of participants with a positive index test result for a specified condition who also have a positive reference standard for the same condition. NPA is the percentage of participants who return negative results for both tests.

The primary study end point was defined as the PPA and the NPA of the index test with the reference standard, with 95% confidence intervals calculated using the Clopper-Pearson method. The probability of positive clinical diagnosis was calculated for each participant by the final classifier model and was used as the decision threshold in the derived ROC curve.

Results

In the prospective testing set, 270 participants met inclusion criteria for and were enrolled in the COPD diagnostic study. Of these, 153 were from the hospital emergency department or inpatient wards, and 117 were respiratory outpatients or from the ambulatory acute care unit.

A total of 252 participants provided a valid index and reference test (Figure 1); 2 were excluded because the clinical diagnosis was recorded as unsure. The mean age of the participants was 59.7 (SD 9.2) years, and 148 of the 252 (58.7%) participants were women. Those with COPD were older than those without COPD (65.5 vs 57.8 years; $P<.001$), although the sex proportion did not differ with the diagnosis. Of the 252 participants analyzed, 215 (85.3%) had at least one of the following respiratory symptoms: acute, chronic, or productive cough; fever; rhinorrhea; shortness of breath; wheeze; or hoarse voice. Participant characteristics are shown in Table 3, including spirometry results where available.

Figure 1. The flow of participants through the study. COPD: chronic pulmonary obstructive disease.

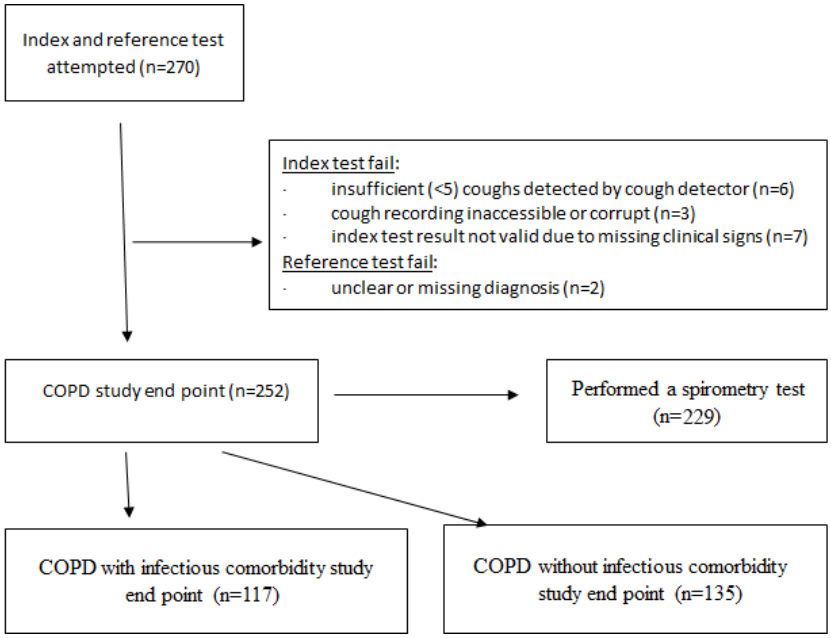


Table 3. Participant characteristics. Data include all participants in analyzed groups (COPD positive and negative).

Characteristic	COPD[a] total cohort (group 1, N=252)	COPD with infectious comorbidity (group 2A, n=117)	COPD without infectious comorbidity (group 2B, n=135)	COPD confirmed by spirometry (group 3, n=229)
Age, mean (SD)	59.7 (9.2)	60.6 (9.1)	59.0 (9.1)	59.0 (9.1)
BMI, mean (SD)	28.8 (7.3)	29.0 (7.9)	28.6 (6.7)	29.2 (7.3)
FEV_1[b], mean (SD)	2.3 (1.0)	0.9 (0.2)	2.3 (1.0)	2.3 (1.0)
FVC[c], mean (SD)	3.2 (1.1)	1.9 (0.4)	3.3 (1.1)	3.2 (1.1)
FEV_1/FVC, mean (SD)	69.1 (16.2)	46.1 (11.3)	70.5 (15.4)	69.1 (16.2)
Predicted FEV_1, mean (SD)	81.2 (28.8)	34.3 (12.3)	84.0 (27.0)	81.2 (28.8)
Predicted FVC, mean (SD)	90.7 (22.2)	57.6 (14.0)	92.7 (21.0)	90.7 (22.2)
Predicted FEV_1/FVC, mean (SD)	83.2 (21.9)	58.4 (14.0)	85.3 (21.1)	83.2 (21.9)
Acute cough, n (%)				
No	136 (54.0)	22 (18.8)	114 (84.4)	129 (56.3)
Yes	116 (46.0)	95 (81.2)	21 (15.6)	100 (43.7)
Fever, n (%)				
No	126 (58.1)	39 (33.3)	87 (87.0)	114 (58.8)
Yes	91 (41.9)	78 (66.7)	13 (13.0)	80 (41.2)
Rhinorrhea, n (%)				
No	116 (53.7)	61 (52.1)	55 (55.6)	101 (52.3)
Yes	100 (46.3)	56 (47.9)	44 (44.4)	92 (47.7)
Wheeze, n (%)				
No	145 (66.8)	84 (71.8)	61 (61.0)	134 (69.1)
Yes	72 (33.2)	33 (28.2)	39 (39.0)	60 (30.9)

[a]COPD: chronic obstructive pulmonary disease.

[b]FEV_1: forced expiratory volume in the first second.

[c]FVC: forced vital capacity.

For cases where spirometry (n=229) was used to confirm the presence or absence of COPD, the mean age of participants was 59.0 (SD 9.1) years and 80 (65.0%) participants were women, with FEV_1 measurements as shown in Table 4. The COPD-negative group included 6 patients with chronic fixed asthma who had an FEV_1 below 80%.

Table 4. Spirometry-derived FEV_1 (GOLD severity categories) in participants with and without COPD [2].

Percent predicted FEV_1[a] (GOLD[b] severity category)	COPD[c] positive, n (%)	COPD negative, n (%)
<30.0% (GOLD 4: very severe)	5 (12)	0 (0.0)
30.0% to 49.9% (GOLD 3: severe)	17 (40)	2 (2)
50.0% to 79.9% (GOLD 2: moderate)	16 (38)	4 (5)
≥80.0% (GOLD 1: mild)	4 (10)	75 (93)
Total	42 (100)	81 (100)

[a]FEV_1: forced expiratory volume in the first second.

[b]GOLD: Global Initiative for Chronic Obstructive Lung Disease.

[c]COPD: chronic obstructive pulmonary disease.

The calculated PPA and NPA of the algorithm with clinical diagnosis and area under the curve (AUC) are shown in Table 5. ROC curves for each test group are shown in Figure 2.

Although the algorithm was developed to discriminate based on GOLD criteria, we repeated the analysis using lower limit of normal (LLN) thresholds to diagnose COPD. Test performance in the COPD confirmed by spirometry group (n=229) returned a PPA of 100% (95% CI 90.75%-100.0%) and an NPA of 75.4% (95% CI 68.65%-81.32%).

Table 5. PPA, NPA, and calculated AUC of the algorithm (index test) compared with clinical diagnosis (reference test).

Group	PPA[a], % (95% CI); n/N	NPA[b], % (95% CI); n/N	AUC[c] (95% CI)
Group 1: COPD[d] total cohort (n=252)	93.8 (85.0-98.3); 61/65	77.0 (70.3-82.8); 144/187	0.95 (0.9-1.0)
Group 2A: COPD with infectious comorbidity	86.7 (69.3-96.2); 26/30	80.5 (70.6-88.2); 70/87	0.93 (0.9-1.0)
Group 2B: COPD without infectious comorbidity	100 (90.0-100.0); 35/35	74.0 (64.3-82.3); 74/100	0.97 (0.9-1.0)
Group 3: COPD confirmed by spirometry	100 (91.6-100.0); 42/42	77.0 (70.3-82.8); 144/187	0.97 (0.9-1.0)

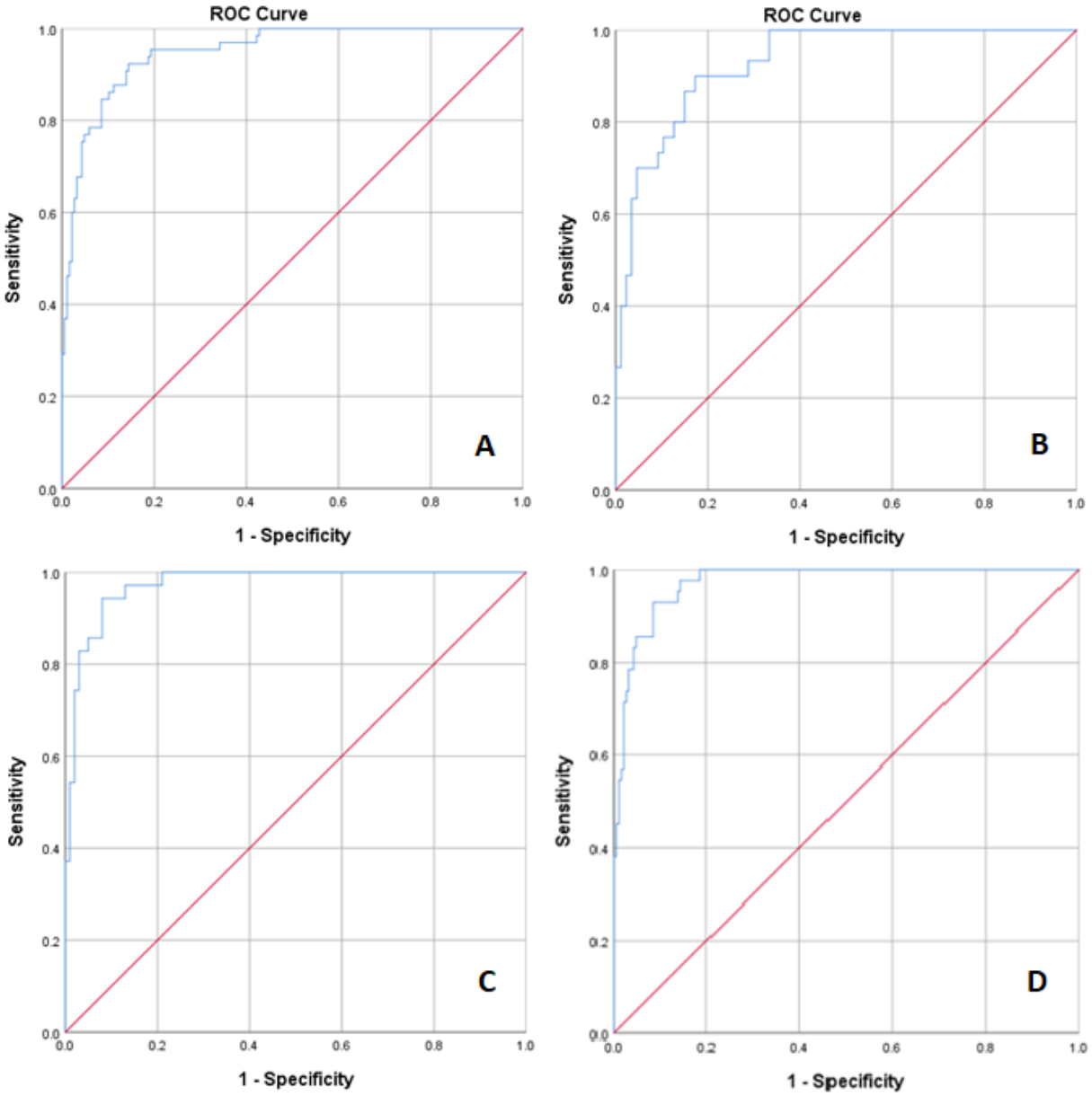
[a]PPA: positive percent agreement.

[b]NPA: negative percent agreement.

[c]AUC: area under the curve.

[d]COPD: chronic obstructive pulmonary disease.

Figure 2. Receiver operating characteristic curve and AUC for (A) COPD total cohort (group 1), AUC=0.95 (95% CI 0.92-0.98); (B) COPD with infectious comorbidity (group 2A), AUC=0.93 (95% CI 0.88-0.98); (C) COPD without infectious comorbidity (group 2B), AUC=0.974 (95% CI 0.95-1.00); (D) COPD diagnosed by spirometry group (group 3), AUC=0.973 (95% CI 0.95-1.00). AUC: area under the curve; COPD: chronic obstructive pulmonary disease.



Discussion

We have described a simple, rapid diagnostic test for COPD that demonstrates high agreement with clinical diagnosis in the acute setting. Diagnostic agreement of the software algorithm with clinical diagnosis of COPD showed a PPA of 93.8% and an NPA of 77.0%. Agreement was maintained when the patient had an acute respiratory infection (PPA of 86.7% and NPA of 80.5%). Notably, the index test retained high diagnostic agreement in cases of spirometry-confirmed COPD (PPA of 100.0% and NPA of 77.0%).

Population and primary care surveys have demonstrated that mild (FEV_1 ≥80% of percent predicted) and moderate (FEV_1 50%-80% of percent predicted) airflow limitation is seldom diagnosed by clinicians [23,24]. In our study, 20 out of 42 (48%) participants with clinically diagnosed COPD had only mild or moderate airflow limitation (Table 4). This group represents those who would benefit most from this algorithm, both because of new treatment possibilities and because they are frequently underdiagnosed.

We used the GOLD criteria for COPD diagnosis (FEV_1/FVC <0.7) when developing our algorithms, although COPD can also be defined using the LLN. When calculated using the LLN thresholds, test performance was not significantly different from values obtained using the GOLD criteria. It should be noted that, as our model was developed to recognize COPD diagnosed using the GOLD criteria, we would expect a lower performance when the diagnostic criteria are changed.

In many European countries, spirometry is available in acute and primary care settings [8]. However, uptake of the test is limited, leading to underdiagnosis or misdiagnosis of patients [6]. Several barriers to using spirometry in primary and acute care settings have been reported, including expense and limitations in access, expertise, and time [25]. Alternative testing methods have been developed. A meta-analysis of the CDQ in ever-smokers in 4 studies had a pooled sensitivity of 64.5% (95% CI 59.9%-68.8%) and a specificity of 65.2% (52.9%-75.8%) [16]. Another study recruiting current and former smokers over 40 years from the general population demonstrated moderate sensitivity and specificity of the CDQ (74% and 72%, respectively), the COPD Population Screener (56% and 90%, respectively), and the Lung Function Questionnaire (79% and 68%, respectively) [26]. An analysis from 3 studies of handheld flow meters showed a sensitivity of 79.9% (95% CI 74.2%-84.7%) and a specificity of 84.4% (95% CI 68.9%-93.0%) [16]. In a scenario comparable to our study, when the CDQ was performed on symptomatic patients in primary care, the AUC was 0.65, sensitivity was 89.2% and 65.8%, and specificity was 24.4% and 54.0% for participants at low risk and high risk of having COPD, respectively [27]. The performance of our software algorithm exceeds that of the currently available COPD screening questionnaires, outperforms the sensitivity of handheld flow meters with comparable specificity, and demonstrates high agreement with the gold standard (spirometry) in under one minute. This algorithm is intended to be used as a stand-alone device, allowing for real-time diagnosis. As it is easy to operate and requires no physical patient contact, infection risk is minimized.

We envisage that the algorithm could be used as an initial screening test in acute care settings for patients who present with nonspecific respiratory symptoms. A positive result could be used to guide immediate care in the acute setting. As the test is delivered via smartphone, it could be applied in person or during a telehealth consultation. A formal diagnosis of COPD requires confirmation by spirometry, the gold standard tool for COPD diagnosis [2]. Confirmatory spirometry could be performed during subsequent specialist follow-up.

In this study, we were able to accurately identify the presence or absence of COPD in patients with lower respiratory tract infections, including pneumonia. In these situations, spirometry can be difficult to perform adequately, and an initial diagnostic test will help detect COPD in acutely unwell patients and identify those individuals most at risk of developing complications. Individuals with COPD are known to experience more frequent complications and higher mortality rates due to seasonal illnesses such as influenza [12]. More recently, a meta-analysis examining the risk of severe outcomes from SARS-CoV-2 infection (admission to the intensive care unit, mechanical ventilation, or death) showed a greater than fivefold increase in the risk of severe disease in patients with coexistent COPD [28]. We recommend that all patients with COPD with a suspected infection be carefully monitored in view of this increased risk. The diagnosis of COPD in patients presenting with SARS-CoV-2 or similar respiratory infections would allow more focused therapeutic pathways and guide health care resources to this at-risk group.

There are several limitations to this study. Our study population was recruited in an urban setting and had smoking-related COPD. The generalizability of these results to COPD of differing etiologies and in other settings requires confirmation. The tests were performed by trained research personnel in controlled environments, although we would consider the device less onerous to use than spirometry. The cough recording can be affected by background noise and positioning of the device, although the program will alert the user if background noise is excessive. The population recruited reflects the intended age range of use. However, as expected, those with diagnosed COPD were slightly older than those without COPD, and it will be important to replicate this study using an older control group.

The COPD diagnostic algorithm described in this study is used in combination with a suite of other respiratory diagnostic algorithms developed in the Breathe Easy program, including tests for asthma, pneumonia, and lower respiratory tract disease [17]. The software provides a diagnostic output for each condition simultaneously every time it is used. Having independent decision algorithms for asthma, COPD, and pneumonia is particularly important due to the considerable clinical overlap between the conditions.

In conclusion, the algorithm was able to accurately identify COPD, even in the presence of infection. The algorithm operates as a stand-alone tool and provides a rapid result. It may find application in the acute care setting as a screening tool to alert clinicians to the presence of COPD, allowing for more rapid, targeted, and appropriate management.

Conflicts of Interest

PP, SC, and UA are scientific advisors for ResApp Health. PP and UA are shareholders in ResApp Health. UA was ResApp Health's chief scientist. ResApp Health is an Australian publicly listed company commercializing the technology under license from the University of Queensland, where UA is employed. UA is a named inventor of the University of Queensland technology. VP and JW are employees of ResApp Health. NB received consultancy fees for statistical analysis. JB, CS, FP, and PD declare no competing interests.

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Abbreviations

AUC: area under the curve
CDQ: chronic obstructive pulmonary disease diagnostic questionnaire
COPD: chronic obstructive pulmonary disease
FEV_1: forced expiratory volume in the first second
FVC: forced vital capacity
GOLD: Global Initiative for Chronic Obstructive Lung Disease
LLN: lower limit of normal
NPA: negative percent agreement
PPA: positive percent agreement
ROC: receiver operating characteristic

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Original Paper

Assessing the Efficacy and Acceptability of a Web-Based Intervention for Resilience Among College Students: Pilot Randomized Controlled Trial

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Abstract

Background: College students are at elevated risk for developing mental health problems and face specific barriers around accessing evidence-based treatment. Web-based interventions that focus on mental health promotion and strengthening resilience represent one possible solution. Providing support to users has shown to reduce dropout in these interventions. Further research is needed to assess the efficacy and acceptability of these interventions and explore the viability of automating support.

Objective: This study investigated the feasibility of a new web-based resilience program based on positive psychology, provided with human or automated support, in a sample of college students.

Methods: A 3-armed closed pilot randomized controlled trial design was used. Participants were randomized to the intervention with human support (n=29), intervention with automated support (n=26), or waiting list (n=28) group. Primary outcomes were resilience and well-being, respectively measured by the Connor–Davidson Resilience Scale and Pemberton Happiness Index. Secondary outcomes included measures of depression and anxiety, self-esteem, and stress. Outcomes were self-assessed through online questionnaires. Intention-to-treat and per-protocol analyses were conducted.

Results: All participants demonstrated significant improvements in resilience and related outcomes, including an unexpected improvement in the waiting list group. Within- and between-group effect sizes ranged from small to moderate and within-group effects were typically larger for the human than automated support group. A total of 36 participants began the program and completed 46.46% of it on average. Participants were generally satisfied with the program and found it easy to use.

Conclusions: Findings support the feasibility of the intervention. Preliminary evidence for the equal benefit of human and automated support needs to be supported by further research with a larger sample. Results of this study will inform the development of a full-scale trial, from which stronger conclusions may be drawn.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN) 11866034; http://www.isrctn.com/ISRCTN11866034

International Registered Report Identifier (IRRID): RR2-10.1016/j.invent.2019.100254

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KEYWORDS

web-based intervention; resilience; well-being; positive psychology; human support; automated support; college students; randomized controlled trial

Introduction

The transition to university represents a period of increased academic and social pressure, financial burden, and change in lifestyle for students, placing them at increased risk for developing mental health problems [1]. The 12-month prevalence rate for mental disorders among college students is an estimated 20% yet only a small proportion of these students receive adequate treatment [2]. Given exposure to new sources of stress, the transitional nature of higher education settings affords a unique and timely opportunity to develop in students the skills needed to cope with new challenges [3]. In line with an increasing emphasis on promotion and prevention in mental health care [4], an approach that builds resilience against these stressors and prevents the development of mental disorders in the first instance may prove preferable to treatment following their onset [5]. Resilience may be understood as the personal assets (internal factors, eg, optimism) and environmental resources (external factors, eg, social support) that contribute to positive psychological adaption, despite exposure to adversity [6]. Resilience has been shown to buffer the effects of stress and burnout and protect against the development of depression, anxiety, and other common mental health problems [7,8].

Resilience interventions seek to promote resilience at an individual, group, or population level with the aim of preparing individuals for the occurrence of future life stressors [9]. This usually takes place through the enhancement of one or more resilience factors (assets and resources) [6]. However, the guiding theoretical framework and related techniques used in these interventions varies (eg, positive psychology, acceptance and commitment therapy, mindfulness, interpersonal therapy, and cognitive behavioral therapy), with no single accepted approach [9,10]. Given their inherent focus on promoting positive adaption and well-being, interventions based on positive psychology are highly compatible within the area of mental health promotion [11]. Several meta-analyses on positive psychology interventions have demonstrated significant improvements in well-being with small to moderate effect sizes [12,13]. For resilience interventions specifically, similar effect sizes have been observed in adults for resilience outcomes [9,14,15]. Encouragingly, initial research on resilience interventions among college students has demonstrated significant improvements in resilience and reductions in stress and symptoms of depression and anxiety [16-18].

An important consideration with the implementation of preventive interventions is ensuring that they can be accessed as widely as possible [11]. The internet is increasingly being used to deliver and improve the availability of interventions for mental health and well-being [19-22]. They may also prove particularly advantageous with students who are heavily immersed in the digital age [5]. Encouragingly, research investigating technology-delivered preventive interventions with college students has demonstrated small to moderate effect sizes for mental health outcomes [19,20] and preliminary support exists for the efficacy of web-based resilience interventions [23]. However, overall, research on web-based resilience interventions is scarce, particularly in youth samples, suggesting that further trials investigating their feasibility are necessary [14].

Despite the advantages of internet-delivery, one of the greatest limitations of web-based interventions are the high rates of dropout that can occur in these interventions [24]. Several meta-analyses show that supported web-based interventions yield lower rates of dropout and better clinical outcomes than unguided interventions [21,22,25,26]. Support may involve clarifying program content, monitoring progress, or motivating users either online or by phone or email [27]. Notably, the type of supporter, therapist or otherwise, has no bearing on effects [28]. This suggests that the greatest benefit resides in providing some form of contact, and opening the possibility of automating this contact [27]. Automated support is differentiated from human support in the related literature in that it is provided automatically through information and communication technologies (eg, automated reminders or feedback) [29]. While initial findings show that automated support is associated with slightly poorer rates of treatment efficacy and adherence compared to human support [28,30], continued improvements in developing high-quality automated support can lead to comparable outcomes, while reducing therapist time and implementation costs [27,29]. Preference for one type of intervention over another (eg, cognitive behavioral versus interpersonal therapy or individual versus group therapy) also has the potential to influence outcomes [31]. For example, increasing evidence shows significant improvements in clinical outcomes and higher rates of treatment adherence and satisfaction when participant preference for and allocation to an intervention group is matched [31,32].

Supported web-based resilience interventions are a promising, cost-effective approach for promoting resilience and preventing the onset of mental health problems. These interventions address issues relating to the accessibility of mental health care and may be of particular benefit to at-risk populations such as college students. This study sought to investigate the preliminary efficacy and acceptability of a new web-based intervention for resilience and well-being, based on positive psychology, in a sample of college students. The study also aimed to determine the effects of different types of support (human and automated) in the intervention on a range of outcomes including resilience, well-being, depressive and anxiety symptoms, self-esteem, and perceived stress.

Methods

Study Setting

The study was conducted in Trinity College Dublin (TCD) the University of Dublin, Ireland, in collaboration with the TCD Student Counselling Service and SilverCloud Health. TCD is a university for all of the major disciplines in the arts and humanities, and in business, law, engineering, science, and health sciences. The study was advertised to all registered students via email, posters, and social media. Students considering participating in the study were invited to visit an online platform through a URL where they received information about the study. Consent was obtained via digital signature. Recruitment started in February 2019 and the trial ran for 4

consecutive months, until June 2019 when data collection was completed.

Research Design

A 3-armed, parallel-group, pilot randomized controlled trial design was used. Using an allocation ratio of 1:1:1, participants were randomized to the intervention with human support, intervention with automated support, or waiting list control group. The randomization schedule was generated by an individual independent of the study via sequentially numbered, opaque sealed envelopes using *Random Allocation Software* [33]. Randomization was performed in blocks of 12 with 3 groups. Given the nature of the trial, participants and researchers were not blinded to group allocation. The CONSORT-EHEALTH guidelines [34] (Multimedia Appendix 1) were followed and the study protocol has been published [35].

Sample Size

Previous data on effect sizes for web-based resilience interventions in college students do not exist [5]. However, findings from 2 meta-analyses on resilience and positive psychology interventions demonstrated small effect sizes for resilience and psychological well-being, respectively [12,14]. A sample size of 25 per arm is recommended for pilot trials when effect sizes are expected to be small [36]. This calculation is based on a main trial designed with 90% power and 2-sided 5% significance. Given a 3-armed pilot trial design and small anticipated effect size for resilience and well-being, a sample size of 75 (25 participants per arm) was determined.

Eligibility Criteria

Inclusion criteria were being over the age of 18 and a registered student at TCD. Exclusion criteria were currently attending counselling or psychotherapy, having an organic mental health condition, or being at risk of suicide.

Intervention

Space for Resilience is a 7-module program aimed at promoting resilience and well-being through the enhancement of several well-evidenced resilience factors [6]. The program was developed by SilverCloud Health in line with the principles of positive psychology [37] and incorporates cognitive behavioral elements including cognitive flexibility, optimism, challenging negative self-talk, behavioral activation, and active coping, alongside information on social support, lifestyle factors, and values. Modules are structured in an identical way and include introductory videos, quizzes, psychoeducational content, personal stories from other users, interactive activities, mindfulness exercises, homework suggestions, goal setting, and summaries. A description of module content is provided in Multimedia Appendix 2 [6,8,37-46] and a screenshot of the program is provided in Multimedia Appendix 3. The program was offered over an 8-week intervention period and was accessible 24/7. It was recommended that participants spend at least an hour a week on the program based on previous studies with the same platform [47,48].

Support

Human

Participants in the human support group were assigned to a supporter from the TCD Student Counselling Service. Supporters were counsellors or trainee counsellors familiar with using the SilverCloud Health platform and received training in the *Space for Resilience* program. The role of the supporter was to monitor and support user progress through the program. On the supporter interface of the platform, an overview of each users' level of engagement with the program is presented. This includes user responses on questionnaires, messages left by the user, module pages viewed, tools and activities used (including content shared by the user), and the number of times the user logged in to the platform. Using this information, supporters spent 10-15 minutes formulating individualized reviews for each participant. Reviews are asynchronous messages sent and received on the platform. Supporters received guidelines on how to support users. These guidelines advise that in every review, the supporter should (1) demonstrate empathy and care to the user, (2) demonstrate knowledge of the theory underlying the program, (3) acknowledge and affirm the user's progress, (4) prompt and encourage further use of the program, (5) ask reflective questions, and (6) set homework. Participants received 4 reviews during the intervention period. An excerpt from a sample review is provided below:

> *Well done for logging in to the Space for Resilience programme again this week. I can see you completed the second module, Self, which supports you in identifying your values, passions, and what matters most to you in life. Did any questions come up for you during this module?*
>
> *I noticed from one of the tools you filled in that building your social network is something you would like to focus on. The Connections module might be particularly helpful for this. It includes useful information on developing relationships and building communities as well as tips for improving communication skills like active listening and expressing gratitude.*
>
> *Remember, applying the skills you lean in this module to your everyday life is like building up a muscle. You might not see the reward straight away but the more time you spend on it, the more your social network will grow and the stronger your communication skills will become.*

Automated

Participants in the automated support group received generic, templated reviews which were automatically sent as messages on the platform. Automated reviews were designed to facilitate user progress through the program and were structured in the same way as reviews in the human support group (eg, users are encouraged to explore new content in the program). However, reviews in the automated support group were standardized as opposed to individualized. They were therefore not tailored to each user's unique level of engagement with the program. Automated reviews were predeveloped by highly experienced

clinicians with in-depth knowledge of providing support for web-based interventions. Participants received 4 reviews during the intervention period. An excerpt from an automated review is provided below:

> *Have you been finding the programme useful so far? No matter how much time you have spent exploring the programme since your last review, we wanted to remind you that even a small effort can make a big difference.*
>
> *You can complete the modules in whatever order suits you best. Over the next two weeks, we suggest that you work through one or two more of the five domains of resilience modules: purpose, self, connections, body, or mind.*
>
> *Remember that this programme is designed to help you, but it is up to you to make the changes. Do what you can, one step at a time.*

Measures

All outcomes were self-assessed through online questionnaires. See Table 1 for measure administration timeline.

Table 1. Measure administration timeline.

Measure	Measurement point	
	Baseline	Postintervention
Sociodemographic and Clinical History Questionnaire	X	
Connor–Davidson Resilience Scale (CD-RISC)	X	X
Pemberton Happiness Index (PHI)	X	X
Brief Resilience Scale (BRS)	X	X
Patient Health Questionnaire—4 Items (PHQ-4)	X	X
Rosenberg Self-Esteem Scale (RSES)	X	X
Perceived Stress Scale—4 Items (PSS-4)	X	X
Satisfaction With Treatment (SAT)[a]		X

[a]Only the active intervention groups completed the SAT.

Screening Measure: The Sociodemographic and Clinical History Questionnaire

The Sociodemographic and Clinical History Questionnaire [49] collects sociodemographic information including age, gender, education level, and computer literacy; and clinical information including current engagement with counselling or psychotherapy, drug and alcohol use, diagnosis of an organic mental health condition, and suicide risk. While group assignment was random, this questionnaire included an item asking participants if they would prefer to receive human or automated support and why.

Primary Outcome Measures

Connor–Davidson Resilience Scale

The Connor–Davidson Resilience Scale (CD-RISC) [50] is a 25-item self-report measure of resilience or ability to cope with stress. The CD-RISC has shown good concurrent validity and internal consistency (α=.89) with college students [51].

Pemberton Happiness Index

The Pemberton Happiness Index (PHI) [52] is a 21-item self-report integrative measure of well-being. Of these items, 11 relate to remembered well-being (ie, general, hedonic, eudaimonic, and social well-being) and 10 relate to experienced well-being (ie, positive and negative events that happened the previous day). The PHI has demonstrated good convergent and incremental validity and strong internal consistency (α>.89) [52].

Secondary Outcome Measures

Brief Resilience Scale

The Brief Resilience Scale (BRS) [53] is a 6-item self-report measure assessing resilience or ability to bounce back or recover from stress. The BRS has shown strong convergent validity and good internal consistency (α>.80) with college students [53].

Patient Health Questionnaire—4 Items

The Patient Health Questionnaire—4 Items (PHQ-4) [54] is a brief self-report measure of depression and anxiety. The PHQ-4 has demonstrated good construct and criterion validity and internal consistency (α=.81) with college students [55].

Rosenberg Self-Esteem Scale

The Rosenberg Self-Esteem Scale (RSES) [56] is a 10-item self-report measure of global self-esteem. The RSES has shown good construct validity, internal consistency (α=.87), and test–retest reliability (r=.84) with college students [57].

Perceived Stress Scale—4 Items

The Perceived Stress Scale—4 Items (PSS-4) [58] is a brief self-report measure of the extent to which recent life events are considered stressful. The PSS-4 has demonstrated acceptable criterion validity and internal consistency (α=.72) [58].

Other Measures

Platform Usage Metrics

Usage refers to the degree to which participants were exposed to the intervention [59]. Related data for active intervention

groups were collected automatically on the online platform. This included number of logins to the program, length of time spent using the program, number of tools and activities used, and percentage of program content viewed. A session was defined as any instance where a participant logged in to the platform. Number of sessions was therefore determined by the total number of participant logins.

Satisfaction With Treatment

The Satisfaction With Treatment (SAT) [60] is an 8-item self-report measure of attitudes toward the web-based intervention. It also includes 2 open-ended questions asking participants what they most and least liked about the intervention.

Procedure

After providing informed consent, participants completed baseline measures. Participants meeting eligibility criteria were randomized to the human support, automated support, or waiting list group and were informed of group assignment immediately. Active intervention groups were given immediate access to the program. The waiting list group was given access to the program after an 8-week waiting period. To minimize dropout, participants received a phone call from a member of the research team (CTL and SF) approximately 1 week following randomization to remind them of group assignment and research procedures. After the 8-week period, participants received an email asking them to complete postintervention measures. Participants were informed of institutional affiliations during the informed consent procedure and were not reimbursed for their participation in the trial.

Data Analysis

Data were analyzed using SPSS software (version 24) [61]. Recruitment and retention rates were examined using descriptive statistics and a Pearson chi-square test. Sociodemographic information and baseline data were examined using descriptive statistics, Pearson chi-square tests, and one-way analysis of variance (ANOVAs). Reliability checks using Cronbach α were conducted on outcome measures.

Intention-to-treat (ITT) and per-protocol analyses were conducted on primary and secondary outcomes measures. Per-protocol analysis considered all participants who completed baseline and postintervention outcome measures and, in the case of active intervention groups, accessed the program at least once. For ITT analysis, missing data were calculated using the expectation-maximization algorithm, a maximum likelihood method used in similar trials [62]. Preliminary efficacy was evaluated using mixed factorial ANOVAs. Within- and between-group effect sizes (Cohen *d*) and 95% confidence intervals were calculated for each group. Effect sizes of 0.2 were considered small, 0.5 were considered medium, and 0.8 were considered large [63]. The use of ANOVAs represents a revision to study protocol which outlined the use of linear mixed models in the analysis plan [35]. However, diagnostic tests on the data revealed inadequate power and model fit to sufficiently address the research questions under investigation. Mixed factorial ANOVAs were therefore deemed more suitable. There was a modest departure from the assumption of homogeneity of variance; however, the *F*-test has shown to be robust against moderate departures and variance heterogeneity is frequently observed in real-world data [64].

Usage data were analyzed using descriptive statistics, Pearson chi-square tests, and unpaired *t* tests. Data from the SAT were analyzed using descriptive statistics, unpaired *t* tests, and descriptive and interpretive analysis [65]. Descriptive and interpretive analysis is an integrative approach to analyzing qualitative data that aims to identify and analyze patterns in the data by delineating meaning units and organizing them into categories. Between-group effect sizes (Cohen *d*) and 95% confidence intervals were also calculated for usage and SAT data.

To explore the effects of intervention preference and allocation, exploratory subgroup analyses were conducted. Participants in the active intervention groups were divided into 2 groups: those who were allocated to their preferred intervention group and those who were not. Pearson chi-square tests, ANOVAs, and unpaired *t* tests were used to examine differences in outcomes, engagement and usage, and satisfaction with the intervention.

Ethical Considerations

The study received full ethical approval from the TCD School of Psychology Research Ethics Committee on January 29, 2019 (approval ID: SPREC112018-12). Ethical considerations are fully outlined in the study protocol [35].

Data Sharing

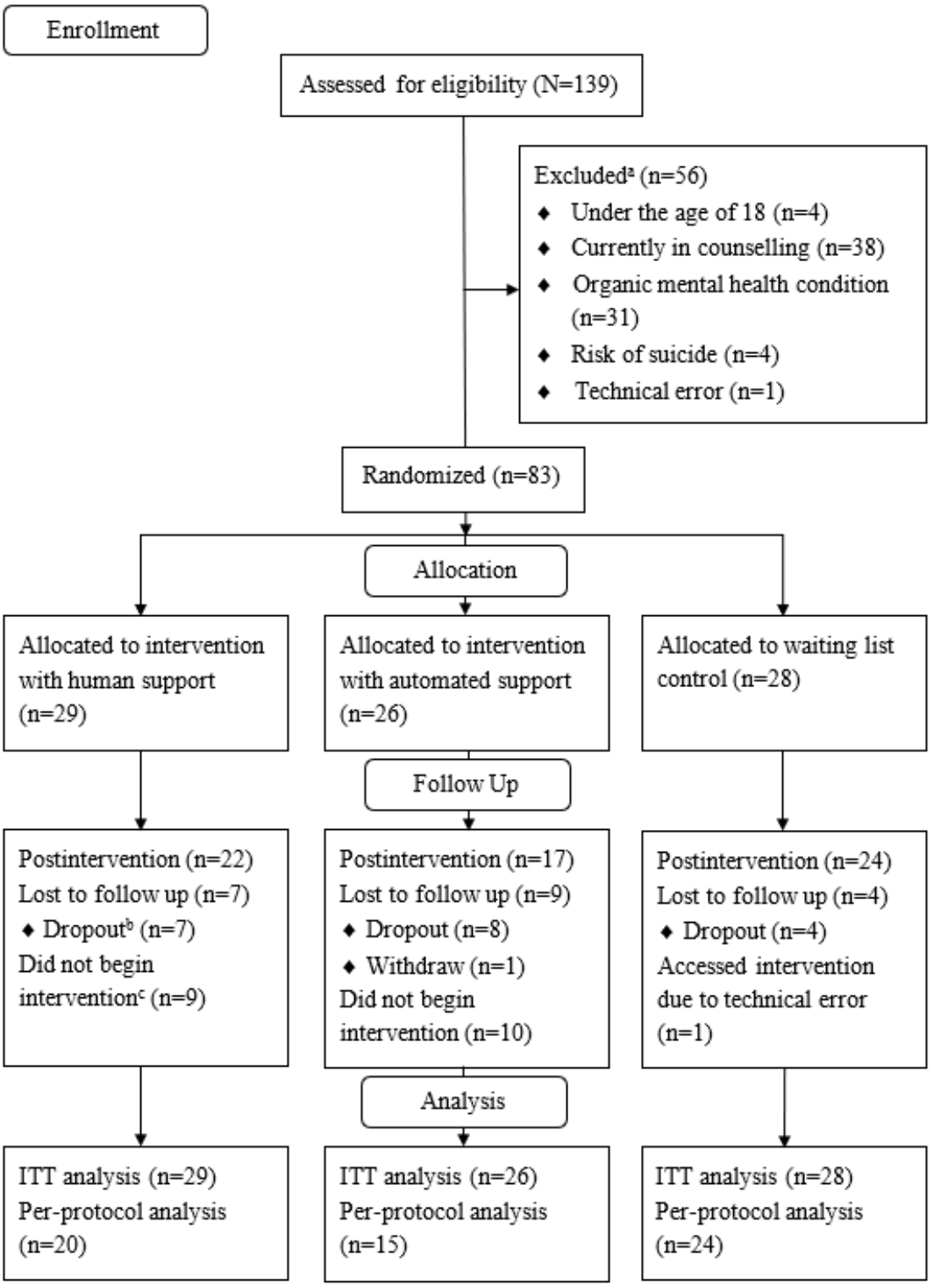
Data will be made available upon request to the corresponding author.

Results

Recruitment and Retention

Out of the estimated 17,000 students invited, 139 (0.82%) students signed up to participate and were assessed for eligibility. A total of 83 (59.7%) participants met eligibility criteria and were included in the trial. Of these, 63 (76%) completed postintervention measures. The dropout rate was therefore 24% (20/83). A Pearson chi-square test revealed no differences between groups in terms of completion of outcome measures at postintervention. Participant flow through the trial is presented in Figure 1.

Figure 1. CONSORT flow diagram. ITT: intention to treat. aSome participants met more than 1 reason for exclusion and are categorized as such. bRefers to participants that did not complete postintervention measures. cRefers to participants who did not start the intervention.



Baseline Characteristics

The median age of participants was 26 years (IQR 11). In terms of computer literacy, most participants were either confident or very confident in using computers and the internet (73/82, 89%). Baseline characteristics of the sample are provided in Table 2.

Pearson chi-square tests and one-way ANOVAs demonstrated no significant differences between groups in terms of sociodemographic variables or scores on baseline measures. Reliability checks demonstrated satisfactory internal consistency for all outcome measures (α>.70).

Table 2. Baseline characteristics of study sample.

Characteristic	Human support (N=29), n (%)	Automated support (N=26), n (%)	Waiting list (N=28), n (%)	Total (N=83), n (%)
Gender (N=81)				
Male	6 (21)	4 (15)	4 (15)	14 (17)
Female	22 (79)	22 (85)	23 (85)	67 (83)
Education level (N=82)				
Undergraduate	6 (21)	4 (15)	0 (0)	10 (12)
Postgraduate	9 (31)	7 (27)	13 (48)	29 (35)
Other studies	14 (48)	15 (58)	14 (52)	43 (52)
Computer literacy (N=82)				
Very confident	14 (50)	15 (58)	17 (61)	46 (56)
Confident	11 (39)	9 (35)	7 (25)	27 (33)
Average	2 (7)	2 (8)	3 (11)	7 (9)
Mildly confident	1 (4)	0 (0)	1 (4)	2 (2)
Not confident	0 (0)	0 (0)	0 (0)	0 (0)
Intervention preference				
Human support	22 (76)	17 (65)	16 (57)	55 (66)
Automated support	7 (24)	9 (35)	12 (43)	28 (34)

Preliminary Efficacy

Descriptive statistics, within- and between-group effect sizes, and confidence intervals for ITT and per-protocol analyses are presented in Table 3.

Table 3. Descriptive statistics, effect sizes, and confidence intervals for intention-to-treat and per-protocol analysesa.

Measure (Construct)	Baseline, mean (SD)	Postintervention, mean (SD)	Within-group effect size, *d* (95% CI)	Between-group effect size, *d* (95% CI)
Intention to treat (N=83)				
CD-RISC[a] (Resilience)				
HS[b]	60.28 (14.02)	66.63 (11.63)	0.44 (–0.08 to –0.97)	HS vs AS: 0.02 (–0.51 to 0.55)
AS[c]	62.58 (13.50)	66.43 (11.02)	0.50 (–0.05 to 1.06)	AS vs WL: –0.14 (–0.68 to 0.39)
WL[d]	61.46 (12.63)	68.17 (12.95)	0.60 (0.07 to 1.14)	HS vs WL: –0.13 (–0.65 to 0.40)
PHI[e] (Well-being)				
HS	6.02 (1.45)	6.79 (0.99)	0.46 (–0.07 to –0.98)	HS vs AS: 0.38 (–0.15 to 0.91)
AS	6.10 (1.59)	6.41 (1.01)	0.25 (–0.30 to 0.79)	AS vs WL: –0.46 (–1.00 to 0.08)
WL	6.68 (1.33)	6.91 (1.15)	0.18 (–0.34 to 0.71)	HS vs WL: –0.11 (–0.63 to 0.41)
BRS[f] (Resilience)				
HS	3.00 (0.70)	3.24 (0.54)	0.57 (–0.05 to 1.10)	HS vs AS: –0.02 (–0.55 to 0.51)
AS	3.15 (0.69)	3.25 (0.63)	0.24 (–0.31 to 0.78)	AS vs WL: 0.09 (–0.44 to 0.63)
WL	2.98 (0.72)	3.18 (0.84)	0.31 (–0.22 to 0.84)	HS vs WL: 0.09 (–0.43 to 0.61)
PHQ-4[g] (Depression/Anxiety)				
HS	4.72 (3.14)	3.93 (2.58)	–0.23 (–0.75 to 0.28)	HS vs AS: –0.02 (–0.54 to 0.51)
AS	4.31 (3.22)	3.89 (2.65)	–0.19 (–0.73 to 0.36)	AS vs WL: –0.38 (–0.92 to 0.16)
WL	3.61 (2.44)	2.95 (2.25)	–0.38 (–0.90 to 0.15)	HS vs WL: –0.40 (–0.93 to 0.12)
RSES[h] (Self-esteem)				
HS	26.79 (5.92)	28.51 (5.27)	0.53 (0.01 to 1.05)	HS vs AS: 0.04 (–0.49 to 0.57)
AS	27.27 (5.02)	28.34 (3.79)	0.34 (–0.21 to 0.88)	AS vs WL: –0.55 (–1.10 to –0.01)
WL	29.71 (5.46)	30.89 (5.27)	0.37 (–0.16 to 0.90)	HS vs WL: –0.45 (–0.98 to 0.07)
PSS-4[i] (Perceived stress)				
HS	8.41 (3.52)	7.36 (2.46)	–0.30 (–0.81 to 0.22)	HS vs AS: –0.08 (–0.61 to 0.45)
AS	7.31 (2.40)	7.17 (2.18)	–0.07 (–0.61 to 0.48)	AS vs WL: –0.34 (–0.87 to 0.20)
WL	6.93 (2.89)	6.27 (3.06)	–0.42 (–0.95 to 0.11)	HS vs WL: –0.39 (–0.92 to 0.13)
Per protocol (N=59)				
CD-RISC (Resilience)				
HS	59.40 (15.40)	63.90 (10.98)	0.37 (–0.25 to 1.00)	HS vs AS: –0.11 (–0.78 to 0.56)
AS	63.80 (13.19)	65.20 (12.21)	0.20 (–0.52 to 0.92)	AS vs WL: –0.24 (–0.88 to 0.41)
WL	61.38 (12.39)	68.29 (13.66)	0.61 (0.03 to 1.19)	HS vs WL: –0.35 (–0.95 to 0.25)
PHI (Well-being)				
HS	6.02 (1.42)	6.63 (0.96)	0.45 (–0.18 to 1.08)	HS vs AS: 0.23 (–0.45 to 0.90)
AS	6.34 (0.96)	6.39 (1.18)	0.07 (–0.65 to 0.79)	AS vs WL: –0.42 (–1.07 to 0.23)
WL	6.64 (1.33)	6.90 (1.23)	0.20 (–0.37 to 0.77)	HS vs WL: –0.24 (–0.84 to 0.36)
BRS (Resilience)				
HS	2.95 (0.76)	3.18 (0.63)	0.50 (–0.13 to 1.13)	HS vs AS: 0.02 (–0.65 to 0.69)
AS	3.13 (0.78)	3.17 (0.66)	0.09 (–0.63 to 0.80)	AS vs WL: 0.04 (–0.61 to 0.68)
WL	2.92 (0.72)	3.14 (0.89)	0.33 (–0.24 to 0.90)	HS vs WL: 0.05 (–0.54 to 0.65)
PHQ-4 (Depression/Anxiety)				
HS	4.90 (3.19)	3.70 (2.27)	–0.39 (–1.01 to 0.24)	HS vs AS: –0.01 (–0.68 to 0.66)

Measure (Construct)	Baseline, mean (SD)	Postintervention, mean (SD)	Within-group effect size, *d* (95% CI)	Between-group effect size, *d* (95% CI)
AS	3.80 (2.91)	3.67 (2.82)	–0.06 (–0.77 to 0.66)	AS vs WL: –0.28 (–0.93 to 0.37)
WL	3.71 (2.51)	2.96 (2.40)	–0.41 (–0.99 to 0.16)	HS vs WL: –0.32 (–0.91 to 0.28)
RSES (Self-esteem)				
HS	26.55 (5.98)	28.35 (5.69)	0.49 (–0.14 to 1.12)	HS vs AS: –0.04 (–0.71 to 0.63)
AS	28.07 (3.95)	28.53 (3.09)	0.11 (–0.60 to 0.83)	AS vs WL: –0.48 (–1.13 to 0.17)
WL	29.46 (5.24)	30.75 (5.35)	0.40 (–0.17 to 0.97)	HS vs WL: –0.44 (–1.04 to 0.17)
PSS-4 (Perceived stress)				
HS	9.00 (3.42)	7.65 (2.60)	–0.33 (–0.95 to 0.30)	HS vs AS: –0.15 (–0.82 to 0.53)
AS	6.87 (2.33)	7.27 (2.63)	0.17 (–0.54 to 0.89)	AS vs WL: –0.31 (–0.96 to 0.34)
WL	7.13 (2.69)	6.33 (3.20)	–0.56 (–1.14 to 0.02)	HS vs WL: –0.45 (–1.05 to 0.15)

[a]CD-RISC: Connor–Davidson Resilience Scale.

[b]HS: human support.

[c]AS: automated support.

[d]WL: waiting list.

[e]PHI: Pemberton Happiness Index.

[f]BRS: Brief Resilience Scale.

[g]PHQ-4: Patient Health Questionnaire—4-items.

[h]RSES: Rosenberg Self-Esteem Scale.

[i]PSS-4: Perceived Stress Scale—4-items.

ITT Analysis

Mixed factorial ANOVAs demonstrated main effects of time for resilience (CD-RISC; $F_{1,80}$=21.56, P<.001), well-being (PHI; $F_{1,80}$=9.40, P=.003), resilience (BRS; $F_{1,80}$=10.08, P=.002), depressive and anxiety symptoms (PHQ-4; $F_{1,80}$=5.96, P=.02), self-esteem (RSES; $F_{1,80}$= 15.18, P<.001), and perceived stress (PSS-4; $F_{1,80}$=5.48, P=.02). No interaction effects or main effects of group were observed for any outcome measure. For main effects of time, mean scores show an increase in resilience, well-being, and self-esteem and decrease in depressive and anxiety symptoms and perceived stress for all participants.

Per-Protocol Analysis

Mixed factorial ANOVAs demonstrated main effects of time for resilience (CD-RISC; $F_{1,56}$=9.16, P=.004), well-being (PHI; $F_{1,56}$=4.20, P=.045), resilience (BRS; $F_{1,56}$=4.26, P=.04), depressive and anxiety symptoms (PHQ-4; $F_{1,56}$=5.34, P=.03), and self-esteem (RSES; $F_{1,56}$=6.51, P=.01). No main effect of time was observed for perceived stress (PSS-4). No interaction effects or main effects of group were observed for any outcome measure. For main effects of time, mean scores demonstrate an increase in resilience, well-being, and self-esteem and decrease in depressive and anxiety symptoms for all participants.

Acceptability

Engagement and Usage

A total of 36/55 (65%) participants in the active intervention groups started the program. A Pearson chi-square test revealed no significant difference between groups in terms of whether or not participants started the intervention. The mean number of sessions was 8.50 (SD 3.65) and average session length was 20.38 minutes (SD 8.95). On average, participants spent a total of 171.55 minutes (SD 101.36) on the program and completed 46.46% (SD 27.80) of the program. Computers were the preferred device for accessing the program (64.30% of total use), followed by mobiles (33.52% of total use) and tablets (2.18% of total use). Independent *t* tests demonstrated no significant differences in engagement and usage between active intervention groups. Descriptive statistics, between-group effect sizes, and confidence intervals for program engagement and usage are presented in Table 4, with effect sizes generally favoring the human support group.

Table 4. Descriptive statistics for program engagement and usage.

Variable	Human support, (N=20), mean (SD)	Automated support, (N=16), mean (SD)	Total, (N=36), mean (SD)	Between-group effect size, *d* (95% CI)
Number of sessions	9.40 (2.93)	7.38 (4.22)	8.50 (3.65)	0.57 (–0.10 to 1.24)
Length of program use per session (in minutes)	20.14 (1.89)	20.68 (2.45)	20.38 (8.95)	–0.25 (–0.91 to 0.41)
Total length of program use (in minutes)	197.15 (110.01)	139.56 (81.72)	171.55 (101.36)	0.58 (–0.09 to 1.26)
Number of tools used	8.40 (3.02)	6.50 (3.86)	7.56 (3.50)	0.56 (–0.11 to 1.23)
% program content viewed	48.95 (24.42)	43.35 (32.08)	46.46 (27.80)	0.20 (–0.46 to 0.86)
% computer use	56.94 (37.25)	73.50 (34.27)	64.30 (36.42)	–0.46 (–1.13 to 0.21)
% mobile use	40.91 (38.24)	24.29 (32.32)	33.52 (36.22)	0.47 (–0.20 to 1.13)
% tablet use	2.16 (6.74)	2.21 (8.83)	2.18 (7.62)	–0.01 (–0.66 to 0.65)

Satisfaction With the Intervention

A total of 34/55 (62%) participants in the active intervention groups started the program and completed the SAT. Independent *t* tests demonstrated no significant differences between active intervention groups in terms of scores on the SAT. Descriptive statistics, between-group effect sizes, and confidence intervals for the SAT are displayed in Table 5, with effect sizes nearly all in favor of the human support group. Both groups liked the flexibility, user-friendliness, and positive psychology approach of the program. The human support group identified liking anonymity and supporter feedback, with one participant reporting that simply "knowing there was support" [participant #17, male] was helpful. Both groups disliked the lack of face-to-face interaction. Participants also reported that the program did not fully meet their individual needs and wants. One participant noted that it "was quite vague at times" [participant #7, female] while another reported that it "felt too prescriptive in how life should be" [participant #35, female]. The human support group disliked the infrequent timing of reviews, reporting that they felt discontinuous. One participant in the automated support group reported that receiving human support may have encouraged greater use of the program. Several participants noted time restrictions and lacking motivation as barriers to program completion.

Table 5. Descriptive statistics for the SAT[a].

Item	Human support, (N=19), mean (SD)	Automated support, (N=15), mean (SD)	Total, (N=34), mean (SD)	Between-group effect size, *d* (95% CI)
I was happy to use the computer to access treatment[b]	3.95 (0.85)	3.67 (0.90)	3.82 (0.87)	0.32 (–0.36 to 1.00)
I found the online treatment easy to use	4.16 (0.96)	4.00 (0.66)	4.09 (0.83)	0.19 (–0.49 to 0.87)
I felt the treatment received will have a long-lasting effect	3.26 (0.93)	3.33 (0.82)	3.29 (0.87)	–0.08 (–0.76 to 0.60)
I would recommend the online treatment to other users	3.82 (0.77)	3.40 (0.83)	3.65 (0.81)	0.53 (–0.16 to 1.22)
Please rate how helpful you found the online treatment program[c]	3.05 (0.62)	2.73 (0.70)	2.91 (0.67)	0.49 (–0.20 to 1.17)
How likely is it that you would recommend this treatment program to a friend or colleague?[d]	6.95 (2.53)	6.07 (2.66)	6.56 (2.58)	0.34 (–0.34 to 1.02)

[a]SAT: Satisfaction With Treatment.

[b]Score range=1-5 for items 1-4.

[c]Score range=1-4.

[d]Score range=1-10.

Intervention Preference and Allocation

With regard to intervention preference, 66% of participants opted for human support (55/83). Main reasons for selecting human support included the belief that human contact cannot be replaced and perceptions that it would be more personalized and beneficial than automated support. Prominent reasons for opting for automated support included a want for greater privacy and an interest in the user experience of receiving automated support.

In terms of primary and secondary outcomes, mixed factorial ANOVAs demonstrated no significant difference between participants who were or were not assigned their preferred

intervention, from baseline to post-intervention, for ITT (n=55) or per-protocol (n=35) analyses. However, a Pearson chi-square test (n=55) revealed that participants who were allocated their preferred intervention were significantly more likely to complete postintervention measures than those who were not (χ^2_1=5.8, *P*=.02).

Regarding engagement and usage, independent *t* tests (n=36) demonstrated a significant difference between participants who started the intervention in terms of length of program use ($t_{33.96}$=3.45, *P*=.002) and number of logins (t_{34}=2.15, *P*=.04). Participants who were allocated their preferred intervention tended to spend more time on the program (n=23; mean 205.42 [SD 106.13]) and log in more frequently (n=23; mean 9.43 [SD 3.06]) than participants who were not, who on average spent less time on the program (n=13; mean 111.64 [SD 56.82]), and logged in less frequently (n=13; mean 6.85 [SD 4.14]). Participants did not differ significantly on any other engagement and usage or satisfaction (n=34) variable.

Additional *post hoc* analyses revealed that participants who elected for and received human support spent significantly longer time on the program (n=16; mean 213.72 [SD 111.70]) than participants who elected for human support and received automated support (n=9; mean 103.10 [SD 44.40]; $t_{21.44}$=3.50, *P*=.002). Similarly participants who elected for and received automated support spend significantly longer on the program (n=7; mean 186.44 [SD 97.52]) than participants who elected for automated support and received human support (n=9; mean 103.10 [SD 44.40]; t_{14}=2.93, *P*=.04).

Discussion

Principal Findings

This pilot study investigated the preliminary efficacy and acceptability of a web-based intervention for resilience, provided with human or automated support, in a sample of college students. All participants demonstrated significant improvements in resilience, well-being, and self-esteem and reductions in symptoms of depression and anxiety, and perceived stress, thereby confirming the beneficial effects of the web-based resilience intervention. With regard to the role of support, the results are preliminary in nature, but results show overall equivalence of outcomes between human and automated support.

Effect sizes were generally moderate for resilience outcomes and small for well-being outcomes, in line with existing research on resilience and positive psychology interventions [9,12-18]. Similarly, for secondary outcomes of self-esteem, depression and anxiety symptoms, and perceived stress, effects ranged from small to moderate. Notably, effects for resilience tended to be larger on the BRS (which measures a resilient outcome) in the human support group and larger on the CD-RISC (which measures the assets and resources that lead to a resilient outcome) in the automated support group [66]. It is possible that the personalized element of human support facilitated the application of skills targeted by the intervention to participants' specific life circumstances, increasing the likelihood of a resilient outcome. Comparably, while the automated support group likely developed these skills, they perhaps lacked the tailored support conducive to applying them, limiting the opportunity for a resilient outcome. However, these results are preliminary and a larger-scale trial is needed to confirm the direction of the findings.

The general equivalence of outcomes across the 2 active intervention arms is in contrast with research demonstrating more favorable outcomes when human support is provided [28,30]. However, this does compare to some preliminary evidence of comparable outcomes between human and automated support [27,29]. This may have been due to a greater sense of agency in the automated support group as participants were not dependent on a therapist and the quality of automated support [27,29]. Nonetheless, effect sizes tended to be larger for the human support group. This may have been due to the personalization of feedback in this group. Therefore, the addition of persuasive technology features such as tailoring or personalization to automated support may bring it up to par with human support in terms of effect [27].

Even more interesting was our finding that observed effects were likely impacted by user preference, demonstrating that those who opted for the human or automated supported intervention and received that had higher engagement. While intervention preference and allocation had no effect on intervention outcomes or satisfaction, participants who received their preferred intervention did use the program more and were more likely to complete postintervention measures. These findings support research showing higher levels of treatment adherence and retention when preference and allocation are matched [31,32]. This may point to the clinical utility of a shared model of decision making when more than 1 intervention option is available [31].

While our findings are, for the most part, in line with existing research, a nonsignificant difference between active intervention groups and controls is something that we did not expect. It is important to note that the effects observed in the active intervention groups cannot be attributed to the intervention with certainty, given significant improvements and comparable effect sizes in the waiting list group. This amelioration may have been due to a self-selection bias in this study whereby students who were more motivated to change signed up to participate [67]. Accordingly, anticipation effects, that is, changes in outcome due to expectation of future change, may have been present in the waiting list group [68]. As there was no follow-up, it cannot be determined if these effects dissipated over time or if effects in the active intervention groups were sustained. Lastly, given that the study was a pilot, sample size was small. Because of greater variability in participant responses, it is likely that the sample was not large enough to differentiate between groups [69].

An initial recruitment rate of less than 1% may be partially attributed to the fact that participants were not reimbursed for participating in the study. However, retention rates in this study were high resulting in a dropout rate of only 24%. This is impressive relative to other web-based intervention research which has demonstrated dropout rates of up to 83% [24]. In terms of program usage, 65% (36/55) of participants in the active intervention groups started the program and completed

46.46% of it on average. It is therefore possible that participants did not receive the full benefit of the intervention in this study, underestimating its true efficacy and further contributing to the nonsignificant difference between intervention and control groups. Potential reasons for low levels of engagement or dropout or both include the lack of time students had to spend on the program and insufficient support, which may have influenced motivation to use the intervention. Both of these were noted in the satisfaction data collected. Given its significant effect on usage, it is also viable that dropout rates were impacted by user preference and allocation to intervention groups.

Overall, participants were satisfied with the intervention, found it helpful and easy to use, and would recommend it to others. Participant satisfaction with the intervention did not vary based on the type of support provided, further indicating the equivalence of human and automated support. In line with previous research on web-based interventions [70], participants liked the flexibility and accessibility of the program and disliked not having enough time to complete it. As the human support group disliked the infrequent timing and discontinuation of reviews, it raises the question as to the role of support in such interventions; perhaps as has been suggested previously, there may be different routes to treatment success that is dependent on user characteristics and type of support required [71]. Knowledge regarding the amount of support necessary in preventive web-based interventions is currently unclear [17]. The decision to provide fortnightly reviews in this study was based on the fact that participants were not drawn from a clinical population and were deemed capable of completing the program with minimal support. However, in order to sufficiently motivate and support user engagement, it is possible that the same degree of support is necessary as in remedial programs, where support is typically implemented on a weekly basis [21,72].

Limitations

The main limitation of the study was the small sample size. This resulted in greater heterogeneity in the data, leading to an unforeseen change to study protocol in terms of data analysis. However, it should be acknowledged that as the study is a pilot, establishing the true efficacy of the intervention was not the primary goal. Second, as data on time spent on the program per week were not collected, it was not possible to determine if participants adhered to the recommended dose of usage [47,48]. Further, reasons for participants not signing up to the intervention and dropout were not collected, limiting related insights around recruitment and attrition. As there was no follow-up assessment, the long-term effects of the intervention could not be gauged. Besides, the study did not examine the occurrence of adverse events following the intervention; change in resilience was based on self-report scales. Therefore, it cannot be determined whether or not participants had the opportunity to apply the skills acquired through the intervention by the time of postintervention assessment. Additionally, the sample included postgraduate students who may not be representative of a high-risk student population given that they are likely to be more well-adjusted than undergraduate students [73].

Implications and Future Research

To the authors' best knowledge, this is the first study to explore the role of human and automated support in a resilience intervention in a college sample. Primarily, the results of this pilot will inform the development and implementation of a full-scale trial. It is possible that more reviews should be provided to groups to increase engagement, with final reviews preparing the human support group for the discontinuation of support. As telephone calls and emails to participants from the research team constituted reminders about research procedures, their omission is not anticipated to affect outcomes or usage in routine application. Preliminary evidence for the equivalence of human and automated support must be replicated before related conclusions are drawn. Future research should further consider the effects of participant preference for support and the role of personalization in automated support, establish recommendations around intervention dose, and include follow-up assessment(s). Applications may then be considered, including the widespread implementation of the intervention at a universal level and for at-risk populations.

Conclusion

Web-based interventions aimed at promoting resilience demonstrate an important protective function in mitigating the effects of stress. They have the potential to reduce the occurrence of mental health problems in those who are at heightened risk and experience difficulties around accessing adequate treatment. Beyond prevention, an emphasis on resilience reflects a larger shift in focus away from pathology and toward psychological well-being and human strengths. These interventions therefore play an important role in the area of mental health promotion in terms of increasing not only the emphasis placed on successful versus stressful life events, but also their prevalence.

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Authors' Contributions

AE and OM designed the study with DR. OM, AS, CTL, and SF coordinated data collection. AE and OM led data analysis and interpretation under the supervision of DR. The first draft of the manuscript was written by OM and revised by AE and DR who approved the final version.

Conflicts of Interest

AE, OM, AS, CTL, SF, and DR were employed by SilverCloud Health during the completion of the study. AE and DR are members of the TCD E-mental Health Research Group.

Multimedia Appendix 1
CONSORT-EHEALTH checklist.
[PDF File (Adobe PDF File), 358 KB - formative_v4i11e20167_app1.pdf]

Multimedia Appendix 2
Space for Resilience: Description of module content.
[DOCX File , 14 KB - formative_v4i11e20167_app2.docx]

Multimedia Appendix 3
Space for Resilience: Screenshot of the intervention.
[PNG File , 30 KB - formative_v4i11e20167_app3.png]

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Abbreviations

ANOVA: analysis of variance
BRS: Brief Resilience Scale
CD-RISC: Connor–Davidson Resilience Scale
PHI: Pemberton Happiness Index
PHQ-4: Patient Health Questionnaire—4 Items
PSS-4: Perceived Stress Scale—4 Items
RSES: Rosenberg Self-Esteem Scale
SAT: Satisfaction With Treatment

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Original Paper

Evaluation of Treatment Descriptions and Alignment With Clinical Guidance of Apps for Depression on App Stores: Systematic Search and Content Analysis

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Abstract

Background: The use of apps for the treatment of depression shows great promise. However, there is uncertainty regarding the alignment of publicly available apps for depression with clinical guidance, their treatment fidelity and evidence base, and their overall safety.

Objective: Built on previous analyses and reviews, this study aims to explore the treatment and safety issues of publicly available apps for depression.

Methods: We conducted a content analysis of apps for depression in the 2 main UK app stores (Google Play and Apple App Store). App store listings were analyzed for intervention content, treatment fidelity, and fit with the National Institute for Health and Care Excellence (NICE) guidelines for the treatment of depression in adults.

Results: A total of 353 apps for depression were included in the review. App descriptions reported the use of 20 treatment approaches and 37 treatment strategies. Many apps used transdiagnostic (155/353, 43.9%) and multitheoretical interventions to treat multiple disorders including depression. Although many interventions appeared to be evidence-informed, there were issues with treatment fidelity, research evidence, and fit with clinical guidelines. None of the apps fully aligned with the NICE guidelines for depression.

Conclusions: App developers have adopted many evidence-informed treatments in their interventions; however, more work is needed to improve clinical validity, treatment fidelity, and the safety of apps. We urge developers to consult relevant guidelines and standards, and to engage in reflective questioning on treatment and safety to address these issues and to improve treatment content and intervention design.

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KEYWORDS

mobile mental health; mHealth; mobile apps; depression; clinical guidance; NICE guidelines; NHS; safety; ethics; content analysis

Introduction

Management and Treatment of Depression

Depression is an affective disorder characterized by persistent low mood; loss of interest or pleasure; increased negative thoughts and feelings; and associated emotional, cognitive, physical, and behavioral difficulties [1-3]. Within the United Kingdom, the National Institute for Health and Care Excellence (NICE) seeks to improve outcomes for people using the National Health Service (NHS) and other public health services through the provision of evidence-based guidance, quality standards, and performance metrics. NICE guidelines for the treatment and management of depression in adults [4,5] recommend a stepped care approach of clinical and cost-effective interventions. Following early intervention through screening, assessment, and psychoeducation, first-line treatments for subthreshold or mild to moderate depression include low-intensity psychosocial interventions, specifically guided self-help based on cognitive behavioral therapy (CBT) or group physical activity programs. Persons with less severe depression who decline or do not respond well to these interventions should be offered high-intensity psychological interventions—specifically CBT, interpersonal therapy (IPT), behavioral activation, or behavioral couples therapy—or antidepressants. If declined, individuals may be offered counseling or short-term psychodynamic psychotherapy.

For moderate to severe depression, NICE advises a combination of antidepressants and high-intensity interventions (CBT or IPT), with relapse prevention consisting of antidepressants and CBT or mindfulness-based cognitive therapy (MBCT). Complex and severe cases of depression receive the highest level of care, which may include multidisciplinary care, specialist mental health services, and crisis resolution.

Network meta-analysis of clinical evidence for the treatment of depression in adults found self-help with support to be more effective than psychoeducation and self-help without support [4]. These self-help interventions included (from better to worse outcomes): computerized psychodynamic therapy with support, computerized CBT with support, computerized behavioral activation with support, computerized CBT without support, psychoeducational website, and computerized mindfulness intervention. Although the 2018 NICE draft guidelines did not specifically recommend mobile apps, their 2019 guidelines for depression in children and young people [6] advised the use of digital CBT in cases of mild depression. This included CBT delivered via a computer, tablet, or phone.

Building on this guidance, NHS England and NICE developed a digitally enabled therapy assessment program aimed at evaluating the use of digital therapy products in the NHS Improving Access to Psychological Therapies (IAPT) services [7,8]. The program assessed 14 digitally enabled therapies (ie, psychological interventions delivered on the web or through apps with the support of a therapist). Of these, 6 targeted depression in adults [9-15]. Digital therapies were assessed based on 4 criteria: content, technical standards, clinical effectiveness, and cost impact. In line with NICE guidance, content assessment of digital therapies for depression evaluated adherence to CBT and fit within a blended care model. Following expert evaluations, only 3 digital therapies were recommended for trialed use within IAPT services [11,12,14]. For those not recommended, treatment issues included misalignment with the therapist-guided model of care [10], poor user and treatment experiences [13], and incomplete treatment content for depression because of the use of a transdiagnostic approach [15]. Only one of the therapies offered a web- and app-based program [12], with others being solely web-based.

Mobile Apps for Depression

The use of apps for the management of depression has shown promise in providing accessible and low-cost mental health interventions. Randomized controlled trials and reviews of apps for depression have reported significant reductions in depressive symptoms [16-22] and improvements in well-being [23]. There is evidence of the use of apps for assessment and psychoeducation [24], symptom tracking or mood monitoring [19,24], cognitive training and problem solving [16], and a range of treatment approaches, including CBT [19,22], behavioral therapy (BT) and dialectical behavior therapy (DBT) [22], mindfulness [19], and transdiagnostic approaches [17].

Although highlighting the potential of mobile mental health, research cautioned that findings did not reflect apps available to the public through the app marketplace. Torous et al [22] showed that only one-third of apps for depression reviewed in the literature were available for download in app stores, with research reviews of the app marketplace uncovering a worrying lack of evidence for most apps [25-27].

Content analyses and marketplace reviews of publicly available apps found hundreds of apps marketed for depression. Given the overwhelming number of apps, reviewers often limited analyses to a subset [27-30] such as apps using specific approaches [25,31,32]. The most common functionalities of apps for depression included psychoeducation [25,27,29-31], assessment [25,28,29,31], and symptom management [25,30,31]. Approximately one-third of apps for depression provided therapeutic treatment [31] or interactive interventions [29]. CBT apps for depression incorporated several strategies but were criticized for overlooking treatment processes such as challenging core beliefs and conceptualization in favor of education, monitoring and tracking, and thought records [24,30]. Overall, the authors commented that although some apps seemed to be evidence informed, reflecting some theoretical principles and strategies, the apps did not demonstrate high fidelity to evidence-based treatments such as CBT or BT [25,32] and generally lacked evidence supporting use and efficacy [21,23,25,27].

Reviews of publicly available apps for depression also highlighted insufficiencies in the treatment and safety information provided, including limited disclaimers [27], limited encouragement for users to seek in-person care [29], and inadequate reporting of affiliations or expert involvement [31,32]. Reviews of the ethics of mobile mental health [33,34] have also raised concerns with acceptance [35], risks and safety of apps [36-47], and the poverty of evidence regarding benefits and outcomes [36-40,42-46,48,49]. Therefore, there is uncertainty as to how well apps for depression match existing

clinical guidelines and recommendations, their treatment fidelity (ie, adherence to components of a treatment orientation) and evidence base, and their safety for use with or without support.

Overview of Study

This study builds on previous analyses and reviews to explore treatment descriptions of publicly available apps for depression and their alignment with clinical guidance as conveyed in app store listings. The decision to review app listings rather than downloaded apps reflects the lack of a comprehensive overview of all treatment options marketed to the public through the marketplace for apps for depression. Guided by NICE guidelines and literature on the ethics and safety of mobile mental health, we conducted content analysis of apps for depression listings in the UK app marketplace. This study aims to answer the following questions: (1) What treatment approaches and strategies are named or described in app listings of apps for depression? (2) Are treatment fidelity and evidence-informed development evident in descriptions of apps for depression? (3) Do descriptions of apps for depression reflect NICE guidelines for the treatment and management of depression? We hope that this study will advance research and discussion on the treatment content and safety of publicly available apps for depression, in particular their marketing to the public, fit with clinical guidance, and discrepancies between public health digital therapies and direct-to-consumer products. In doing so, we seek to promote improved standards and best practices in the design and marketing of mental health apps.

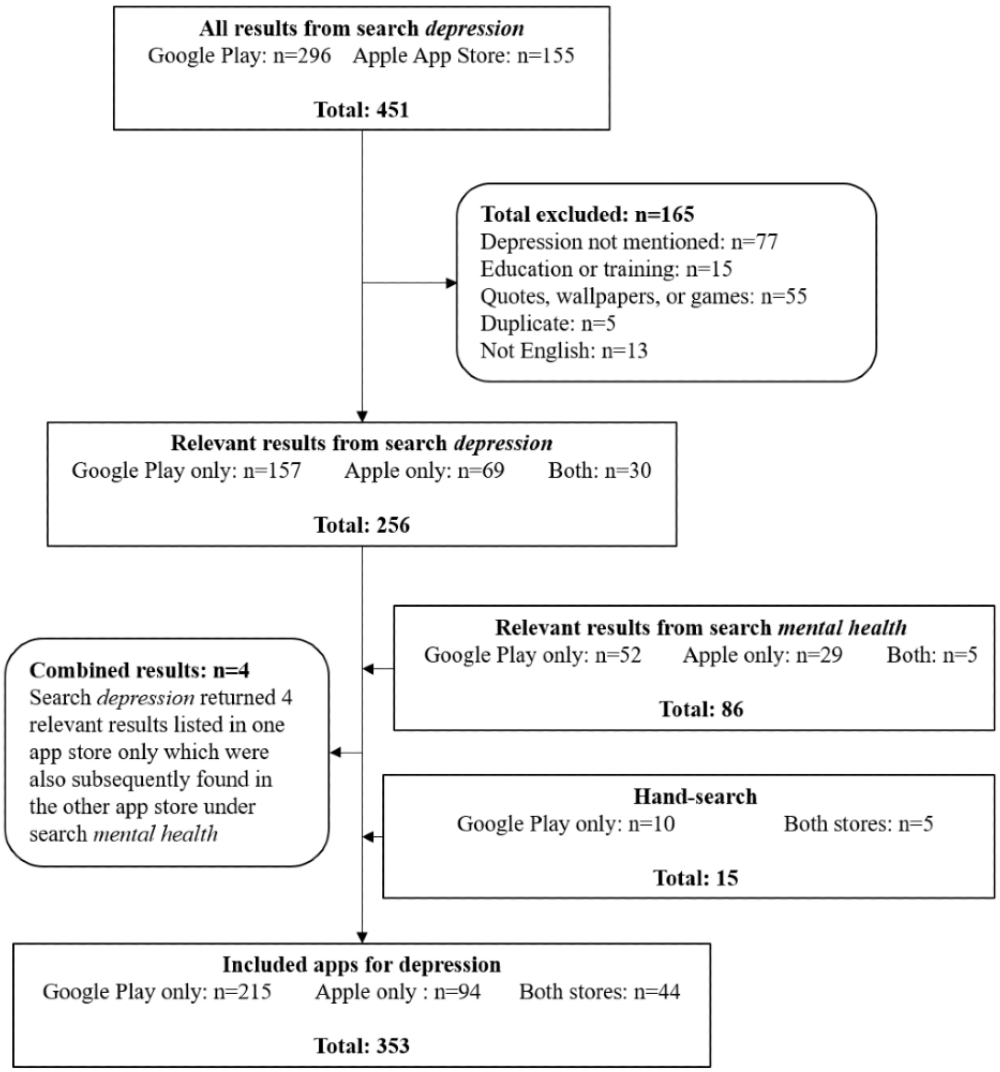
Methods

Sampling Methods

App search and data collection was conducted between October and November 2018, guided by methods used by Shen et al [31] and Stawarz et al [32]. The first step involved search of apps in the 2 main UK app stores: Google Play and Apple App Store. The initial search was performed using the search term *depression*. For the review, apps for depression were defined as apps with app store listings mentioning depression or depressive symptoms. Apps were included in the review if they met the following criteria: (1) app description included terms *depression*, *low mood* or *mood disorder*, *mood management*, *negative thoughts*, or *distress* and (2) app listing was in English. Apps were excluded if they (1) did not mention depression or depressive symptoms, (2) were for professional training, (3) only provided quotes or wallpapers, or (4) were duplicates, that is, copies of an app listed within the same app store. Duplicates did not include free and paid versions of apps or apps listed in both stores; in these cases, all relevant apps were included in the review. Apps were also not excluded if they targeted another mental health problem (eg, anxiety) once they mentioned depression or depressive symptoms. This initial search returned 451 apps (296 in Google Play and 155 in Apple App Store). Of these, 256 unique apps met the inclusion criteria (Figure 1).

A second search of the same app stores was performed using the term *mental health* aimed at detecting apps for depression that were not returned in the primary search. Finally, a hand search of the same app stores for apps for depression that were reported in previous research but not returned in the searches was performed. These searches yielded an additional 97 eligible apps. This resulted in a total of 353 unique apps for depression being included in the analysis (Multimedia Appendix 1).

Figure 1. Sampling flowchart.



Content Analysis

This study aims to explore treatment descriptions and fit with clinical guidance of apps for depression, as evident in app store listings and websites. Before the review, a list of variables was compiled to extract data on app information, developer information, treatment information, and usage. Data were initially extracted from app listings and websites verbatim or using yes or no coding to indicate the presence or absence of variables. Throughout this process, coding was developed iteratively as treatment information emerged. Treatment codes were informed by NICE guidelines [4-6], literature on the treatment of depression [50,51], and app reviews [25,29]. Final coding is presented in Multimedia Appendix 2. Data extraction and coding were led by the first author and revised through group discussion until consensus was reached among all authors.

Descriptive statistics of the app data were computed using SPSS version 25. Categorical variables were recoded numerically before analysis. Spearman rank correlation coefficient was used to explore associations within- and between-treatment approaches and treatment strategies as part of the analysis of treatment fidelity and evidence-informed interventions. Chi-square tests were also performed to determine associations between developer type and treatment variables.

Results

Treatment Descriptions of Apps for Depression

App store descriptions typically touted the suitability and benefits of apps for depression or related difficulties. The findings indicate that 28.3% (100/353) of apps targeted solely depression, with most apps targeting depression alongside other difficulties, notably anxiety and stress (Table 1). Just under one-half (174/353, 49.3%) of all apps targeted multiple (4 or more) disorders.

Less than one-third of apps (108/353, 30.6%) offered a disorder-specific intervention, that is, an intervention designed to treat a single mental health problem (eg, depression), whereas 43.9% (155/353) of apps described transdiagnostic interventions treating multiple disorders using the same treatment content. A further 25.5% (90/353) of apps reported treatment of multiple disorders with varied content for each.

In this analysis, the treatment approach was defined as theoretical or treatment orientation such as CBT, whereas treatment strategies were the techniques employed in the delivery of the intervention, such as cognitive reappraisal. Our review identified 20 treatment approaches and 37 treatment

strategies. For some apps, approaches (36/353, 10.2%) and strategies (115/353, 32.6%) were not clearly presented. As per previous research, the most common approach was psychoeducation, with assessment and CBT frequently used (Table 2). There was also a high use of complementary and alternative therapies.

Table 1. Frequency of target disorders in apps for depression (N=353).

Target disorders	Apps, n (%)
Multiple	174 (49.3)
Depression	100 (28.3)
Depression and anxiety	34 (9.6)
Depression, anxiety, and stress	27 (7.7)
Suicide or self-injury	4 (1.1)
Anxiety and stress	3 (0.8)
Stress	3 (0.8)
Depression, anxiety, and bipolar disorder	2 (0.6)
Anxiety	1 (0.3)
Sleep	1 (0.3)
Depression and stress	1 (0.3)
Depression and bipolar disorder	1 (0.3)
Depression, bipolar disorder, and schizophrenia	1 (0.3)
Depression, anxiety, and trauma	1 (0.3)

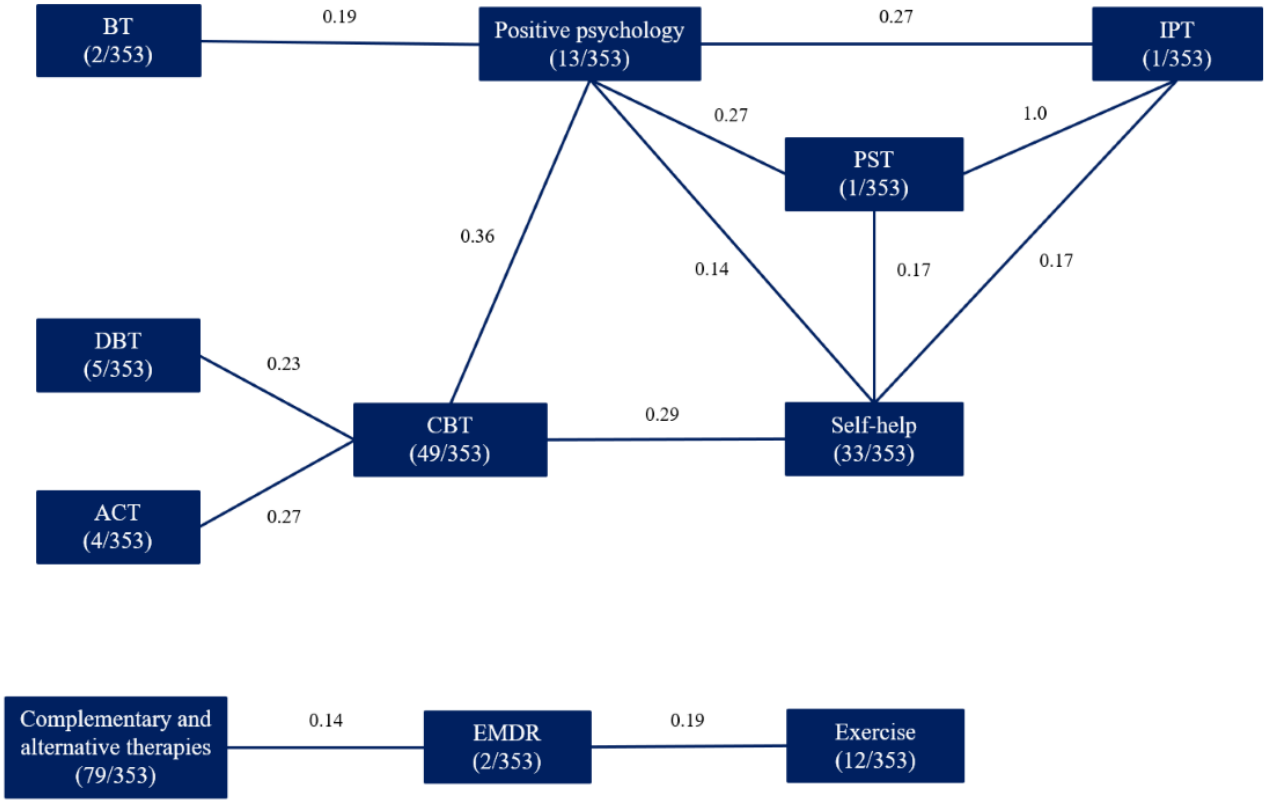
Table 2. Treatment approaches of apps for depression (N=353).

Treatment approach	Apps, n (%)[a]
Psychoeducation	141 (39.9)
Complementary and alternative therapies	79 (22.4)
Screening or assessment	66 (18.7)
Cognitive behavioral therapy	49 (13.9)
Psychosocial	46 (13.0)
Self-help	33 (9.4)
Online therapy	19 (5.4)
Positive psychology	13 (3.7)
Exercise	12 (3.4)
Dialectical behavior therapy	5 (1.4)
Acceptance and commitment therapy	4 (1.1)
Cognitive training	4 (1.1)
Spiritual or faith based	3 (0.9)
Behavioral therapy	2 (0.6)
Eye movement desensitization and reprocessing	2 (0.6)
Interpersonal therapy	1 (0.3)
Mindfulness-based cognitive therapy	1 (0.3)
Motivational interviewing	1 (0.3)
Neurostimulation	1 (0.3)
Problem-solving therapy	1 (0.3)

[a]Percentages do not add up to 100% because some apps use multiple approaches.

Our review found that 59.2% (209/353) of app listings reported only 1 identifiable treatment approach, with others describing combinations of 2 to 6 approaches (n=317 [missing cases excluded]; mean 1.53, SD 0.92; mode 1). There were 59 unique combinations of approaches. This is captured in Figure 2, which maps significant positive associations between treatment approaches, providing insight into the most commonly used treatment combinations (the correlation table is given in Multimedia Appendix 3). Despite the low frequency of some approaches, these results illustrate patterns in the treatments used, such as combinations of different cognitive approaches (acceptance and commitment therapy, CBT, and DBT).

Figure 2. Significant associations between treatment approaches in apps for depression (Spearman rank correlation coefficients, *P*<.01). ACT: acceptance and commitment therapy; BT: behavioral therapy; CBT: cognitive behavioral therapy; DBT: dialectical behavioral therapy; EMDR: eye movement desensitization and reprocessing; IPT: interpersonal therapy; PST: problem-solving therapy.



Eclecticism in treatment was also evident in the variety of treatment strategies (Table 3). Overall, 22.9% (81/353) of apps described only 1 identifiable treatment strategy, with the remaining naming between 2 and 16 strategies (n=238 [missing cases excluded]; mean 2.53, SD 1.82; mode 1). There were 112 unique combinations of strategies (Multimedia Appendix 1).

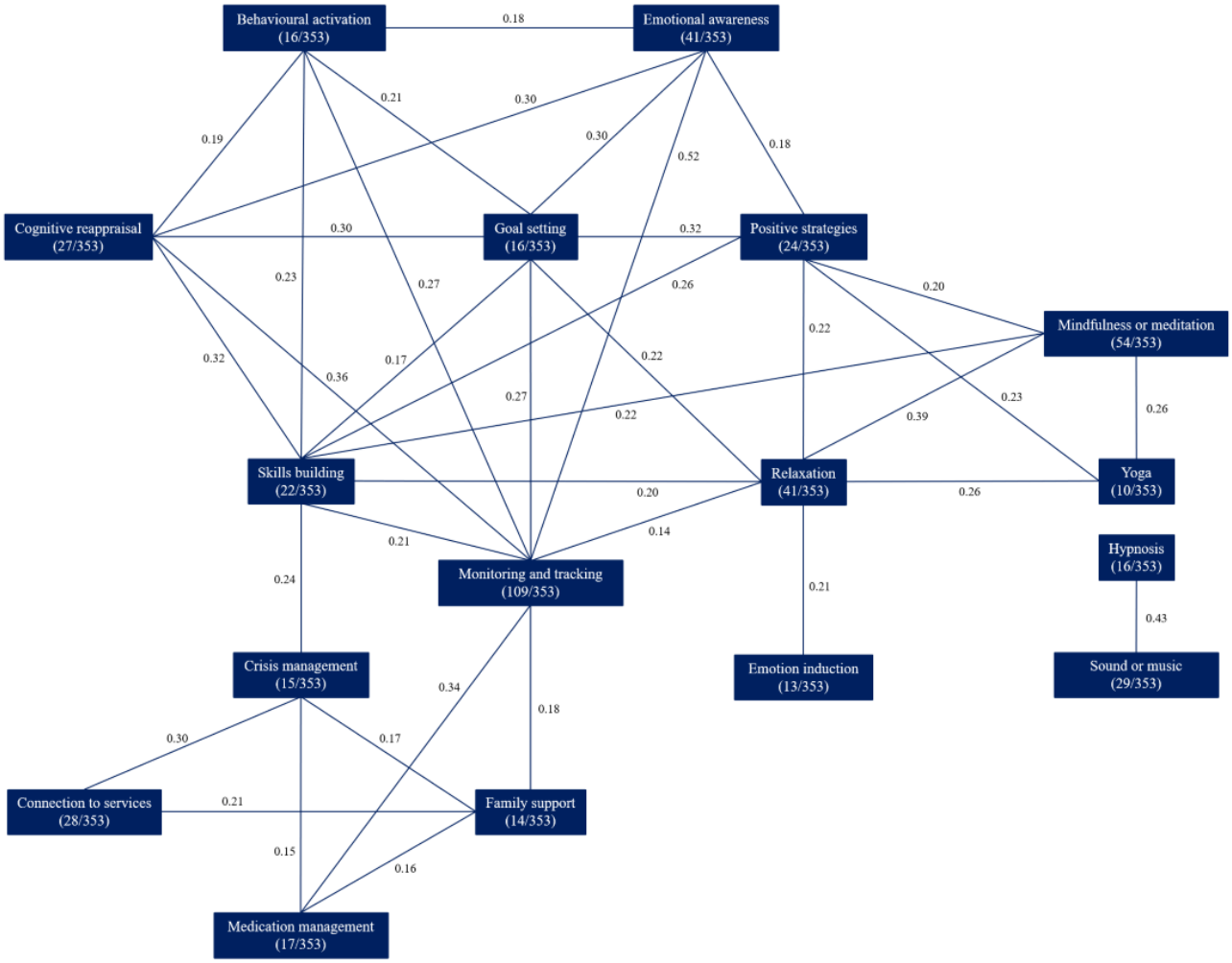
These strategy combinations are illustrated in Figure 3, which captures the significant positive associations between the most commonly identified strategies (n>9; the correlation table is given in Multimedia Appendix 4). As with the treatment approaches, patterns emerged in the reported use of treatment strategies. Such patterns suggest evidence-informed development, as seen with the associations between the use of emotional awareness, cognitive reappraisal, behavioral activation, and monitoring and tracking, which are all emotion regulation techniques typically employed in treatments for depression, such as CBT and evidence-based multitheoretical [50] and transdiagnostic [51] approaches.

Table 3. Treatment strategies of apps for depression (N=353).

Treatment strategies	Apps, n (%)[a]
Monitoring and tracking (including diaries)	109 (30.9)
Mindfulness or meditation	54 (15.3)
Emotional awareness	41 (11.6)
Relaxation	41 (11.6)
Peer support	34 (9.6)
Sound or music	29 (8.2)
Connection to services	28 (7.9)
Cognitive reappraisal	27 (7.7)
Positive strategies	24 (6.8)
Lifestyle or nutrition	22 (6.2)
Skills building	22 (6.2)
Medication management	17 (4.8)
Behavioral activation	16 (4.5)
Goal setting	16 (4.5)
Hypnosis	16 (4.5)
Crisis management	15 (4.2)
Family support	14 (4.0)
Emotion induction	13 (3.7)
Yoga	10 (2.8)
Distraction or grounding	5 (1.4)
Acupressure	4 (1.1)
Chatbot	4 (1.1)
Self-compassion	4 (1.1)
Bodily awareness	3 (0.9)
Coaching	3 (0.9)
Gamification	3 (0.9)
Motivation enhancement	3 (0.9)
Problem solving	3 (0.9)
Cognitive bias modification	2 (0.6)
Exposure	2 (0.6)
Neuro-linguistic programming	2 (0.6)
Acceptance	1 (0.3)
Art therapy	1 (0.3)
Chromotherapy	1 (0.3)
Emotional freedom techniques	1 (0.3)
Havening	1 (0.3)
Transcranial direct current stimulation	1 (0.3)

[a]Percentages do not add up to 100% as some apps use multiple strategies.

Figure 3. Significant associations between most common treatment strategies in apps for depression (Spearman rank correlation coefficients, $P<.01$).



CBT was associated with 13 of the 37 strategies (where significant associations are $P<.01$), including cognitive reappraisal, monitoring and tracking, and emotional awareness (Table 4).

Mindfulness meditation was also often used in CBT apps; however, only one app was identified as having a mindfulness-based cognitive approach. Although these associations suggested some evidence-informed development, there were shortcomings in the reported use of these strategies across CBT app listings. Specifically, except for monitoring and tracking (41/49, 84%), less than half of all CBT app store descriptions mentioned the use of these strategies (Multimedia Appendix 5). Only 49% (24/49) CBT app listings described the use of cognitive reappraisal, whereas 45% (22/49) mentioned emotional awareness, 16% (8/49) used goal setting, and 14% (7/49) reported the use of behavioral activation. In addition, although a high number of CBT apps employed the use of monitoring and tracking of mood, thoughts, and behaviors, fewer reported the use of screening or assessment (8/49, 16%), with only half of these app listings naming the measure used. More often, CBT apps described the use of psychoeducation (15/49, 31%), although this too was underutilized or underreported.

Table 4. Spearman rank correlation coefficients for cognitive behavioral therapy and all strategies (N=353).

Treatment strategies	Spearman correlation coefficient, ρ	*P* value
Cognitive reappraisal	0.62	<.001
Monitoring and tracking (including diaries)	0.44	<.001
Emotional awareness	0.42	<.001
Skills building	0.30	<.001
Relaxation	0.29	<.001
Goal setting	0.23	<.001
Mindfulness or meditation	0.22	<.001
Behavioral activation	0.19	<.001
Chatbot	0.19	<.001
Exposure	0.19	<.001
Self-compassion	0.19	<.001
Positive strategies	0.15	.004
Coaching	0.14	.008
Emotional freedom techniques	0.13	.01
Havening	0.13	.01
Connection to services	–0.12	.03
Crisis management	0.12	.03
Sound or music	–0.09	.09
Cognitive bias modification	0.08	.14
Neuro-linguistic programming	0.08	.14
Yoga	0.08	.14
Bodily awareness	0.05	.33
Motivation enhancement	0.05	.33
Problem solving	0.05	.33
Hypnosis	–0.05	.37
Family support	0.04	.41
Acupressure	–0.04	.42
Gamification	–0.04	.49
Distraction or grounding	0.02	.69
Acceptance	–0.02	.70
Art therapy	–0.02	.70
Chromotherapy	–0.02	.70
Transcranial direct current stimulation	–0.02	.70
Medication management	–0.01	.80
Emotion induction	0.01	.87
Peer support	0.008	.88
Lifestyle or nutrition	–0.002	.97

Alignment With Clinical Guidelines on the Treatment of Depression

In terms of adherence to clinical guidance, 67.1% (237/353) of apps reported the use of at least one treatment approach recommended in NICE guidelines for the treatment of depression. Over half of all apps (181/353, 51.3%) described an early intervention, namely, assessment or psychoeducation, whereas 19.8% (70/353) of apps described the use of a NICE-recommended psychological approach (ie, CBT, BT, IPT, or web-based therapy).

Although 13.9% (49/353) of apps adhered, to some extent, to NICE's recommendation for digital CBT, only 3.7% (13/353) of CBT apps suggested use with in-person support (Multimedia Appendix 5). Most CBT apps (37/49, 76%) appeared to use a transdiagnostic approach to treat multiple disorders, including depression. However, app descriptions did not specifically address the treatment of comorbidities or the suitability for use in complex cases. Moreover, only 18% (9/49) of CBT apps appeared to have published research on use or outcomes. In total, only 1 CBT app (MoodKit-Mood Improvement Tools) was found to have both published research and advice to use on its own or to enhance professional treatment. However, this app was not marketed as a comprehensive CBT program but rather as a mood improvement toolbox incorporating principles and techniques of CBT. Overall, none of the app store descriptions aligned with clinical guidance when assessed for evidence of NICE-recommended evidence-based interventions, therapist-guided models of care, and clinical effectiveness.

Further Treatment and Safety Issues

Overall, evidence of app use, safety, and outcomes was not available for most apps (314/353, 89.0%). Despite this, most app store descriptions (285/353, 80.7%) did not provide a disclaimer regarding treatment, appropriate use, or limitations. When provided, disclaimers ranged from caution that the app does not replace traditional care, guidance to contact a health care provider in cases of emergency, explicit statements of when the app should not be used, or nonliability claims. Less common but concerning were instances where app descriptions included inaccurate information (15/352, 4.3%)—such as unsupported claims that specific techniques (eg, daily journaling) were the most effective in treating depression—or unsafe claims (8/352, 2.3%), for instance, unsupported statements that users would not need to see a health care professional, would not experience any risks or harms, or would experience immediate benefits.

Our review of the identified skills and expertise of developers found that about one-third (117/353, 33.1%) of apps for depression explicitly mentioned the involvement of health care professionals, either in consultation or as a part of the development team. As many as 57.8% (204/353) of apps appeared to be developed by private entities without explicit mention of the involvement of health care or other multisector stakeholders. The importance of multidisciplinary development teams was reflected in the absence of research conducted by private entities without mention of stakeholder involvement—specifically, all but one app, which reported published (29/353, 8.2%) or unpublished (10/353, 2.8%) research involved health care (22/39, 56%) or academia (17/39, 44%). Differences in developer type and treatment approach were also noted. The reported use of psychoeducation was associated with development by private entities without stakeholders (χ^2_1=5.4; *P*=.02) but was less associated with academia (χ^2_1=4.5; *P*=.04). Private entities (without stakeholders) were also associated with the use of complementary and alternative therapies (χ^2_1=4.7; *P*=.03) but less associated with the use of CBT (χ^2_1=14.7; *P*<.001). Comparatively, development teams with health care were associated with the use of CBT (χ^2_1=20.3; *P*<.001), with 61% (30/49) of CBT apps explicitly mentioning the involvement of health care in app design or development.

Discussion

Principal Findings

The app marketplace offers potential users a range of apps marketed for the treatment and management of depression. To the best of our knowledge, this study is the first to provide a comprehensive review of treatment descriptions of publicly available apps for depression, exploring all reported treatment approaches and strategies and the interrelations between them. In doing so, we considered issues of treatment fidelity and the quality of information presented to potential users to allow them to make informed treatment decisions. This research is particularly novel in its consideration of the alignment of publicly available apps for depression with clinical guidelines [4,5]. Our findings highlighted notable shortcomings in treatment descriptions and clinical relevance, demonstrating the need for improved regulation and evaluation of direct-to-consumer mental health technologies.

Treatment Descriptions of Apps for Depression

The Popularity of Transdiagnostic Approaches

App store descriptions provided a range of treatment information, with no standardized reporting of intervention details, such as target disorder, intervention type, and treatment approaches and strategies. As such, there was wide variation in the amount and quality of treatment information provided by different apps.

With regard to target disorder, less than one-third of apps targeted solely depression, with the majority marketed for multiple disorders. To cater to this multiplicity of mental health problems, over 40% (155/353, 43.9%) of apps adopted transdiagnostic approaches. Proponents of transdiagnostic approaches [51-54] highlight the shared constructs and mechanisms underlying many disorders, suggesting benefits in the development and use of treatments across multiple mental health problems. Sauer-Zavala et al [54] presented 3 categories of transdiagnostic approaches, namely, universally applied therapeutic principles, as seen in the application of CBT to treat multiple disorders; modular treatments, whereby evidence-based strategies are selected based on a client's individual needs rather than diagnosis; and shared mechanism treatment that targets the underlying mechanisms in a class of disorders. There is potential value in the development of transdiagnostic apps for the treatment of depression [17]. However, as seen in the categorizations of transdiagnostic approaches, such treatments require a strong evidence base and rationale underlying development and use. Developers seeking to design transdiagnostic interventions should therefore consider the type of transdiagnostic approach to be employed, the evidence base underlying their intervention, and the evidence needed to justify use and effectiveness with the target populations. Although many apps appeared to adopt transdiagnostic approaches, this was not explicitly stated in app listings, with none reporting use of existing transdiagnostic treatment models [51,53].

Treatment Approach and Evidence-Informed Development

Developers typically described at least one treatment approach, with several app descriptions reporting the use of 2 or more approaches. Psychoeducation was the most popular approach, as per previous reviews [25,27,29-31]. This is not surprising given the relative ease of creating informational apps rather than interactive interventions. More surprising was the frequency of complementary and alternative approaches, which were more common than assessment and CBT. This may also reflect the ease in developing complementary and alternative app therapies, which typically provided content such as sound, music, or hypnosis or mindfulness meditation recordings. This was supported by our findings that private entities without stakeholder input were more likely to develop psychoeducation and complementary and alternative app therapies rather than interactive evidence-based interventions. Although complementary and alternative therapies may offer supplementary management of mental health difficulties, research is needed to demarcate how and by whom such apps should be used, the effectiveness and outcomes of their use for depression, and fit within existing evidence-based treatment models.

Our analysis also identified 37 unique treatment strategies, with just under half of all apps describing the use of 2 or more strategies. The plethora of strategy combinations suggested idiosyncrasies in depression treatments or their marketing within app stores. Without standardized reporting of treatment approaches and strategies in app stores, potential users are left to decipher app store descriptions for clues of the intervention before download. Further research is therefore needed to determine how accurately app interventions reflect their app store descriptions and the range of unique combinations of approaches and strategies in depression treatments as determined by use of the apps.

This study provides novel insights into patterns of approaches and strategies across all apps for depression, with significant associations found between theoretically similar orientations and methods. CBT apps for depression demonstrated significant associations with several elements of CBT, including cognitive reappraisal, monitoring and tracking, goal setting, behavioral activation, emotional awareness, and skills building [25,55-57]. However, except for monitoring and tracking, less than half of all CBT apps for depression reported use of these strategies. Moreover, as noted by Huguet et al [25], other core elements were either underreported or absent. Therefore, apps demonstrated some treatment fidelity in their described interventions; however, there remained significant gaps in descriptions of theoretical principles and methods.

Eclecticism in Apps for Depression

Although many apps appeared to lack the core elements of specific approaches, several apps reported the use of multiple approaches and unique combinations of strategies. These seemingly multitheoretical interventions are reflective of the eclecticism in treatment seen in traditional mental health care [58-61]. In real-world settings, decisions to offer eclectic or integrative treatments require clinician judgment, knowledge, and expertise to adapt established interventions to meet the needs of individual cases. In this sense, integrative care may be more complex than manualized treatments; therefore, they may be more difficult to deliver effectively outside of in-person care. Most mental health apps do not benefit from flexible clinical decision making and in-the-moment expertise and thus require clear information and evidence supporting their methods, use, and outcomes. Therefore, the lack of research for most apps is concerning and questions the validity of apps to deliver the promised effects. Apps did not report use of multitheoretical treatment models [50,58] but rather tended to cite benefits of individual treatment approaches that were then combined in their intervention. This design approach further supported the suggestion that apps were evidence informed rather than evidence based [25,27,32].

Alignment With Clinical Guidelines on the Treatment of Depression

Another important consideration in assessing app validity and suitability is their alignment with clinical guidance. For our study, we focused on fit with NICE guidelines for the treatment and management of depression in adults [4,5,7]. First, we considered the reported use of NICE-recommended treatment approaches that are not specific to mobile mental health. We then considered alignment with NICE recommendations on digital therapies for depression, specifically the use of CBT, provisions for in-person support, and evidence of clinical effectiveness. Superficially, approximately two-thirds of app descriptions mentioned the use of treatment approaches outlined in NICE guidelines, that is, at face value, most apps appeared to incorporate aspects of clinically recommended treatments, including psychoeducation, CBT, IPT, and BT [4,5,50,62,63]. A more detailed review of these apps is warranted to determine fidelity to these approaches.

Specific reference to the use of mobile mental health within NICE guidelines was reflected in recommendations for guided self-help [4] and digital CBT [6,7]. Few apps fit this framework, with only 13 apps offering CBT with suggested use with practitioner support. Given the lack of evidence of clinical effectiveness of these apps and pervasive shortcomings in descriptions of core components of CBT, we did not find any of the 353 app listings reviewed to fully align with treatment criteria in NICE guidelines. In their present state, apps may be more suited to provide supplement treatment for depression through their focus on specific aspects of care, such as mood tracking or goal setting. There were several strategies in apps for depression that aligned with aspects of treatment in the NICE framework, namely, apps offering monitoring and tracking, mindfulness, peer support, crisis management, and medication management. These strategies could act as tools to support treatment within the stepped care model utilized by the NHS. For example, monitoring and tracking apps could be utilized in active monitoring, whereas medication management apps could play an important role in increasing patient adherence to pharmacological treatments [64,65]. NICE analysis of the clinical effectiveness of mindfulness and peer support found both offered potential benefits in treating and managing depression but lacked enough evidence to support recommended use [4]. Therefore, there is some justification in the use of these

techniques to complement clinically effective treatments, as determined by individual needs and preferences of users.

Implications for App Design, Development, and Marketing

This study highlights notable shortcomings in the treatment design and marketing of direct-to-consumer apps for depression. There are persisting uncertainties regarding the treatment fidelity and validity of these apps, with more research needed to support the prevalent use of transdiagnostic and multitheoretical approaches and complementary and alternative app therapies. Our review shows a marked discrepancy between the digital interventions recommended for use within the UK public health system and apps for depression available to the public via the app marketplace. Developers hoping to create digital therapy products for use within the NHS should consult relevant guidance [4-7,63,66], standards [67-70], and technical specifications [71,72] to ensure that their app aligns with key criteria, including the use of evidence-based treatments, provisions for blended care, and evidence of clinical effectiveness. Although developers not targeting the public health system are not bound by these guidelines, we urge all developers of apps for depression to be au fait with best practices and to use these as a foundation in developing their digital interventions and innovations. New treatment approaches and methods are encouraged but must emerge from existing knowledge, evidence, and best practices.

In creating and distributing mental health interventions, app developers have a duty of care and responsibility for the content they design and develop and how it is marketed to the public. Regardless of the choice of treatment, developers and app stores have an obligation to provide potential users with enough information to help them make informed decisions regarding an app's suitability for their needs. Insufficient treatment information and lack of research evidence impair the abilities of potential users to make safe and informed choices and to adequately prepare for risks and outcomes [44,73]. The lack of evidence-based apps and the eclectic nature of some interventions warrant greater safety considerations given the use by potentially vulnerable persons. Efforts should be made to assess and mitigate potential risks and harms, to protect vulnerable groups, and to provide potential users with accurate and transparent information regarding treatment, safety, and outcomes. App stores should facilitate standardized reporting of information about target users, target disorders, intervention type, treatment approach, clinical evidence, compliance with guidelines and standards, expected benefits and outcomes, potential risks, safety and safeguarding, and general guidance on use and stage in treatment. App listings should also clearly outline the level of support provided and guidance on additional support for optimal use and outcomes.

Developers are encouraged to embrace the complexities of mobile mental health and to be innovative in their intervention design and development through multidisciplinary collaboration to produce clinically valid, effective, and safe treatments. To facilitate this process, we present several reflective questions for developers to engage with at the outset and throughout the design and development of mental health technologies. These questions aim to help developers to frame the rationale for their intervention, to assess their strengths and limitations in the design and development process, and to consider the treatment and safety needs involved.

Reflective Questioning for the Design and Development of Mobile Mental Health

Skills and Expertise

The following questions encourage reflection on the skills and expertise of the development team, specifically their competencies, multidisciplinary expertise, and user involvement:

- What knowledge and skills do you require for your project to be a success?
- Are you part of a multidisciplinary team? Do you need expert involvement?
- Is the development team sufficiently knowledgeable and skilled in clinical care, psychological interventions, theoretical principles, evidence-based practices, safety and safeguarding, clinical guidelines and standards, ethics, and codes of conduct?
- How will you involve user groups in planning, design, development, and research?

Treatment Design

Questions on treatment design aim to assist developers in considering the rationale for their app interventions, the intended target disorders and users, and the appropriate treatment orientation and strategies required to produce a quality app:

- Who are you developing the app for (consider demographics, target disorder, mental health difficulties and needs of users, and treatment histories and needs of users)?
- Why have you selected that group of target users?
- What stage of treatment will your app address (consider early intervention, first-line intervention, relapse prevention, crisis management, etc)?
- Will your app span more than one treatment stage? How will this be achieved through your intervention and app design?
- Do you intend your app to be used as a standalone intervention or supplementary to traditional care? How will this be reflected in your intervention and app design?
- What level of support will you provide users (consider connection to in-person services, crisis management, blended care, etc)?
- Do you wish to develop a disorder-specific intervention, or will you target multiple disorders using a transdiagnostic approach?
- What type of transdiagnostic approach will you employ (consider the 3 categories of transdiagnostic approaches discussed by Sauer-Zavala et al [54])?
- Will your app intervention target the disorder (eg, depression) or specific symptoms (eg, poor sleep)? How will this be reflected in your intervention and app design?
- What is your treatment approach?
- Why have you chosen this treatment approach? How does it align with your rationale, skills and expertise, and intervention design?

- How does your app intervention reflect evidence-based treatments and clinical guidelines?
- For app interventions adapted from evidence-based treatments (eg, CBT), will your app include all core treatment elements? How will this be achieved through your intervention and app design?
- What innovations will your app offer? Will these fit the existing models of care?
- What would make this project a success for you?

Safety and Duty of Care

Developers should also reflect on the safety of mental health apps and their role in designing, developing, and maintaining safe mobile mental health:

- What do you consider to be your roles, responsibilities, and duty of care as the developer of a mental health app? How is this reflected in your app design, development, and marketing?
- What values are important to you in the design, development, and deployment of this technology?
- Has your app been designed, developed, and marketed with safety in mind?

We encourage developers to use these reflections not only throughout design and development but also in the deployment, maintenance, and marketing of their apps.

Limitations

This study explores treatment descriptions and alignment with the clinical guidance of apps in the UK app marketplace for depression. It builds on previous content analyses to provide a comprehensive overview of treatment content and clinical validity as evident in app store descriptions; however, it is not without limitations. First, we chose to conduct manual search and data extraction of app listings rather than to use a script to pull data from the app stores. Both methods have been used in previous marketplace reviews and offer their own benefits and limitations. Our decision to perform manual search reflects our focus on the marketing of apps to the public, with this method allowing for a first-person experience of searching, identifying, and evaluating all returned apps. This meant that search results—and therefore the final list of apps reviewed—may differ slightly from those returned through a script. However, we believe our findings benefited from the firsthand navigation of the app marketplace and the challenges potential users may encounter in their search for suitable apps.

Similarly, although a strength of the review was the inclusion of all apps for depression, this limited our focus on app store descriptions rather than downloaded apps. Our review captured issues in the marketing and treatment descriptions of apps but acknowledges that there may be discrepancies between app store listings and in-app content. Therefore, there is scope for further research to explore these issues through the use and in-depth evaluation of apps. The iterative nature of the review also allowed for rich data collection but limited rigorous research methods such as blinded coding and interrater reliability. Therefore, future reviews would benefit from the use of these methods to strengthen the current findings.

Although the analysis was largely descriptive, correlation calculations were performed to explore relationships within- and between treatment approaches and strategies. The large number of calculations may have resulted in increased type II errors. To mitigate this, findings are reported as significant at $P<.01$. We opted to not perform a correction calculation (eg, the Bonferroni correction or false discovery rate), as we believe it more beneficial for the development of future research to limit the risk of type I errors, which would exclude potentially interesting findings from the discussion. Results should be interpreted with this in mind. Finally, this study was framed and conducted within the United Kingdom. It is expected that findings will be relevant to other health care markets; however, country-specific practices may exist. The application of findings should be done with this in mind.

Conclusions

This study advanced previous content analyses by providing a comprehensive overview of treatment descriptions of publicly available apps for depression. This is the first content analysis of apps for depression to explore the full range of reported treatment approaches and strategies and their fit with clinical guidelines. App developers have adopted many evidence-based treatments in their interventions; however, much work remains in improving the validity, fidelity, clinical relevance, and safety of apps offered directly to consumers. We encourage developers to consult guidelines and standards and engage in reflective questioning regarding treatment and safety. Developers are urged to transfer this information to potential users through transparent and sufficiently detailed app listings to allow users to make informed decisions before app download and use.

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Authors' Contributions

DB is the guarantor of this study. This study forms part of DB's PhD research. DB was responsible for the study design, data extraction, coding and analysis, and drafting of the manuscript. SS, CS, and HI provided ongoing consultation and supervision. All authors have reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of all 353 apps for depression included in the review.
[XLSX File (Microsoft Excel File), 53 KB - formative_v4i11e14988_app1.xlsx]

Multimedia Appendix 2
Full code list used in content analysis of apps for depression.
[DOCX File , 20 KB - formative_v4i11e14988_app2.docx]

Multimedia Appendix 3
Spearman rank correlation coefficients for treatment approaches.
[DOCX File , 51 KB - formative_v4i11e14988_app3.docx]

Multimedia Appendix 4
Spearman rank correlation coefficients for treatment strategies.
[DOCX File , 131 KB - formative_v4i11e14988_app4.docx]

Multimedia Appendix 5
Treatment content of cognitive behavioral therapy apps for depression.
[XLSX File (Microsoft Excel File), 23 KB - formative_v4i11e14988_app5.xlsx]

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Abbreviations

BT: behavioral therapy
CBT: cognitive behavioral therapy
DBT: dialectical behavioral therapy
IAPT: Improving Access to Psychological Therapies
IPT: interpersonal therapy
MBCT: mindfulness-based cognitive therapy
NHS: National Health Service
NICE: National Institute for Health and Care Excellence

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Original Paper

Artificial Intelligence Chatbot for Depression: Descriptive Study of Usage

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Abstract

Background: Chatbots could be a scalable solution that provides an interactive means of engaging users in behavioral health interventions driven by artificial intelligence. Although some chatbots have shown promising early efficacy results, there is limited information about how people use these chatbots. Understanding the usage patterns of chatbots for depression represents a crucial step toward improving chatbot design and providing information about the strengths and limitations of the chatbots.

Objective: This study aims to understand how users engage and are redirected through a chatbot for depression (Tess) to provide design recommendations.

Methods: Interactions of 354 users with the Tess depression modules were analyzed to understand chatbot usage across and within modules. Descriptive statistics were used to analyze participant flow through each depression module, including characters per message, completion rate, and time spent per module. Slide plots were also used to analyze the flow across and within modules.

Results: Users sent a total of 6220 messages, with a total of 86,298 characters, and, on average, they engaged with Tess depression modules for 46 days. There was large heterogeneity in user engagement across different modules, which appeared to be affected by the length, complexity, content, and style of questions within the modules and the routing between modules.

Conclusions: Overall, participants engaged with Tess; however, there was a heterogeneous usage pattern because of varying module designs. Major implications for future chatbot design and evaluation are discussed in the paper.

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KEYWORDS

chatbot; artificial intelligence; depression; mobile health; telehealth

Introduction

Background

According to the World Health Organization [1], there is a global shortage of health workers trained in mental health. Many mental health interventions do not reach those in need, with approximately 70% with no access to these services [2]. In the United States, 42.6% of adults with mental illness received mental health services in 2017 [3]. More specifically, in primary care settings, 75% of patients with depression have one or more structural or psychological barriers that interfere with access to behavioral treatments [4]. To address these challenges, Kazdin and Rabbitt [2] called for new models of delivering psychosocial interventions. Mohr et al [4] suggested that behavioral intervention technologies (BITs) offer a potential solution to overcome barriers that prevent access and expand mental health care.

BITs are the application of behavioral and psychological intervention strategies through the use of technology features that address behavioral, cognitive, and affective components that support physical, behavioral, and mental health [4]. BITs,

such as internet interventions for anxiety and depression, have empirical support with outcomes similar to therapist-delivered cognitive behavioral therapy (CBT) [5]. Several BITs involve the same content as face-to-face CBT programs that allows it to reach larger numbers of people at lower costs [6].

Chatbots represent a particular type of BIT to address mental health conditions. Chatbots are computer programs that engage in text-based or voice-activated conversations [7] and that respond to users based on preprogrammed responses or artificial intelligence (AI) [8]. Ho et al [9] found that interactions with chatbots were as effective as human interactions in offering emotional, relational, and psychological benefits and that they focused on the impact of personal disclosure.

A total of 2 reviews have covered studies on mental health chatbots in mental health [10,11]. Abd-alrazaq et al [10] reported that the inconsistency of outcome measures made it difficult to compare the efficacy of chatbots. Vaidyam et al [11] reported that there is little understanding of the therapeutic effect of chatbots and a lack of consensus in the standards of reporting and evaluation. Some of the chatbots targeting mental health that have been reported in the literature are Woebot [12], Shim [13], KokoBot [14], Wysa [15], Vivibot [16], Pocket Skills [17], and Tess [18].

Woebot is an automated conversational agent designed to deliver CBT in a brief way, and it also performs mood tracking [12]. Shim focuses on positive psychology and the components of CBT [13]. KokoBot teaches cognitive reappraisal skills and facilitates peer-to-peer interactions through a postresponse platform where users post about a situation and other users respond back [14]. Wysa is an AI-based emotionally intelligent mobile chatbot aimed at enforcing mental resilience and promoting mental well-being using a text-based conversational interface [15]. Woebot, Wysa, and Shim did not provide information on how much time users spent engaging with these chatbots [12,13,15]. Vivibot [16] is a chatbot that delivers positive psychology for young individuals after cancer treatment. Finally, Pocket Skills [17] is a conversational mobile web app that supports clients with dialectical behavioral therapy.

Tess (X2AI Inc) is an automated mental health chatbot powered by AI. It engages its users with text-based conversations that deliver coping strategies based on the emotional needs of the users [18]. Research suggests that using Tess has been helpful in a variety of contexts. In a pilot study, Ackerman et al [19] found that conversations with Tess were useful in providing emotional support to a small sample (n=26) of employees in a health care system, and most participants found it helpful as Tess provided relevant support and coping tips. Fulmer et al [18] reported that using Tess helped reduce depressive and anxiety symptoms among college students (n=74) at higher rates than those in a control condition after 2 and 4 weeks of engagement with Tess. Furthermore, in a feasibility study by Stephens et al [20] with a small sample (n=23) of adolescents coping with weight management and prediabetes symptoms, the authors found conversations with Tess useful in supporting them toward their goals and high usefulness ratings.

Although findings from these studies suggest that using Tess has been effective in providing support to adults and adolescents in reducing the severity of mental health conditions, these studies do not provide information on how this chatbot works. Some chatbots include different modules (ie, preset dialogs about specific topics), and each module has different items (ie, questions or messages sent to the user). Users may follow a different path within the modules and between modules. Research that explores the potential flow of modules allows researchers to compare the treatments that are actually being delivered to users. Moreover, this flow can be helpful to determine for how long users utilize these treatments and how the AI decides to funnel users. This could prove to be insightful in both understanding what treatments are being delivered and how this flow might be further optimized. In addition, exploring item-level interactions allows researchers to gain a fine-grained understanding of how users navigate through the modules and identify when they discontinue the use of the platform. Although emerging evidence shows that chatbots may reduce symptoms and result in favorable outcomes, it is still unclear how chatbots work at the item level (within module) and module level (between modules), which represents a major limitation of chatbot research. Furthermore, there is a lack of models informing the design or implementation of BITs in general [21] and chatbots in particular. There is a need to examine how chatbots are designed and utilized at the item level and module level. Understanding the unique courses of users through Tess is a key first step in understanding how chatbots work.

Objectives

This study attempts to understand how the chatbot Tess works, to provide a framework for future research. The first aim is to describe the overall utilization of Tess, including the total number of interactions with the depression modules, user messages, characters typed, and average time of engagement with the modules. The second aim is to understand the participant flow between the modules. The third aim is to describe the utilization of each module through the number of user messages, characters typed, average time of utilization, and completion rates. The fourth aim is to understand participant flow within modules by evaluating the number of items, duration of usage, characters used, number of messages sent, and patterns of utilization. In addition, recommendations for developers will be offered so that chatbots can be studied empirically.

Methods

Participants

A total of 4967 users engaged with Tess between July 27, 2017, and September 15, 2018. Of the 4967 users, 354 interacted with at least one of the 12 modules on depression, which is the sample used in this study. Users were engaged in natural conversations with Tess through Facebook Messenger, and no demographic variables were systematically collected; therefore, the demographic makeup of the sample used in this study is unknown.

Tess

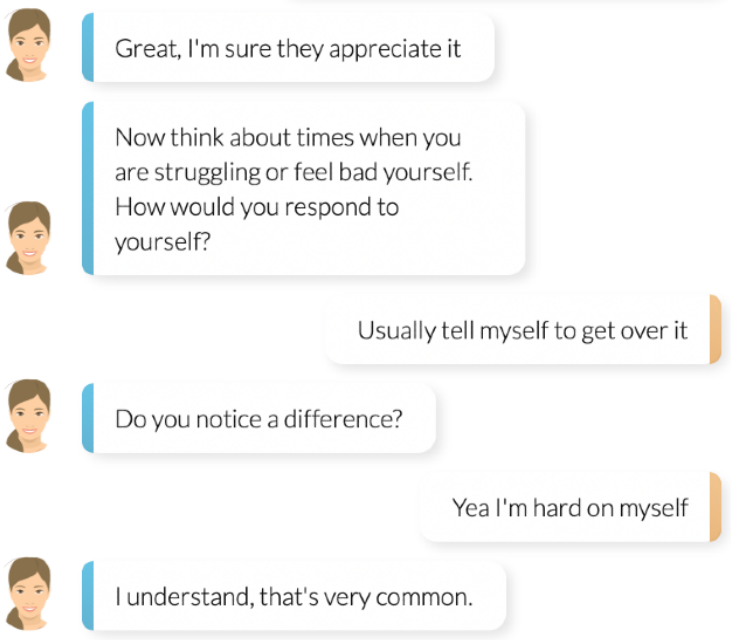
Tess is a mental health chatbot designed by X2AI that is trained to react to the user's emotional needs by analyzing the content of conversations and learning about the user that she is chatting

with. Users can chat with Tess in multiple ways, such as through text message conversations or Facebook Messenger. Although Tess is designed to act like a therapist, she is not a substitute for traditional therapy. Tess's algorithm is organized into distinct modules that focus on different types of treatment modalities and differ in content and length (Table 1). See Figure 1 for a sample transcript of a user interacting with Tess.

Table 1. Descriptions of the depression modules of Tess.

Module name	Treatment modality	Description	Chatbot messages per module, n
Cognitive distortion	Cognitive behavioral therapy	Provides information to identify and challenge irrational or maladaptive thought patterns	56
Self-soothing	Stress management	Education and instruction to use the 5 senses to self-soothe for stress management	33
Body scan	Stress management	Education and encouragement of body scan meditation exercises for stress reduction	33
Depression diet	Psychoeducation	Provides nutrition information such as eating tips and suggestions for increased mental well-being	27
Coping statements	Mindfulness	Guided usage of coping statements to build resilience through actively practicing nonjudgmental evaluations	25
Values	Acceptance and commitment therapy	Education and awareness of personal values to reappraise negative thoughts	21
Self-compassion	Self-compassion therapy	Encourages the use of self-compassion through guided meditation exercises and practice reminders	21
Transtheoretical	Transtheoretical model	Encourages behavior evaluation and intentional behavior change exercises	18
Self-talk	Self-compassion therapy	Encourages the use of self-compassion through positive reinforcements and self-talk	17
Thought journaling	Cognitive behavioral therapy	Education and guided instructions for utilizing thought journaling to track mood over time	17
Radical acceptance	Dialectical behavioral therapy	Education and practice using radical acceptance to build resilience against challenging situations	15
Solution focus	Solution-focused brief therapy	Encourages seeking and expanding social support for increased mental and physical health	13

Figure 1. A sample transcript of a participant interacting with Tess.



Technical Terms

From Tess

Messages initiated by the AI are referred to as *from Tess* in this paper. These messages are standardized, which means that they contain predetermined information and are meant to guide a user through a given intervention.

To Tess

Messages written by the user are referred to as *to Tess* in this paper. Data were collected on these messages, including the time when they were sent, the number of characters they contained, and the overall number of messages each user sent within a certain module and overall.

Routing

The flow of each module and the transition between modules is determined by the *routing* designed for Tess. Each module is made up of a set of 13 to 56 standardized messages from the AI. If within a module the user references another issue that Tess determines to be more urgent, the user will be routed to a different module.

Within-Module Interactions

Each module is made up of a variable number of interactions that are predesigned to fit the goals of the given module. These messages are sent by Tess to the user. The number of messages from Tess to the user for each module is shown in Table 1.

Between-Module Interactions

Between module is the term used to describe the transition from one module to another. Each module was considered to be an additional step that the user initiated. It is important to note that this study only analyzed data on the 12 depression modules, and it is likely that users also completed or attempted another module outside of depression.

Discontinued (Depression Modules)

The term *discontinued* is used in this paper to indicate when the users stopped using one of the modules for depression. It is important to note that discontinuation may be because of several reasons. Discontinuing a module may mean that the user moved to a different depression module because they or Tess found it to be more relevant at a certain time, the user moved to a nondepression module on which data were not collected in this study, or the user stopped using Tess completely. It is important to note that if a user stopped using one of the modules, they did not necessarily stop using Tess overall. With these data, the explanation for user discontinuation is not known.

Procedures

The Institutional Review Board determined that this study is not human subject research. All the users in this study used Tess through Facebook Messenger. Users interacted with Tess for free and were not compensated. Users could find Tess through social media advertisements. Once users got to Tess, they provided written consent to participate in the study.

When users report depression, Tess selects 1 of the 12 modules for treating depression based on the conversations that she has had with other users, previous (if any) conversations with the user, and other information that is input into an algorithm.

Analyses

Descriptive statistics were used to analyze the overall chatbot usage and module usage. Data collected included total messages sent by the user to Tess, total messages sent by Tess to the user, total characters typed by the user, and duration of usage. The overall chatbot usage of the depression modules was analyzed using slide plots [22] that were created from the messages sent to and from Tess. These slide plots show the sequence between the depression modules, such as where the users started, where the users were directed to, and where the users discontinued. The slide plots show the aggregated trajectories of individuals. The thickness of a segment is proportional to the frequency of transition from one state to another.

Descriptive statistics were used to analyze how participants utilized each depression module. Means, SDs, and ranks for characters per message to Tess; completion composites; and time spent on each module are reported. Characters per message were used over characters or messages separately to account for the variance in module length. Completion composite scores were calculated for each module. The composite was calculated by multiplying the proportion of users who completed each module by the number of module interactions. The completion composite was used in favor of simply using the proportion completed to account for differences in length between modules. For the time spent per module, when there was a period of inactivity of more than 2 SDs above the mean, those periods were excluded from the calculation. This was done because conversations with a chatbot tend to be asynchronous; therefore, long breaks between user messages are expected. Slide plots were also used to analyze the flow of each depression module individually.

Results

Overall Utilization of Tess

Descriptive statistics were used to analyze the data from the messages sent by the participants to Tess. The 354 participants included in this study had at least one interaction with one of the modules (mean 2.18, SD 1.56; range 1-10 modules) and sent a total of 6220 user messages (mean 17.57, SD 19; range 1-73 messages) with a total of 86,298 characters (mean 243.78, SD 299.29; range 2-1644 characters). The average duration for which the participants engaged with the depression modules was 46 days (range 1-314 days) during the 14-month period of data collection, and the duration for which they engaged in conversations with the depression modules was 24 min and 49 seconds.

Users Flow Between Modules

To understand the participant flow through the depression modules of Tess, the sequence of interactions with the modules was analyzed using 2 criteria. The first criterion utilized was the messages from Tess (Figure 2), and the second criterion utilized was the messages to Tess (Figure 3). When using messages from Tess, most users started with the depression diet module (112/354, 31.6% users), and then they were directed to

the body scan module (22/112, 19.6% users) and the transtheoretical module (18/112, 16.1% users). When using messages to Tess, most users started with the depression diet module (103 users) and then discontinued. Both Figures 2 and 3 are only representative of the sequence between depression modules. This does not account for nondepression modules completed.

Figure 2. Modules initiated by Tess. The figure presents the first 5 module steps that participants interacted with that were initiated by Tess. The timeline reflects the module number to which the participant was exposed (ie, timeline 1 is the module that people started with, and timeline 2 is the second module that participants began). The line thickness describes the transitions from one module to the next and not the number of users in a given module. Body-scan: body scan; Cog-dis: cognitive distortion; Compassion: self-compassion; Cope-state: coping statements; Dep-diet: depression diet; Rad-accept: radical acceptance; Self-soothe: self-soothing; Sol-foc: solution focus; Tht-jrnl: thought journaling; Trans-T: transtheoretical.

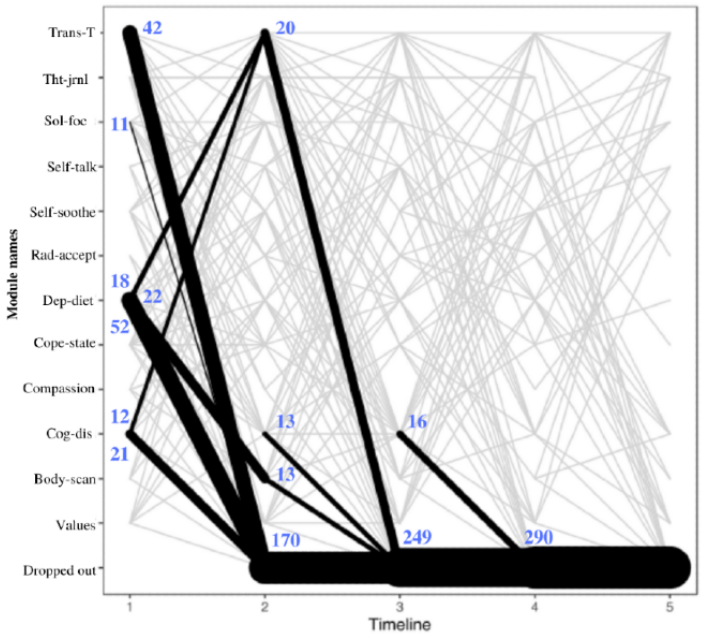
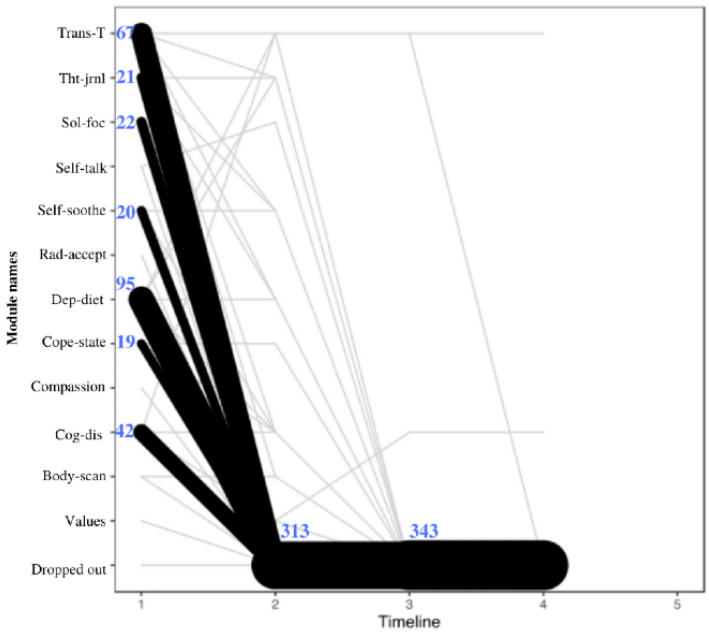


Figure 3. Modules initiated by user. The figure presents the first 5 module steps that participants interacted with that were initiated by the participant. The timeline reflects the module number to which the participant was exposed (ie, timeline 1 is the module that people started with, and timeline 2 is the second module that participants began). The line thickness describes the transitions from one module to the next and not the number of users in a given module. Body-scan: body scan; Cog-dis: cognitive distortion; Compassion: self-compassion; Cope-state: coping statements; Dep-diet: depression diet; Rad-accept: radical acceptance; Self-soothe: self-soothing; Sol-foc: solution focus; Tht-jrnl: thought journaling; Trans-T: transtheoretical.



From the modules initiated by Tess (Figure 2), the first pattern observed was that in step 1 most users (112/354 users, 31.6%) were routed to the depression diet module, from which 46.4% (52/112) users discontinued, 19.6% (22/112) user were routed to body scan module, and 16.1% (18/112) users were routed to the transtheoretical module in step 2. Among those who started cognitive distortion module at step 1 (49/354, 13.8% users), 24% (12/49) users went to transtheoretical module and 42%

(21/49) users discontinued at step 2. Among those who started transtheoretical module at step 1 (79/354, 22.3% users), 53% (42/79 users) discontinued at step 2. Parallel lines in Figure 2 indicate that the user repeated the same module in sequence. From the modules initiated by users, 88.4% (313/354 users) discontinued by module step 2 (Figure 3).

Utilization of Each Module

The total number of characters typed per message across the 12 modules was 11,948.66, with an average of 995.72. Across the 12 modules, the average completion rate was 40%, and the total time spent was 146 hours, 23 min, and 36 seconds, with an average of 12 hours, 11 min, and 58 seconds per module.

The module with most characters typed per message was the self-compassion module (n=10; mean 39.18; SD 15.59), followed by the transtheoretical module (n=139; mean 24.27). Although the self-compassion module had the most characters typed per message, it had the lowest number of users who had at least one interaction with this module. The module with the least number of characters typed per message was the coping statements module (n=45; mean 8.46; Table 2).

Table 2. Characters per message (N=354).

Rank[a]	Module	Users with at least one interaction with the module, n (%)	Total characters per message, n	Characters per message, mean (SD)
1	Self-compassion	10 (2.8)	391.82	39.18 (15.59)
2	Transtheoretical	139 (39.3)	3373.8	24.27 (16.41)
3	Values	38 (10.7)	792.19	20.85 (14.83)
4	Thought journaling	70 (20.2)	1335.74	19.08 (11.49)
5	Self-talk	39 (11.0)	742.53	19.04 (16.87)
6	Depression diet	145 (41.0)	1924	13.27 (9.79)
7	Solution focus	49 (13.8)	607.14	12.39 (18.52)
8	Cognitive distortion	116 (32.8)	1248	10.76 (8.45)
9	Self-soothing	52 (14.7)	520	10 (12.86)
10	Radical acceptance	22 (6.2)	213.6	9.71 (11.98)
11	Body scan	46 (12.9)	419.21	9.11 (5.1)
12	Coping statements	45 (12.7)	380.63	8.46 (23.22)

[a]Rank is based on the average number of characters per message for each module, with higher characters per message associated with a higher rank.

The module with the highest completion composite was the cognitive distortion module (19.79), with 35.3% (41/116) of users that interacted with the module, completed it. The module with the lowest completion composite was the transtheoretical module (5.31), with 29.5% (41/139) of users that interacted with the module, completed it (Table 3).

Table 3. Completion composite of users that interacted with the modules.

Rank[a]	Module	Users who had at least one interaction with the module (N=354), n (%)	Users who completed the module		Proportion completed[b] (%)	Completion composite[c]
			n (%)	N		
1	Cognitive distortion	116 (32.7)	41 (35.3)	116	35.3	19.793
2	Body scan	46 (12.9)	24 (52.2)	46	52.2	17.217
3	Self-compassion	10 (2.8)	6 (60.0)	10	60.0	12.600
4	Radical acceptance	22 (6.2)	18 (81.8)	22	81.8	12.273
5	Self-soothing	52 (14.7)	17 (32.7)	52	32.7	10.788
6	Thought journaling	70 (19.7)	41 (58.6)	70	58.6	9.957
7	Self-talk	39 (11.01)	21 (53.8)	39	53.6	9.154
8	Coping statements	45 (12.7)	16 (35.5)	45	35.6	8.889
9	Depression diet	145 (40.9)	42 (28.9)	145	29.0	7.821
10	Solution focus	49 (13.8)	29 (59.2)	49	59.2	7.694
11	Values	39 (11.0)	13 (33.3)	39	33.3	7.000
12	Transtheoretical	139 (39.3)	41 (29.5)	139	29.5	5.309

[a]Rank is based on the completion composite, with higher completion composite scores associated with a higher rank.

[b]The proportion completed represents the ratio of users who completed each module to the users who had at least one interaction with the module.

[c]The completion composite was calculated by multiplying the proportion completed by the number of interactions in each module to account for the differences in module length.

The module with the most time spent was the values module, with users spending an average of 58 min and 29 seconds. The second module with the most time spent was the cognitive distortion module, with users spending an average of 26 min and 22 seconds. Users spent the least amount of time on the radical acceptance module, spending an average of 1 min and 52 seconds (Table 4).

Table 4. Time (N=354).

Rank	Module	Users who had at least one interaction with the module, n (%)	Total time[a]	Time, mean (SD)	Time, median
1	Values	23 (6.5)	22:25:08	0:58:29 (2:41:31)	0:06:11
2	Cognitive distortion	109 (30.8)	48:20:42	0:26:22 (0:57:57)	0:09:10
3	Body scan	46 (12.9)	10:44:18	0:14:00 (0:58:37)	0:02:54
4	Thought journaling	66 (18.6)	12:57:38	0:11:47 (0:20:59)	0:05:04
5	Self-soothing	48 (13.5)	9:05:25	0:11:22 (0:24:32)	0:04:16
6	Coping statements	42 (11.9)	7:42:31	0:11:01 (0:18:10)	0:04:37
7	Depression diet	132 (37.3)	16:24:04	0:07:27 (0:15:46)	0:03:06
8	Transtheoretical	121 (34.2)	13:55:02	0:06:54 (0:09:18)	0:04:15
9	Self-compassion	8 (2.3)	0:31:51	0:03:51 (0:04:35)	0:02:35
10	Solution focus	48 (13.6)	2:12:31	0:02:46 (0:06:50)	0:01:20
11	Self-talk	31 (8.8)	1:23:30	0:02:42 (0:02:30)	0:01:39
12	Radical acceptance	22 (6.2)	0:40:56	0:01:52 (0:01:14)	0:01:34

[a]Total time was calculated as the duration, in hours, between the first message sent by the user and the last message sent by the user in each module. When there was a period of inactivity of more than 2 SDs above the mean, those time periods were excluded from the calculation. Time is presented in the format hh:mm:ss.

The modules with larger sample sizes were the depression diet (n=145), transtheoretical (n=139), and cognitive distortion modules (n=116; Table 2). The depression diet module was ranked sixth for the number of characters typed per message, ranked ninth for completion, and ranked seventh for time. The transtheoretical module was ranked second for the number of characters typed per message, ranked 12th for completion, and ranked eighth for time. The cognitive distortion module was ranked eight for the number of characters typed per message, ranked first for completion, and ranked second for time.

User Flow Within Modules

Each of the 12 modules was unique in terms of the number of questions it had, duration of usage by the user, characters used, messages sent, and completion rate. The content of each module also differed in terms of the type of questions and messages used by Tess as well as the utilization of links that direct users to leave the platform.

Overall, 2 of the 12 modules were selected to highlight the possible differences that can be seen when evaluating modules that were created in different ways. The body scan and cognitive distortion modules differed most noticeably in terms of duration. The body scan module had 33 messages from Tess (Figure 4), whereas the cognitive distortion module had 56 messages (Figure 5). In addition, the body scan module included links that directed users to leave the platform at several points.

Figure 4. User flow through the body scan module. The timeline reflects the module number to which the participant was exposed. Frequencies are based on messages sent by the participant in association with each module question sent by Tess. The line thickness describes the transitions from one module to the next and not the number of users in a given module.

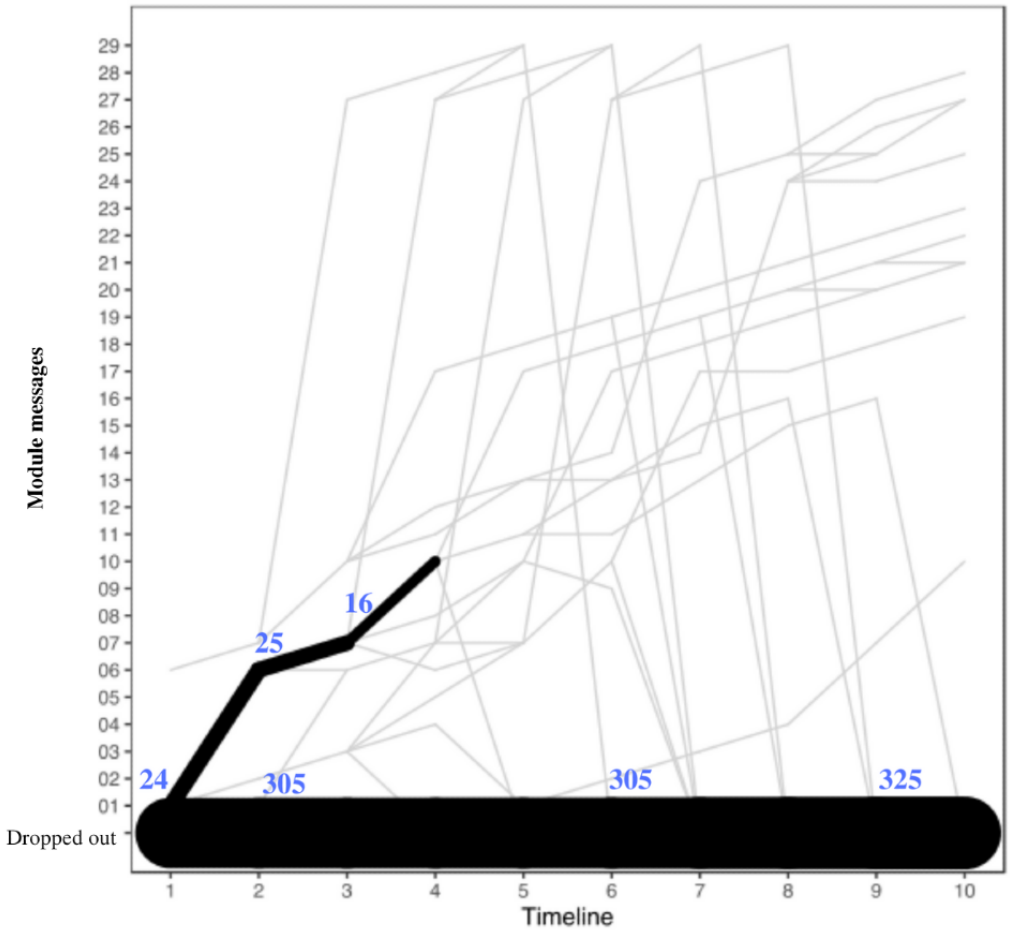
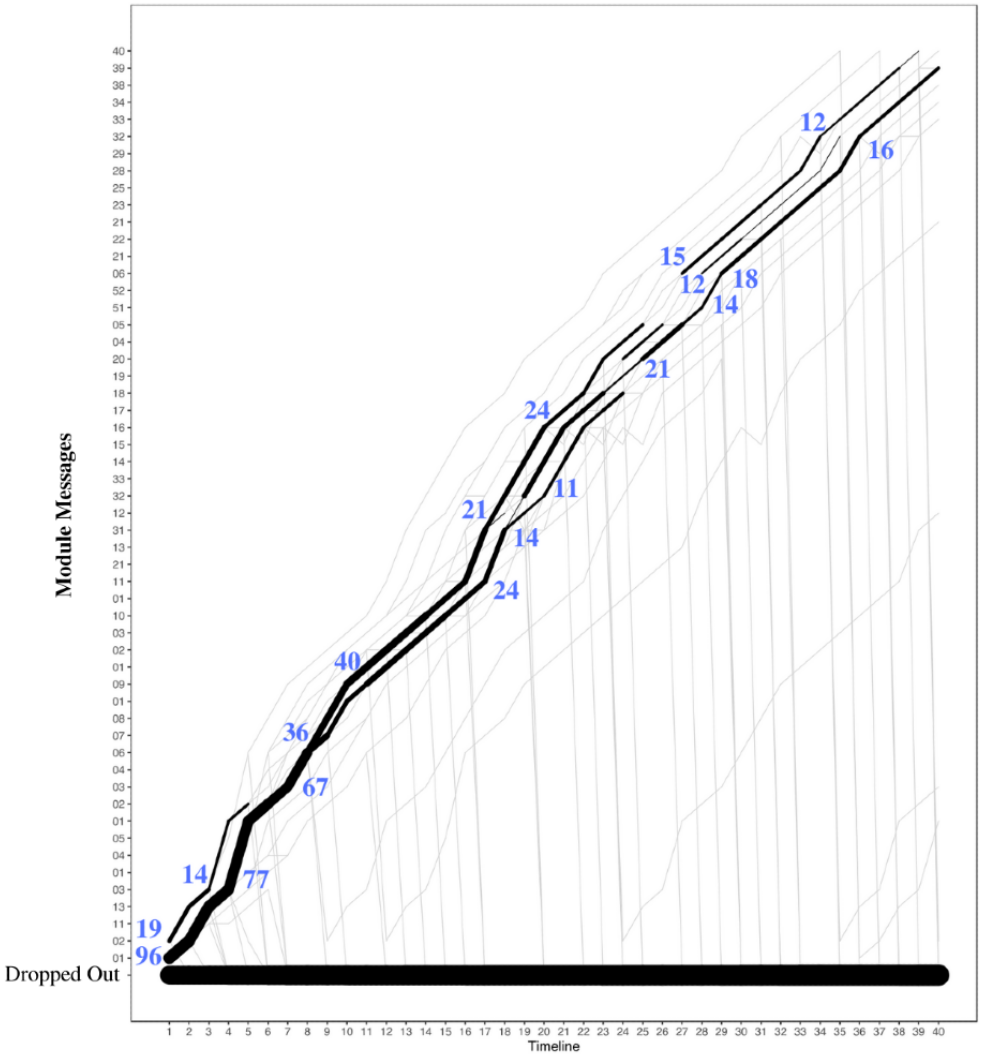


Figure 5. User flow through the cognitive distortion module. The timeline reflects the module number to which the participant was exposed. Frequencies are based on messages sent by the participant in association with each module question sent by Tess. The line thickness describes the transitions from one module to the next and not the number of users in a given module.



The body scan module shows a heterogeneous pattern of usage that shows that most users were branched to different items and that there were few consistent transition points, whereas the cognitive distortion module did not have much branching, as most users were routed through the module in a consistent and linear way.

Discussion

Principal Findings

Although previous studies on chatbots show promising results, little is known about how chatbots work. Understanding how chatbots work, especially chatbots that utilize modules as Tess, is essential for researchers to compare the treatments that are actually being delivered and provide guidance on how chatbots could be designed. Studying how users engage with the modules and the aspects of modules that are associated with completion or engagement can help future chatbot developers. This study is a first attempt to understand how a specific chatbot (Tess) works, including the organization by modules, module length, and other characteristics, and to provide a framework for future chatbot research.

The first aim of this study is to understand the overall utilization of the depression modules from Tess. This was done by analyzing the number of user messages, characters per message, the average time of utilization, and participant flow through Tess. The 354 users included in this study sent a total of 6220 messages and typed a total of 86,298 characters across an average of 46 days, which illustrates that the users engaged with Tess. However, when the time spent was analyzed, the participants engaged with Tess for an average of 25 min. A cautious interpretation of this number may suggest that 25 min is not sufficient to provide strategies that can help users cope with depression. A more enthusiastic interpretation suggests that as chatbots are highly accessible and scalable, 25 min of an asynchronous conversation delivered right when users need it can help boost their mood, and if this is delivered to large populations, this could be a major contribution to the mental health resources.

With regard to the second aim, when analyzing the participant flow between the depression modules, the sequence of interactions with the modules was heterogeneous, and users were more likely to engage with modules when they were initiated by Tess rather than by the user (Figures 2 and 3). In

addition, most users discontinued the depression modules after completing 1 to 2 modules. Although there might be several reasons for why the participants discontinued the module (eg, not being depressed any more or not being interested in the module; refer to the *Limitations* section), chatbots researchers should keep in mind that the attrition problems of most digital interventions are still present with chatbots [23]. Thus, when developing a chatbot, it may be better to focus first on developing a few good modules, rather than many modules that may not be used or comparable.

The third aim of this study is to compare the utilization patterns across the depression modules based on the messages sent, characters typed, completion rate, and average time of utilization. The results showed that the overall utilization was heterogeneous across modules. More specifically, the differences between characters typed per message and the average time of utilization across modules may be because of the differences in how the modules were designed. Most probably, user engagement changes depending on what type of messages the AI sends to the user. For example, a module that uses more open-ended questions may trigger more characters to be typed than a module that uses close-ended questions that elicit yes or no answers from the users.

The overall completion rate of 40% may be considered as a good engagement level for digital interventions [24-27], especially considering that AI may redirect users to more relevant modules as they chat. For users to whom the module was not relevant, being directed away from the module actually indicates the effectiveness of the AI. This should be considered when evaluating the completion rate as a measure of AI usability. In addition, the relation between completion rate and composite score (which accounts for the number of interactions) may yield useful information. For example, the radical acceptance module had the highest completion rate but was ranked third based on the completion composite because this module had 15 interactions, as it was one of the shorter modules. The cognitive distortion module was the longest module and had one of the lowest completion rates. When evaluating completion, one aspect to be considered is the balance between the complexity of the conversation and the user experience. It may be difficult to present complex concepts in a succinct manner. At the same time, if users do not finish the conversation, their experience may be less positive. Therefore, assessing completion rates using a holistic approach, rather than as an isolated variable, may be more appropriate. For example, completion could be assessed by integrating completion rates, composite scores, number of characters typed, time spent in conversation, and the duration required to communicate specific concepts (a problem-solving explanation may be shorter than an explanation of cognitive distortions).

With regard to the time of utilization, the engagement with each module was variable, ranging from 31 min to 48 hours. As interactions with chatbots are asynchronous, users may engage with each module over the course of a day, week, or longer, and determining what period of inactivity indicates that the user is no longer engaged in a module leads to arbitrary decisions. Therefore, judging the time spent with the module may be limited. Although the time spent in a conversation should be considered as a measure of the usability of a chatbot, it is unclear as to what would be the best way to measure it. One possibility is that a composite score based on the time spent, number of sessions initiated, number of sessions per day, and number of days (from the first session to the last session) could yield more meaningful information.

Overall, the wide heterogeneity in both the design and usage patterns suggested that there were no typical patterns of user engagement (as measured by the characters typed, messages sent, completion, and time) across modules. This is because each module was constructed differently (eg, differing in length, type of questions). To assess if a module achieves a good level of usability, the design of modules should be comparable.

The fourth aim of this paper is to describe participant flow within each module. In this case, 2 of the 12 modules were selected to highlight the possible differences that could be seen when evaluating modules that were created in different ways. The body scan module included links that directed users to resources outside Tess at several points. This amount of branching may be one of the explanations for why there were much fewer consistent transition points with the body scan module compared with the cognitive distortion module. The cognitive distortion module did not have much branching and had no links to external sources; consequently, most users were routed through the module in a consistent way.

Limitations

There were several limitations to this study. First, no demographic information was collected; therefore, the demographic makeup of the sample analyzed was unknown. The usage patterns were heterogeneous, but the source of the heterogeneity is unknown (ie, because of differences among modules or differences among sample characteristics). Second, the data set did not contain information about whether a user discontinued the usage of Tess entirely or if they were redirected to a nondepression module. There are several reasons for a user to discontinue a module. They may not complete a module simply because they do not like it and decide to stop or not respond to Tess. They can also be redirected to another module partway through if the user mentions a more urgent topic. In addition, not all users who begin a module will necessarily benefit from it; therefore, if Tess realizes that a user's responses indicate that they do not need a module, the user may be directed to a different module without completing the current one. Moreover, system errors were found for module instances from 2 users. Third, given the asynchronous nature of chatbots, it was not possible to know the precise time at which a user was actively engaged with the chatbot (no data were collected about when the user viewed the messages; only data for when they sent them were collected). Fourth, the notion of modules does not apply to all chatbots; therefore, these recommendations would not generalize to every chatbot.

Guidelines for Developing and Assessing a Chatbot

Developers of future mental health chatbots may benefit from some insights gathered from this study. Given the scant literature on how chatbots work and are utilized, it is important to highlight that developing an engaging chatbot may be the first

step to assess its efficacy. For such purposes, a table containing 6 preliminary recommendations on how to develop engaging chatbots is presented in Table 5. Due to the limitations of this study, this is not an exhaustive list but can provide guidance to those attempting to develop chatbots for mental health. Together with the recommendations, the rationale is also presented in Table 5. The list includes 5 recommendations specifically for the development of chatbots and 1 recommendation oriented to assessing the usability and engagement of the chatbot.

Table 5. Guidelines for developing engaging chatbots.

Tip	Definition	Rationale
Focus on the first module	Emphasis should be placed on the development of the first module to increase the chance of participants continuing to engage with the chatbot.	Most participants use only 1 module (or 2). It is important to provide the best intervention possible from the beginning.
Start small	Developers should focus on creating a few engaging and effective modules at the beginning rather than developing a large variety of untested modules.	On the basis of participant's flow through Tess, most individuals tend to discontinue after the second module.
Develop comparable modules	To compare module utilization, modules should be built with similar characteristics (eg, length, number and type of questions, and the inclusion of links).	Utilization of modules that differ in characteristics may not allow for meaningful comparisons.
Balance length and complexity	Modules with fewer interactions may have better completion, but more complex topics may need longer modules. Developers should strive to find a module length that enhances intervention fidelity without compromising engagement.	Modules that had more interactions from the artificial intelligence had lower completion rates.
Be aware of personalization and standardization	Standardization provides streamlined data and requires less work, whereas personalization has more complexity and consequently requires more effort both in development and analysis. However, personalization may provide richer interactions.	Without understanding the efficacy of the overall modules, it is difficult to assess whether branching promoted engagement.
Holistic assessment	There is no single variable that can provide an accurate measure of utilization, rather a combination of such variables can provide a broad idea of general utilization and specific information regarding specific aspects of the intervention.	Number of messages, characters used, time spent, and completion should be considered alongside helpfulness and satisfaction in the assessment of chatbots.

As an overall recommendation at the initial stages of development, developers should focus on small steps, test them with small iterative studies until a satisfactory level of engagement is achieved, and then move toward expanding the content (or modules) of the chatbot. As with most digital interventions, the attrition rates are significantly high; therefore, developing an extensive set of modules that users do not end up engaging with is not a good use of the resources. In addition, focusing on the initial modules and developing modules that are consistent may help developers and researchers to understand and compare how users respond to the modules.

Future Directions

The goal of research on chatbots should help researchers answer the question on the usage of specific chatbots (or modules), the people to whom they would be helpful, the circumstances under which they can be used, and how they can be used, as in psychotherapy research [28]. So far, the research conducted on chatbots does not allow for strong conclusions about the usability and efficacy of mental health chatbots or their outcomes. There are several variables that should be considered in future research on chatbots.

Usability and efficacy should be evaluated together because the process of how individuals use the chatbot (similar to process research in psychotherapy) is as important as their outcomes (similar to efficacy studies on psychotherapy), and both combined will allow for a faster pace of improvement. With regard to the process of how chatbots work, a Markov chain analysis can be utilized to predict the probability of a user completing a certain module based on their previous responses. In addition, the efficacy of the modules should be evaluated subjectively (eg, using net promoter scores, "would you recommend this to a friend") and objectively (ie, comparison of scores on PHQ-9 (Patient Health Questionnaire-9) before and after engagement with the chatbot). Finally, research should also examine the factors that predict chatbot satisfaction and efficacy.

Conclusions

Research on chatbots is in the initial stages, and although findings show that chatbots can be effective, more information is needed on how they work. This study showed that although many individuals used the chatbot, there was large heterogeneity in user engagement across different modules, which appeared to be affected by the length, complexity, content, and style of questions within the modules and routing between modules. At the initial stages of mental health chatbot research, developers should aim to reach acceptable levels of usability and then focus on efficacy. To increase usability and engagement, the focus should be on developing short, simple, and consistent modules and testing them with small iterative studies. Then, developers can move toward expanding the content (or modules) of the chatbot. As with most digital interventions, the attrition rates

are significantly high; therefore, developing an extensive set of modules that users do not end up engaging with is not a good use of resources. Research on frameworks for developing engaging and effective chatbots offers the opportunity to create and test scalable interventions. Data from large studies on chatbots could lead to effective personalized interventions that could eventually answer the question of which intervention works for which individual.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BITs: behavioral intervention technologies
CBT: cognitive behavioral therapy

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Original Paper

Use of the Consumer-Based Meditation App Calm for Sleep Disturbances: Cross-Sectional Survey Study

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Abstract

Background: Over 30% of Americans report regular sleep disturbance, and consumers are increasingly seeking strategies to improve sleep. Self-guided mindfulness mobile apps may help individuals improve their sleep. Despite the recent proliferation of sleep content within commercially available mindfulness apps, there is little research on how consumers are using these apps for sleep.

Objective: We conducted a cross-sectional survey among subscribers to Calm, a popular, consumer-based, mindfulness-based meditation app, and described and compared how good sleepers, poor sleepers, and those with self-reported insomnia use the app for sleep.

Methods: Participants who were paying subscribers of Calm and had used a sleep component of Calm in the last 90 days were invited to complete an investigator-developed survey that included questions about sleep disturbance and the use of Calm for sleep. Based on self-reports of sleep disturbances and of insomnia diagnosis, participants were categorized as “good sleepers,” “poor sleepers,” or “those with insomnia diagnosis.” Chi-square tests compared reasons for downloading the app and usage patterns across participants with and without sleep disturbance.

Results: There was a total of 9868 survey respondents. Approximately 10% of participants (1008/9868, 10.21%) were good sleepers, 78% were poor sleepers (7565/9868, 77.66%), and 11% reported a diagnosis of insomnia (1039/9868, 10.53%). The sample was mostly White (8185/9797, 83.55%), non-Hispanic (8929/9423, 94.76%), and female (8166/9578, 85.26%). The most common reasons for sleep disturbances were racing thoughts (7084/8604, 82.33%), followed by stress or anxiety (6307/8604, 73.30%). Poor sleepers and those with insomnia were more likely than good sleepers to have downloaded Calm to improve sleep (χ^2_2=1548.8, P<.001), reduce depression or anxiety (χ^2_2=15.5, P<.001), or improve overall health (χ^2_2=57.6, P<.001). Respondents with insomnia used Calm most often (mean 5.417 days/week, SD 1.936), followed by poor sleepers (mean 5.043 days/week, SD 2.027; F_2=21.544, P<.001). The most common time to use Calm was while lying down to sleep (7607/9686, 78.54%), and bedtime use was more common among poor sleepers and those with insomnia (χ^2_2=382.7, P<.001). Compared to good and poor sleepers, those with insomnia were more likely to use Calm after waking up at night (χ^2_2=410.3, P<.001). Most participants tried to use

Calm on a regular basis (5031/8597, 58.52%), but regular nighttime use was most common among those with insomnia (646/977, 66.1%), followed by poor sleepers (4040/6930, 58.30%; χ^2_2=109.3, *P*<.001).

Conclusions: Of the paying subscribers to Calm who have used one of the sleep components, approximately 90% have sleep difficulties, and 77% started using Calm primarily for sleep. These descriptive data point to areas of focus for continued refinement of app features and content, followed by prospective trials testing efficacy of consumer-based meditation mobile apps for improving sleep.

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KEYWORDS

insomnia; mental health; mindfulness; meditation; mobile apps; consumer behavior; mobile phone

Introduction

A large body of research suggests that mindfulness has positive effects on both mental and physical health [1-3]. In recent years, there has been a noticeable surge in the use of commercially available mindfulness-based smartphone apps [4,5], and there is growing evidence that individuals are using these apps specifically to help improve their health, mood, and sleep [6]. Because content is consistently available and accessible to users whenever it is needed, mindfulness apps provide users with just-in-time resources to navigate feelings of anxiety, stress, or frustration [7], thus reinforcing resilient responses to stressors [7]. Hence, mindfulness apps represent a convenient, cost-effective way to improve health and well-being [6,8].

Sleep disturbance is prevalent in over 30% of the general population, with rates increasing over the last decade and contributing to mental and physical health problems [9,10]. Consumers are increasingly seeking strategies to improve sleep. Almost 75% of US adults own smartphones, and apps for sleep have become highly popular [11]. However, most apps that are specifically designed for sleep are used to measure or observe sleep, rather than deliver an intervention to improve sleep [11]. Although recent randomized controlled trials (RCTs) provide preliminary evidence supporting the benefits of mindfulness meditation for improving sleep quality [3], reviews of sleep app content and delivery indicate that most apps focus on traditional cognitive behavioral interventions and/or provision of sleep education and none are based on mindfulness meditation strategies [11,12].

Given the growing evidence of the value of meditation for improving sleep, and the increase in popular knowledge about this benefit, it is likely that sleep concerns are becoming a driving force in consumers' selection of meditation apps. In a recent survey of 12,151 subscribers to one of the most widely disseminated meditation apps, Calm, over 75% reported having some form of sleep disturbance at the time of purchase, and improving sleep was one of the primary reasons for downloading the app [13]. Moreover, those who reported sleep difficulties were more likely to use Calm on a regular basis.

To address users' sleep-specific concerns, developers of commercial mindfulness apps have begun to diversify content and add components designed to target sleep [14]. For example, in addition to their library of mindfulness meditations, Calm has developed narrated sleep programs that use traditional literary and storytelling methods that listeners can use to help fall asleep (ie, Sleep Stories), meditations that are specifically created to improve sleep (eg, to help listeners fall asleep at night and to help develop a positive mindset surrounding sleep), and a curated collection of relaxing music and soundscapes that are softer, have a slower tempo, and are generally longer in duration (eg, 30-60 minutes) than some of the other music and soundscape tracks available in the app. Other meditation apps, such as Headspace and Insight Timer, have also begun to incorporate sleep-specific content. Despite the recent proliferation of sleep content within commercially available mindfulness apps, there is little research related to the characteristics of individuals who use these apps for sleep and/or how they are using apps for sleep [15]. For example, we do not currently know much about the demographics of users, how they use sleep content, or the specific reasons that they use these apps for sleep (eg, to fall asleep, to prevent early waking, to get restful sleep). A more nuanced understanding of consumers' sleep-related usage patterns is needed in order to personalize these strategies within mindfulness apps, which has the potential to augment adherence to these apps and enhance their efficacy in improving sleep disturbance.

To address this knowledge gap, we conducted a cross-sectional survey among subscribers to the Calm mobile app who had accessed at least one sleep-related feature in the past 90 days. First, we categorized participants as good sleepers, poor sleepers, or those diagnosed with insomnia, and described the types of specific sleep disturbance reported within each category (eg, falling asleep, staying asleep, not waking too early, and getting restful sleep). Next, we described and compared the self-reported app engagement of good sleepers, poor sleepers, and those with insomnia, including reasons for downloading the app, frequency of use, and how they use the app for sleep.

Methods

Ethics Approval

The Institutional Review Board at Arizona State University approved this study (STUDY00011083). All participants provided electronic consent before participating in the survey. The data sets generated or analyzed during the study are available from the corresponding author upon request.

Study Design and Recruitment

The study was cross-sectional. Participants were paying subscribers to the Calm meditation app. Participants were recruited via email in December 2019. Calm subscribers were

sent a recruitment email if they had (1) completed at least one session of Calm using a sleep-related component in the last 90 days, so as to enrich the sample with those who used sleep-related app content, and (2) opened at least one email from Calm within the last 90 days, to target more active users who would be more likely to see and open the email. Prior to consenting, potential participants were asked to verify their eligibility by confirming that they (1) were at least 18 years old and (2) were able to read and understand questions written in English. Eligible subscribers were then directed to an electronic consent form stating that by choosing to continue to the survey questions on the next page, they were agreeing to participate. They were informed that at the conclusion of the survey, they would have the option to provide their email address to be included in a drawing for one of two US $99 Amazon gift cards.

Survey

Participants completed a demographic questionnaire followed by an investigator-developed quantitative survey that included seven questions about using Calm for sleep, which are presented in Textbox 1 (see Multimedia Appendix 1 for the complete sleep survey). Specifically, there were three questions about whether or not sleep difficulties were experienced and, if so, the types of sleep disturbance participants were experiencing when they initially downloaded Calm (ie, type of difficulties, reasons for sleep difficulties, and use of sleep aids), and four questions about their app engagement (ie, reason for downloading Calm, frequency and time of Calm use, and how Calm was used at night). The survey included branching logic so that questions were only presented if they were relevant to the participant based on their previous responses describing their sleep disturbance and app engagement (eg, those who reported that they did not have sleep disturbance were not asked about the reasons they had disturbed sleep).

Textbox 1. Survey questions used in the analyses.

When you downloaded Calm, had you been diagnosed with insomnia? Y/N

When you first started using Calm, did you have difficulty falling asleep or staying asleep? (Check all that apply.)

- Falling asleep
- Staying asleep
- Getting restful sleep
- Waking up too early
- None of the above (ie, no sleep difficulties)

What are some reasons why you think you have trouble sleeping? (Check all that apply.)

- Racing thoughts or not being able to turn your mind off
- Stress or anxiety
- Nightmares
- Noise in the environment
- Light in the environment
- Work or sleep schedules (eg, working late at night and taking late-afternoon naps)
- Fluctuating hormones
- Physical pain or discomfort
- Medications that interfere with sleep
- Caffeine
- Other(s)
- I don’t know

During the last 90 days: Aside from Calm, what other things have you used to help you sleep? (Check all that apply.)

- Professional medical treatment (eg, sleep specialist)
- Professional psychological treatment for sleep
- Prescription sleep medications
- Over-the-counter sleep medications (not melatonin)
- Melatonin
- Noise machine
- ASMR (autonomous sensory meridian response) videos and audio
- Relaxation exercises and routines (eg, progressive muscle relaxation)
- Yoga before bed
- Other relaxation apps
- Other activities

Why did you download Calm? (Check all that apply.)

- Improve overall health
- Reduce stress
- Reduce depression or anxiety
- Improve sleep
- Friend recommended the app
- Someone bought it for me
- Curious
- Other

Generally, when do you use Calm? (Check all that apply.)

- Within the 30 minutes after waking up in the morning
- In the morning, but not within 30 minutes of waking up
- In the afternoon
- In the evening
- At night, but not within 30 minutes of going to bed
- Within the 30 minutes before laying down to go to bed at night
- While laying down to go to bed at night (eg, to fall asleep)
- When I wake up during the night

Which best describes the way you use Calm at night? (Check one.)

- I try to use Calm at night on a regular basis
- I sometimes or occasionally use Calm at night
- I use Calm at night only when I need it (eg, because of sleep difficulties that night)

When you use Calm at night because you need it, what do you usually need it for? (Check all that apply.)

- Falling asleep
- Staying asleep
- Falling back to sleep after I wake up
- Getting restful sleep
- Waking too early

Defining Good Sleepers, Poor Sleepers, and Those With Insomnia Diagnosis

Respondents were categorized based on their self-reports regarding (1) the presence or absence of sleep disturbance at the time they downloaded Calm and (2) the presence or absence of an insomnia diagnosis at the time they downloaded Calm. *Good sleepers* reported their sleep disturbance to be "none (ie, no sleep difficulties)." *Poor sleepers* reported experiencing at least one type of sleep disturbance (ie, difficulty falling asleep, staying asleep, waking too early, or getting restful sleep) but *did not have* a diagnosis of insomnia. Those who endorsed at least one type of sleep disturbance and self-reported a diagnosis of insomnia were categorized as such (ie, *insomnia diagnosis*).

Statistical Analysis

Data were analyzed using SPSS Statistics for Mac, version 26.0 (IBM Corp). Chi-square tests were used to compare sleep characteristics and health diagnoses across participants with and without sleep difficulties. Chi-square tests were also used to compare sleep characteristics, reasons for downloading Calm, and app-usage patterns across participants with and without sleep difficulties. Significant chi-square tests were followed up with *z* tests of column proportions using Bonferroni-corrected *P* values to adjust for multiple comparisons.

Results

Overview

Of the 366,173 subscribers who received an invitation to participate, 130,849 opened the invitations (35.73%). There were 19,341 subscribers who clicked the link to the survey (14.78% of those who opened the email), 14,642 (11.19%) consented to participate, and 11,095 completed the full survey (completion rate 75.78%). This completion rate was likely negatively impacted by the high volume of responses immediately following the release of survey invitations, which initially overtaxed host servers such that survey loading times were substantially slowed (see Limitations section below).

Although all participants had completed at least one session with a Calm sleep component, participants were included in the analyses only if they reported that they used at least one Calm component for the specific purpose of helping their sleep (9868/11,095, 88.94% of survey completers). Approximately 10% of participants were classified as good sleepers (ie, no sleep disturbance; 1008/9868, 10.21%), 78% were poor sleepers (ie, at least one type of sleep disturbance but without an insomnia diagnosis; 7565/9868, 77.66%), and 11% reported a diagnosis of insomnia (ie, at least one type of sleep disturbance and an insomnia diagnosis; 1039/9868, 10.53%). The remaining participants (185/9868, 1.87% of survey completers) were excluded from the analyses because they either (1) reported an insomnia diagnosis but did not endorse any type of sleep disturbance (27/9868, 0.27% of survey completers) or (2) they did not respond to questions about sleep disturbance or health diagnoses (158/9868, 1.60% of survey completers).

Demographic Characteristics

On average, respondents were 47.2 years old (SD 14.1). The majority were White, non-Hispanic, and female (see Table 1). The median household income was US $80,000 (IQR US

$50,000-$130,000), and most participants had received a higher education degree and were employed.

Table 1. Demographic characteristics of the sample (N=9868).

Category	Values, n (%)
Race (n=9797)	
White, European American, or Caucasian	8185 (83.55)
Asian or Asian American	307 (3.13)
Black, African American, or Native African	238 (2.43)
Biracial or multiracial	270 (2.76)
Other	411 (4.20)
Ethnicity (n=9423)	
Non-Hispanic	8929 (94.76)
Hispanic	494 (5.24)
Gender (n=9578)	
Female	8166 (85.26)
Male	1380 (14.41)
Other	32 (0.33)
Education (n=9531)	
11th grade or less	40 (0.42)
High school or General Educational Development	454 (4.76)
Some college	967 (10.15)
2-year college or technical school degree	936 (9.82)
Bachelor's degree	3608 (37.86)
Graduate degree	3397 (35.64)
Other	129 (1.35)
Employment status (n=9500)	
Full-time employment	5933 (62.45)
Part-time employment	1170 (12.32)
Unemployed	338 (3.56)
Disability	234 (2.46)
Full-time student	279 (2.94)
Other	1546 (16.27)

Types of Sleep Disturbances

The most common type of sleep disturbance was difficulty falling asleep, which was endorsed by 73% of those reporting a sleep disturbance (5523/7565, 73.00%) (see Table 2).

Table 2. Types of sleep disturbance reported by poor sleepers and respondents with insomnia.

Type of sleep disturbance	Poor sleepers (n=7565), n (%)	Those with self-reported insomnia diagnosis (n=1039), n (%)
Falling asleep	5523 (73.01)	848 (81.62)
Staying asleep	4012 (53.03)	724 (69.68)
Getting restful sleep	3488 (46.11)	603 (58.04)
Waking up too early	1182 (15.62)	296 (28.49)

Among those who reported sleep disturbance, the most commonly reported reasons for having sleep disturbance were racing thoughts (6220/7565, 82.22%), followed by stress or anxiety (5508/7565, 72.81%) (see Table 3). Other reasons, such as pain, were relatively infrequent, occurring in less than 20% of poor sleepers or those with insomnia. Attribution of sleep problems to racing thoughts did not differ between poor sleepers and those with insomnia; however, compared to poor sleepers, respondents with insomnia were significantly more likely to report that sleep difficulties were caused by stress or anxiety, physical pain, fluctuating hormones, nightmares, or use of medications that interfere with sleep.

Table 3. Reasons for sleep disturbance reported by poor sleepers and respondents with insomnia.

Reason	Poor sleepers (n=7565), n (%)	Those with self-reported insomnia diagnosis (n=1039), n (%)	Chi-square (*df* 1)	*P* value[a]	ϕ
Racing thoughts	6220 (82.22)	864 (83.16)	0.6	.46	.008
Stress or anxiety	5508 (72.81)	799 (76.90)	7.8	.005	.030
Physical pain or discomfort	1437 (19.00)	354 (34.07)	126.0	<.001	.121
Fluctuating hormones	1446 (19.11)	243 (23.39)	10.6	.001	.035
Noise in the environment	1187 (15.69)	176 (16.94)	1.1	.30	.011
Work or sleep schedule	858 (11.34)	128 (12.32)	0.9	.35	.010
Nightmares	512 (6.77)	142 (13.67)	61.9	<.001	.085
Light in the environment	503 (6.65)	85 (8.18)	3.4	.07	.020
Caffeine	569 (7.52)	59 (5.68)	4.6	.03	.023
Medications that interfere with sleep	256 (3.38)	112 (10.78)	122.0	<.001	.119
Others	379 (5.01)	73 (7.03)	7.5	.006	.029
I don’t know	188 (2.49)	29 (2.79)	0.3	.56	.006

[a]Tests are adjusted for multiple comparisons within the table using the Bonferroni correction.

Across all participants, rates of reported use of sleep aids were highest among those with insomnia and lowest among good sleepers, with the exception of practicing yoga before bed, which did not significantly differ across sleeper types (see Table 4). Those with insomnia were the most likely to use almost all listed sleep aids, followed by poor sleepers, and then good sleepers; all pairwise differences were significant. However, good sleepers were more likely than poor sleepers and those with insomnia to report using other relaxation apps for sleep, although poor sleepers and those with insomnia did not differ with regard to the use of other apps for sleep.

Table 4. Use of sleep aids reported by good sleepers, poor sleepers, and respondents with insomnia.

Type	Good sleepers (n=1008), n (%)	Poor sleepers (n=7565), n (%)	Those with self-reported insomnia diagnosis (n=1039), n (%)	Chi-square (*df* 2)	*P* value[a]	ϕ
Melatonin	143 (14.19)	2243 (29.65)	429 (41.29)	183.7	<.001	.138
Over-the-counter sleep medications	54 (5.36)	1566 (20.70)	337 (32.44)	233.9	<.001	.156
Prescription sleep medications	47 (4.66)	1077 (14.24)	565 (54.38)	1145.9	<.001	.345
Relaxation exercises and routines	181 (17.96)	2017 (26.66)	377 (36.28)	87.9	<.001	.096
Noise machine	138 (13.69)	1317 (17.41)	239 (23.00)	31.7	<.001	.057
Yoga before bed	146 (14.48)	1149 (15.19)	158 (15.21)	0.4	.84	.006
Professional medical sleep treatment	16 (1.59)	344 (4.55)	209 (20.12)	435.5	<.001	.213
Professional psychological treatment	11 (1.09)	255 (3.37)	162 (15.59)	350.6	<.001	.191
ASMR[b] videos and audio	28 (2.78)	357 (4.72)	67 (6.45)	15.4	<.001	.040
Other activities	166 (16.47)	1154 (15.25)	124 (11.93)	9.7	.008	.032
Other relaxation apps	74 (7.34)	757 (10.01)	134 (12.90)	17.5	<.001	.043

[a]Tests are adjusted for multiple comparisons within the table using the Bonferroni correction.

[b]ASMR: autonomous sensory meridian response.

App Engagement by Type of Reported Sleep Disturbance

Reasons for Downloading Calm

The reasons for downloading Calm varied in relation to the presence of sleep disturbance. As expected, those with poor sleep and insomnia were more likely to cite improving sleep as their reason for downloading Calm. Poor sleepers and those with insomnia were also more likely to report additional reasons for downloading the app as compared to good sleepers, including to reduce depression and anxiety and to improve overall health (see Table 5).

Table 5. Reasons for downloading Calm reported by good sleepers, poor sleepers, and respondents with insomnia.

Reason	Good sleepers (n=1008), n (%)	Poor sleepers (n=7565), n (%)	Those with self-reported insomnia diagnosis (n=1039), n (%)	Chi-square (*df* 2)	*P* value[a]	ϕ
Improve sleep	286 (28.37)	6186 (81.77)	937 (90.18)	1548.8	<.001	.401
Reduce stress	602 (59.72)	4443 (58.73)	572 (55.05)	5.9	.054	.025
Reduce depression and anxiety	477 (47.32)	3398 (44.92)	532 (51.20)	15.5	<.001	.040
Improve overall health	392 (38.89)	2080 (27.50)	283 (27.24)	57.6	<.001	.077
Curious	232 (23.02)	1186 (15.68)	104 (10.01)	65.6	<.001	.083
Friend recommended	146 (14.48)	1070 (14.14)	134 (12.90)	1.4	.51	.012
Gift	25 (2.48)	96 (1.27)	15 (1.44)	9.4	.009	.031
Other	135 (13.39)	392 (5.18)	38 (3.66)	118.8	<.001	.111

[a]Tests are adjusted for multiple comparisons within the table using the Bonferroni correction.

Frequency of Using Calm

There were significant differences in how often good sleepers, poor sleepers, and those with insomnia used Calm (F_2=21.544, *P*<.001). Respondents with an insomnia diagnosis used Calm most often, on average 5.417 (SD 1.936) times per week, followed by poor sleepers, who used Calm 5.043 (SD 2.027) times per week, and then good sleepers, who used Calm 4.852 (SD 2.165) times per week. All pairwise comparisons were statistically significant (insomnia > poor sleepers, *P*<.001; insomnia > good sleepers, *P*<.001; poor sleepers > good sleepers, *P*=.02).

Using Calm for Sleep

When asked about the most frequent times to use Calm, in general (ie, not specific to using for sleep), all sleeper types reported that the most common time they used Calm was while lying down to go to bed (7607/9686, 78.54%). Poor sleepers and those with insomnia were significantly more likely to use Calm while lying down to go to bed than good sleepers (see Table 6). Poor sleepers were also significantly more likely than good sleepers to report using Calm after waking up at night, but using Calm to fall back asleep was most common among those with insomnia.

Participants significantly differed with regard to how they used Calm at night ($^2_2$=109.3, *P*<.001, ϕ=.107). Among those who used Calm at night (8597/9612, 89.44%), most reported that they tried to use Calm at night on a regular basis (5031/8597, 58.52%). Regular nighttime use was most common among those with insomnia, followed by poor sleepers (see Table 7).

Table 6. Time of day to use Calm reported by good sleepers, poor sleepers, and respondents with insomnia.

Time	Good sleepers (n=1008), n (%)	Poor sleepers (n=7565), n (%)	Those with self-reported insomnia diagnosis (n=1039), n (%)	Chi-square (*df* 2)	*P* value[a]	ϕ
Within the 30 minutes after waking up in the morning	257 (25.50)	1112 (14.70)	127 (12.22)	88.8	<.001	.096
In the morning, but not within 30 minutes of waking up	249 (24.70)	916 (12.11)	106 (10.20)	132.2	<.001	.117
In the afternoon	232 (23.02)	1097 (14.50)	156 (15.01)	49.5	<.001	.072
In the evening	229 (22.72)	1427 (18.86)	234 (22.52)	14.4	.001	.039
At night, but not within 30 minutes of going to bed	69 (6.85)	360 (4.76)	61 (5.87)	9.4	.009	.031
Within the 30 minutes before laying down to go to bed at night	226 (22.42)	1531 (20.24)	239 (23.00)	6.1	.047	.025
While laying down to go to bed at night (eg, to fall asleep)	559 (55.46)	6200 (81.96)	848 (81.62)	382.7	<.001	.200
When I wake up during the night and I can’t fall back asleep	185 (18.35)	3759 (49.69)	610 (58.71)	410.3	<.001	.207

[a]Tests are adjusted for multiple comparisons within the table using the Bonferroni correction.

Table 7. Routine, occasional, and as-needed nighttime use of Calm reported by good sleepers, poor sleepers, and respondents with insomnia.

Usage pattern	Good sleepers (n=690), n (%)	Poor sleepers (n=6930), n (%)	Those with self-reported insomnia diagnosis (n=977), n (%)
I try to use Calm at night on a regular basis	345 (50.0)	4040 (58.30)	646 (66.1)
I sometimes or occasionally use Calm at night	219 (31.7)	1247 (17.99)	130 (13.3)
I use Calm at night only when I need it	126 (18.3)	1643 (23.71)	201 (20.6)

Among those who used Calm at night only when they needed it, it was used most for falling asleep, followed by falling back to sleep after waking (see Table 8). Reasons for needing Calm also differed across participants. As shown, poor sleepers and those with insomnia were more likely than good sleepers to need Calm to fall asleep. Those with insomnia were the most likely to report needing Calm to fall back to sleep after waking, followed by poor sleepers. There were no differences with regard to needing Calm to stay asleep, get restful sleep, or not wake up too early.

Table 8. Reasons for as-needed nighttime use of Calm reported by good sleepers, poor sleepers, and respondents with insomnia.

Reason	Good sleepers (n=126), n (%)	Poor sleepers (n=1643), n (%)	Those with self-reported insomnia diagnosis (n=201), n (%)	Chi-square (*df* 2)	*P* value[a]	ϕ
Falling asleep	95 (75.4)	1270 (77.30)	153 (76.1)	0.4	.84	.013
Falling back to sleep after waking up	39 (31.0)	922 (56.12)	133 (66.2)	40.3	<.001	.143
Getting restful sleep	23 (18.3)	336 (20.45)	41 (20.4)	0.4	.84	.013
Staying asleep	5 (4.0)	343 (20.88)	53 (26.4)	25.6	<.001	.114
Waking up too early	4 (3.2)	144 (8.76)	19 (9.5)	5.0	.08	.050

[a]Tests are adjusted for multiple comparisons within the table using the Bonferroni correction.

Discussion

Principal Findings

We conducted a cross-sectional survey of subscribers to the Calm mobile app that had used a sleep-related component within the past 90 days. First, we categorized participants as good sleepers, poor sleepers, or having a diagnosis of insomnia, and described the specific types of sleep disturbance reported by individuals within each category (eg, falling asleep, staying asleep, not waking too early, and getting restful sleep). Next, we described and compared how good sleepers, poor sleepers, and those with insomnia engage with Calm, including reasons for downloading the app, frequency of app usage, and how the app was used specifically for sleep. This is the first study to report the use of mindfulness meditation apps for sleep among mobile app consumers.

Only 10% of the respondents indicated they had no difficulty with sleep. Given the high rates of sleep disturbance among US adults, it is not surprising that sleep disturbance is highly represented in our sample. We do, however, acknowledge that the rates of sleep disturbance and insomnia in our sample may be inflated, due to our specific recruitment of subscribers who had recently used sleep components of the Calm app. Despite this, it is of interest to describe this sample and examine their perceptions regarding the causes of their sleep disturbance, other sleep remedies they may be exploring, and how they use Calm for sleep.

Across the entire sample, the most common type of sleep disturbance reported was difficulty falling asleep, closely followed by difficulty staying asleep. Poor sleepers and those with insomnia indicated that the most common reasons for disturbed sleep were racing thoughts and stress or anxiety; however, reports of sleep disturbance due to stress or anxiety were more prevalent among those with insomnia than in poor sleepers without insomnia. These results are consistent with both the larger sleep-related literature [9,10,16] and insomnia-specific literature [17-19]. Further, findings are consistent with research on the comorbidity between sleep and anxiety disorders [9,10,16].

Those with insomnia were more likely than good or poor sleepers to use Calm to help them sleep, and they used Calm for sleep more often. Those with insomnia diagnoses were also more likely to use Calm in conjunction with other sleep aids. This is consistent with research showing that current treatment options for insomnia and sleep disturbance (eg, pharmacological and behavioral therapies) are not meeting the needs of individuals in this population [20]. Given this, mindfulness-based apps that can deliver sleep-specific tools, on demand, may be an innovative strategy to improve sleep difficulties and self-manage sleep, beyond other treatment options [21].

Although most of Calm's sleep content is designed for general relaxation and is intended to allow for flexible usage at any time of day, some components (eg, Sleep Stories) are specifically designed to be used right before bed, such that it is not surprising that most participants used Calm at night. However, rates of nighttime usage were significantly higher among poor sleepers and those with insomnia compared to rates among good sleepers (eg, 81% vs 51% used at bedtime). Although both poor sleepers and those with insomnia primarily used Calm when laying down for bed to fall asleep, those with insomnia were significantly more likely than poor sleepers to use Calm to fall *back* asleep after waking up at night. While falling asleep may be primarily a function of high presleep arousal, insomnia is often characterized by middle-of-the-night awakenings and challenges falling back asleep [22,23]. Problems with middle-of-the-night awakening may, to some extent, differentiate less severe sleep disturbance from more severe sleep disturbance that may warrant diagnosis and clinical attention [22,23], highlighting a specific need within this population. Our findings show that, in addition to using Calm to fall asleep at night, some Calm subscribers with insomnia may also be using the app as a means of returning to sleep after nighttime awakenings.

Additional research is needed to assess the app content that is most attractive to, and utilized by, Calm users with sleep disturbance, including those with insomnia diagnoses, and to test the effects of different types of sleep content on sleep improvements. Findings from this line of research will likely be relevant in determining the extent to which specific results may generalize to other mindfulness meditation apps. Additionally, of course, these same questions should be pursued in examining sleep-related and general meditation features of other mindfulness-based apps.

When asked to describe how they used Calm at night, most participants reported that they "try to use Calm at night on a regular basis" (ie, rather than using it on an occasional or as-needed basis). This finding is encouraging and suggests perceived benefit in using the app for regular sleep. Interestingly, good sleepers were almost twice as likely to report that they used Calm at night sometimes or occasionally, as opposed to most nights. Research on adherence to sleep interventions indicates that participants who perceive the intervention to be relevant or necessary are more consistently engaged in their prescribed treatment [24,25]. Future studies using app-based interventions for sleep should consider insomnia, or severity of baseline sleep disturbance, as a potential moderator of adherence and, by extension, treatment effects. Additionally, given that some poor sleepers and participants with insomnia (over 20%) reported that they use Calm for sleep only when experiencing acute or immediate sleep disturbance, more research on the effects of as-needed use of meditation apps is warranted.

Limitations

Although this was the first study to report usage characteristics among a large sample of subscribers to a mobile app with and without self-reported sleep disturbance, there are some limitations to note. First, participants were mostly White, female, and highly educated, limiting generalizability across populations. Also, because participants had to have opened at least one email from Calm in the last 90 days, the sample was likely made up of highly engaged users of Calm. This is reflected in that, of those who opened the invitation, less than 15% chose to participate (3% of those who were sent emails to participate). Additionally, the large influx of traffic shortly following the release of email invitations temporarily overloaded the host server, and survey loading times were substantially slowed, such that survey completers were likely more committed to sharing their feedback compared to those who did not complete the entire survey. Second, as the sample had to have used a sleep component on the app in the last 90 days, we cannot assume the findings are representative of Calm users who do not use the app for sleep. However, even with this eligibility requirement, there was a portion of the sample who did not endorse sleep difficulties and those who did not use the app for sleep, such that we may be capturing at least some of the patterns associated with other uses of sleep-related content among good sleepers. Third, this was a cross-sectional survey, relying on participants' retrospective self-reports. Future research that includes objective usage data in addition to self-reported usage would allow for a more nuanced understanding of these findings and broaden the range of research questions that could be explored. This may be particularly useful for addressing

questions regarding if and how various types of sleep-related content within the app may be used differently, and the extent to which those with sleep difficulties prefer different types of sleep content than those without sleep difficulties. Additional research is needed to understand the extent to which these factors may drive or explain some findings presented here. Finally, the study was limited in scope because it did not address the efficacy of Calm's sleep content. Given the potential for using mobile apps to deliver highly scalable, accessible interventions for sleep disturbance, future RCTs are warranted to determine the effectiveness of mindfulness meditation apps for sleep and to assess the usage and effects of different types of sleep content among those with sleep disturbance.

Conclusions

We are the first to report how subscribers to the Calm meditation app use the app for sleep. Our data suggest that a high proportion of Calm subscribers experiencing sleep disturbance, including insomnia, use the app to improve their sleep. Poor sleepers and those with insomnia are specifically using Calm at night and on a regular basis, suggesting they are intentionally using the app for the self-management of sleep. We describe subscribers' use of other pharmacological and nonpharmacological sleep aids, highlighting the extent to which sleep support is needed among Calm users experiencing sleep disturbance.

Our findings have important implications for future research and the development of content and interventions for meditation apps that aim to reduce sleep disturbance. There is a need for RCTs that can determine whether consumer-based meditation mobile apps are efficacious for improving sleep in those experiencing sleep disturbance, including those diagnosed with insomnia. Additional studies are necessary to determine the dose (ie, extent of app engagement) that is necessary for reducing sleep disturbance. Our findings also offer directions for designers of consumer-based apps that aim to develop content to help users fall asleep and return to sleep after waking in the night.

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Conflicts of Interest

JH is currently consulting as the Director of Science at Calm. JH has been conducting research with Calm as a partner for 5 years prior to the Director of Science role. JH directs the Scientific Advisory Board (SAB) at Calm. AMV, LL, and MI are members of Calm's SAB and are independent from Calm leadership. JH and the SAB's role is to ensure the quality of Calm's science. JH and the SAB have no stock in Calm and receive no financial incentives from the sales of Calm.

Multimedia Appendix 1
Sleep survey questions.
[DOCX File , 26 KB - formative_v4i11e19508_app1.docx]

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Abbreviations

RCT: randomized controlled trial
SAB: Scientific Advisory Board

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Original Paper

A Cardiovascular Health and Wellness Mobile Health Intervention Among Church-Going African Americans: Formative Evaluation of the FAITH! App

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Abstract

Background: In light of the scarcity of culturally tailored mobile health (mHealth) lifestyle interventions for African Americans, we designed and pilot tested the Fostering African-American Improvement in Total Health (FAITH!) App in a community-based participatory research partnership with African American churches to promote cardiovascular health and wellness in this population.

Objective: This report presents the results of a formative evaluation of the FAITH! App from participants in an intervention pilot study.

Methods: We included 2 semistructured focus groups (n=4 and n=5) to explore participants' views on app functionality, utility, and satisfaction as well as its impact on healthy lifestyle change. Sessions were audio-recorded and transcribed verbatim, and qualitative data were analyzed by using general inductive analysis to generate themes.

Results: In total, 6 overarching themes emerged among the 9 participants: overall impression, content usefulness, formatting, implementation, impact, and suggestions for improvement. Underpinning the themes was a high level of agreement that the intervention facilitated healthy behavioral change through cultural tailoring, multimedia education modules, and social networking. Suggestions for improvement were streamlining the app self-monitoring features, prompts to encourage app use, and personalization based on individuals' cardiovascular risk.

Conclusions: This formative evaluation found that the FAITH! App had high reported satisfaction and impact on the health-promoting behaviors of African Americans, thereby improving their overall cardiovascular health. Further development and testing of the app among African Americans is warranted.

Trial Registration: ClinicalTrials.gov NCT03084822; https://clinicaltrials.gov/ct2/show/NCT03084822.

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KEYWORDS

mobile health; eHealth; community-based participatory research; health promotion; African Americans; mobile phone

Introduction

Ideal cardiovascular (CV) health has been defined by the American Heart Association (AHA) as the achievement of optimal levels of 7 key components, including health-promoting behaviors (optimal diet and physical activity [PA], achieving normal weight, and abstaining from smoking) and controlling health factors (blood pressure, cholesterol, and blood glucose). Each of these components is independently associated with lower CV disease risk in a stepwise fashion; however, there are striking racial and ethnic disparities in ideal CV health [1]. Compared with White Americans, African Americans (AAs) have a lower prevalence of ≥5 ideal components (11.8% vs 19.2%) [2] and an 82% lower likelihood of achieving ≥5 of the 7 ideal components [3]. Furthermore, it has been estimated that the components with the greatest potential for improvement in AAs are health behaviors, including diet, PA, and weight management [4]. Even modest shifts in the distribution toward improved CV health in the AA population could result in appreciable reductions in incident CV disease in this group. Thus, innovative, individual, and population-based interventions to promote ideal CV health through lifestyle changes among AAs are desperately needed.

Mobile health (mHealth) [5] lifestyle interventions hold potential for diffusing CV health promotion in AA communities. AAs are embracing mobile technologies with rapid smartphone use expansion and frequent internet searches for CV disease–related health information [6] and positively view mHealth interventions as viable strategies to improve health outcomes [7,8]. However, only a handful of studies have tested mHealth interventions to improve CV health in AAs, with many studies focusing only on health behaviors (eg, diet, PA, weight loss) or single chronic medical conditions (eg, diabetes, hypertension, heart failure) [9-17].

Emboldened by the AHA 2020 Impact Goals to improve the overall CV health of AAs, we co-designed a culturally tailored digital app, Fostering African-American Improvement in Total Health App (FAITH! App), to promote CV health within the AA faith community using an iterative participatory approach within an established academic-community partnership [18,19]. The intervention is grounded in behavioral theoretical frameworks, including principles from the health belief model [20], social cognitive theory [21], and the community mobilization model [22,23]. At the heart of the intervention are multimedia education modules that were guided in design by the health belief model, which incorporates an individual's perceived susceptibility, benefits, and barriers to predict behavior change. The social cognitive theory model, or learning through a collective agency to influence health behaviors, was incorporated in specific app features (eg, group sharing board, testimonials on healthy lifestyle) as well as our inclusion of an established social construct within the AA community, the Black Church [24]. To this end, we also embraced the community mobilization model by actively engaging in a strategic community partnership while leveraging the norms, values, and resources it embodied to develop and implement an intervention [25].

To our knowledge, our parent study is among the first to combine a culturally tailored and app-based lifestyle intervention to promote ideal CV health within the context of a primary CV disease prevention program [18,19,26]. Participants within our pilot study achieved improvements in key CV health behaviors and factors and reported overall high acceptability and satisfaction of the intervention [18,26]. To address the dearth of literature integrating formative processes to design and evaluate culturally tailored mHealth interventions, we used a qualitative approach to further explore participant experiences of taking part in the intervention.

This program evaluation aims to gain insight into the impact of an mHealth lifestyle intervention (FAITH! App) on the CV health behaviors of AAs participating in a quasiexperimental behavioral intervention pilot study. We sought to include participants' perspectives to evaluate the intervention with the goal of integrating this information in future iterations of our mHealth intervention to more effectively influence CV health in this population.

Methods

The parent study was approved by the Mayo Clinic Institutional Review Board and registered (ClinicalTrials.gov [NCT03084822]), and participants provided written informed consent before participation.

Research Design and Participant Recruitment

The parent study comprised 3 community-driven phases: (1) app design with the AA community through formative app development [18], (2) app pilot testing [26], and (3) app evaluation using quantitative and qualitative research methods. This analysis (phase 3) evaluates qualitative data on participants' perceptions of app pilot testing, who were subsequently recruited to participate in the evaluation component of our study. Details on the parent study rationale, recruitment procedures, and participant inclusion/exclusion criteria for the overarching parent study have been described [27]. Briefly, we collaborated with 5 predominately AA churches in Rochester and Minneapolis-St Paul, Minnesota, using a community-based participatory research (CBPR) approach to co-design a CV health and wellness digital app–based program (ie, the FAITH! App) [18]. A total of 50 AA church parishioners were enrolled into a single-group pilot study to follow a 10-week intervention centered on the FAITH! App. Its components included 10 core multimedia education modules delivered by health professionals on CV health, interactive diet and PA self-monitoring, and social networking through a group sharing board. Participants completed health assessments, including self-administered electronic surveys of sociodemographic and health behavior

information as well as physical examinations and laboratory studies of biometrics at baseline and 28 weeks postintervention. Following the final health assessment, participants from the pilot study were invited to participate in the postintervention focus groups by email. Participants involved in the co-design of the FAITH! App were not invited to participate in the focus groups. There was a 32% response rate (16 out of 50 pilot study participants) to the email invitation. Ultimately, 9 participants were able to participate on the most convenient dates and times chosen by a polling of the interested invitees. Participants received a US $50 cash card for participation in the focus groups.

Data Collection

Two separate focus groups (N=9) were held to assess participant perceptions of the FAITH! App (one each in Rochester, Minnesota [focus group 1: n=4], and Minneapolis-St Paul [focus group 2: n=5]). Participants' sociodemographic information, including age, sex, marital status, education level, employment status, and eHealth literacy (measured by the eHealth literacy scale [eHEALS], an assessment of an individual's perception of their ability to understand and apply electronic health information) [28-30], were derived from baseline electronic surveys completed at the time of pilot study enrollment.

We developed a comprehensive moderator guide inclusive of neutrally worded, open-ended questions to facilitate open discussion and to obtain feedback on the FAITH! App intervention including the following core topics: app satisfaction, dislikes, and suggestions for improvement. The moderator guide was developed from a literature review [31], our participatory intervention design process [18], informal discussions with participants and church partners as well as quantitative evaluations of the FAITH! App. The primary moderator (CS) had substantial experience conducting focus groups among racial and ethnic minority populations and previously collaborated with the study team during the formative design of the FAITH! App with a similar group of AAs [18]. The study principal investigator (LB) was intentionally not present during the focus groups to minimize social desirability bias and coercion among the study participants. However, the moderator and study principal investigator met before each focus group to review specific strategies to encourage group discussion and culturally tailor questions to place the group at ease to share their valued opinions. Each focus group was 90 min and audio-recorded. The focus group in Rochester was held in a conference room in an outpatient clinical practice in the evening. The Minneapolis-St Paul focus group took place in the evening in a conference room at a community center. Each focus group commenced with a friendly *ice-breaker* to promote sharing among the group, "What is your favorite thing about Minnesota?" Following each focus group, the moderator compiled summary analysis notes of the most salient participant responses, which were then reviewed by the study principal investigator. All sessions were subsequently transcribed verbatim by an experienced transcriptionist.

Data Analysis

For qualitative analyses, the first author (LB) and a trained qualitative methods specialist (AK) first read the transcripts several times with reference to the focus group moderator guide. The 2 coders collaboratively developed a code book in an iterative process to better organize and categorize the data in accordance with the open coding method, a process that enhances the probability of garnering novel insights [32]. In the code book, each code was described with a concrete definition, and at least one example quote from the data was included. QSR NVivo software version 10 was utilized to organize and manage transcribed data from the focus group sessions. General inductive analysis was used as it aligned with the exploratory and formative nature of the study in the following ways: (1) it condenses raw textual data into a more succinct summary; (2) it links the evaluation (in our case of an intervention) to the summary findings from the raw data; and (3) it cultivates a framework of the underlying structure of experiences or processes evident in the raw data [33]. Two coders (LB and AK) coded all transcripts independently and assigned codes for subsequent categorization around salient themes. To mitigate interpretative biases and to maintain the consistency of coding, the 2 coders met regularly and discussed all coded data until they reached a consensus. Whenever the 2 coders had difficulty assigning a common code, a third team member (CP) assisted with resolving discrepancies or assigned new codes to ensure consensus. Through this collaborative process, the team attained very good agreement on coding [34]. While ensuring intercoder reliability, the 2 coders discussed the main themes in detail, and provisional subthemes also emerged from the coded data [35]. Finally, to further enhance reliability and as a part of our CBPR approach to formative evaluation [18], we reviewed the compiled themes/subthemes with community church partners for member checking and feedback on the themes. We provided the 4 church partners with a preliminary summary of the main themes and subthemes for their review. We then organized a 1-hour teleconference to discuss the preliminary summary (community member checking) among the group with the study principal investigator (LB) and qualitative research expert (AK) moderating. The church partners were in overall agreement with the themes/subthemes and felt that they were in concordance with the general feedback they informally received from study participants at their respective churches. This triangulated process of integrating input from participants, church partners, and the study team provided an additional layer of corroboration to the finalized main themes and subthemes [36,37]. Quotations from participants were extracted from transcripts that best represented participants' experiences. Descriptive analyses were completed for all sociodemographic data with the calculation of frequencies and proportions. Participants were categorized by app frequency of use as follows: high frequency users (viewing at least 50% of the 10 education modules, tracking at least weekly diet/PA, and posting on the sharing board at least once per month) and low frequency users (those not meeting high frequency usage patterns). All quantitative analyses (demographic data) were conducted in 2017 with SAS version 9.4 (SAS Institute Inc).

Results

The results of the quantitative survey revealed that focus group participants (N=9) had a mean age of 47.9 years (SD 12.1;

median 49.0), were primarily women (6/9, 67%), reported an education level of some college (5/9, 56%), and were mostly employed (8/9, 89%; Table 1).

The average eHealth literacy score was 31.7 (high range by eHEALS ≥26); 7 of 9 participants were classified as high frequency app users. Overall, participants in the Rochester and Minneapolis-St Paul focus groups had similar responses as the vast majority of the generated codes were mentioned by both groups. Thus, data were pooled for both focus groups. Findings of the focus group discussions were grouped into 6 main themes that were divided into corresponding subthemes: (1) overall impression, (2) content usefulness, (3) formatting, (4) implementation, (5) impact, and (6) suggestions for improvement (Table 2).

We present the results by starting with the participants' global perceptions of the FAITH! App that encompasses their overall acceptability and utility of the intervention. We then examine more granular insights regarding app content and delivery modalities, which could inform future iterations of the intervention. Next, we move to the app's impact by highlighting its influence at the individual, interpersonal, and community levels. Finally, we conclude with feedback for app enhancement.

Table 1. Sample characteristics (N=9).

ID	Age (years)	Sex	Marital status	Employed, at least part-time	Education level	eHealth literacy score	App use frequency
1	26	Male	Married	Yes	Some college	36	Low
2	57	Female	Single	Yes	Technical or associate's degree	31	High
3	64	Female	Divorced	Yes	College graduate	32	Low
4	52	Female	Committed relationship	No	Some college	27	High
5	43	Male	Married	Yes	Some college	37	High
6	60	Male	Married	Yes	Some college	25	High
7	49	Female	Married	Yes	College graduate	30	High
8	44	Female	Widowed	Yes	Some college	31	High
9	36	Female	Divorced	Yes	Technical or associate's degree	36	High

Table 2. Core themes and subthemes.

Themes	Subthemes
Theme 1: Overall impression	• Promotion of healthy behaviors by self-monitoring • Accessible and instructional health content • Influence on healthy lifestyle adoption of the church • Technical difficulties with self-monitoring
Theme 2: Content usefulness	
Education modules: General	• Thought-provoking and self-reflective • Descriptive on cardiovascular health • Easy to comprehend health information
Education modules: Videos	• Engaging presentations • Convenient and succinct • Effective visual learning
Education modules: Premodule and postmodule self-assessments	• Complementary to video series
Education modules: Brochure content	• Reinforcement and summary tool • Time-consuming • Technical difficulties with access
Recipes	• Inspired action toward healthy eating • Better understanding of benefits of healthy eating
Sharing board	• Motivational to healthy lifestyle change • Support network • Information exchange between participants
Testimonials	• Preferred heart disease survivors or those making healthy lifestyle changes
Self-monitoring (diet and physical activity)	• Fostered personal accountability toward a healthy lifestyle
Theme 3: App format	
General	• Fulfilled expectations for continued engagement • Diversity of health care professionals within the education modules
Attentiveness to nuanced cultural perspectives	• Importance of linking faith to health for the African American community • Cardiovascular health disparities affecting African Americans • Implications of visual representations of African Americans
Theme 4: App implementation	
Facilitators for use	• Positive messaging supported engagement • Focus on benefits of healthy lifestyle • Simple navigation • Visual display of education module progress • Education module variety of activities appealed to differing learning styles • Overview of cardiovascular risk factors at start of education modules • Consolidation of cardiovascular health information through mobile technology
Barriers to use	• Cumbersome data entry and log-in process • Inability to download app on other personal mobile devices
Theme 5: App impact	• Positive changes to dietary patterns • Better awareness of long-term benefits and motivation to make healthy lifestyle changes • Team-based lifestyle changes among couples and across generations • Positive influence on the patient-provider relationship • Health promotion within the church congregation
Theme 6: Suggestions for app improvement	• Visuals to see progress of diet and physical activity self-monitoring/tracking • Automatic syncing function from other diet and physical activity apps • Additional functions for education modules and sharing board • Individual tailoring of the app to encourage app use and increase its relevance

Theme 1: Overall Impression

The focus groups opened with questions about the impressions of the app as a whole. The most common positive perceptions identified by the participants were related to health promotion through the easily accessible health information delivered by the education modules. The most common source of challenges with app use came from technical difficulties with the diet and PA self-monitoring feature.

Promotion of Healthy Behaviors by Self-Monitoring

Participants saw great value of the app self-monitoring features as they compelled them to keep track of their diet and PA patterns. One participant mentioned how this feature provided accountability to meet personal goals to eat healthier and remain active:

> *And one thing I did really appreciate about the tracking, I never knew how few vegetables I ate. I would walk down to the cafeteria and purposely go get more fruits and more stuff like that...I gotta go work this off...making sure that I'm staying on track.* [Focus group 1, participant]

Accessible and Instructional Health Content

Most participants reported that the app provided easily accessible and useful information and found the pictorial images and visuals to explain the health information helpful:

> *I did like how it gave you details and pictures of what they were showing you and explaining.* [Focus group 2, participant]

Influence on Healthy Lifestyle Adoption of the Church

A fundamental concept from several participants was that the genuine commitment to improving the health and well-being of the study participants conveyed by the study team inspired a commitment from the church congregations to focus on adopting healthy lifestyles. The app intervention as a whole seemed to awaken the church congregations to create an endurable culture of healthy living even beyond the completion of the study:

> *It was really needed, and it took you all to awaken us and start to awaken the church of an area where the church had been negligent...when you're talking about health. This is a life-time commitment that we're making, not for one year, but you certainly have put that in the congregation to be more healthy…and then because you got the pastors on board, then that would help plan it, and it will keep going. Hopefully, if this come out for everybody to use.* [Focus group 2, participant]

Technical Difficulties With Self-Monitoring

Participants provided shared challenges with technical difficulties with the app self-monitoring feature, specifically troubleshooting to enter their diet and PA information.

Theme 2: Content Usefulness

Naturally, discussions transitioned to participant perceptions of the core app features. Overall, the participants found the features useful to better understand the impact of CV risk factors on CV physiology and the development of CV disease. They also mentioned that the app provided them with tools to improve their CV health.

Education Modules: General

Thought-Provoking and Self-Reflective

One participant felt that the app offered a new awareness of their own health and wellness through the information provided:

> *Even if there was a day I was thinking about my health and the way that I'm taking care of myself, there was information in here that I wouldn't normally think about, even on a day when I was thinking about it. So I thought the information was excellent.* [Focus group 2, participant]

Descriptive Content on CV Health

Participants appreciated the descriptive content that allowed them to connect health behaviors such as diet as well as psychosocial factors such as stress to heart functioning:

> *Sometimes you don't think about how one thing can affect another thing, and so you looked at everything and how...eating too much sodium can affect how your heart pumps and how stress does this. So everything was very informative, gives you some ideas to think about.* [Focus group 2, participant]

Easy to Comprehend Health Information

The participants felt that the information was presented at an optimum level for understanding across different learning styles. They also appreciated that the speakers avoided extensive use of medical jargon but instead relayed information in layman's terms:

...the speakers were very descriptive; and for me personally, they didn't get so deep that they was over my head where I didn't understand...So it wasn't like it was a doctor speaking to a nursery school person or something. It was right in the ballpark academically as far as understanding the information that was given; and for me, it was excellent! [Focus group 2, participant]

Education Modules: Videos

Engaging Presentations

Participants provided positive feedback about the education module video series, describing it as an engaging and interactive tool that prompted further insights into healthy behavior change:

> *...the speakers, just the way they presented held my attention. I didn't doze on any of them. I wasn't, [like] I wish they'd hurry up and get done. I actually was listening to what they were saying and, even taking mental notes about what I could do differently my own self.* [Focus group 2, participant]

Convenient and Succinct

Participants found the video series format to be a convenient and succinct way to view and access health information both independently and with their families. Several shared how they

would watch the videos from a variety of locations (eg, home, work) and revisit the modules for reinforcement. Keeping the videos brief and concise was also viewed favorably. Another participant enjoyed having the summary video at the end of each module to tie together the key concepts:

> *...and the review at the end...to me, that was the best part because it summarized everything.* [Focus group 1, participant]

Effective Visual Learning

Overall, participants enjoyed the videos with visual depictions of normal and abnormal heart physiology. Several participants commented extensively on the usefulness of slide illustrations and graphics integrated by speakers:

> *...when they was talking about the heart, showing me how my heart works...for a visual person, that was really helpful to see...not just talking but actually showing me what's happening to my body.* [Focus group 2, participant]

Education Modules: Premodule and Postmodule Self-Assessments

Complementary to Video Series

Participants felt that the premodule and postmodule self-assessments (quizzes) were a great addition to the modules and complementary to the video series. They unanimously recommended that they should remain mandatory in order to mark completion of the education module as they were beneficial self-assessment tools. The quizzes also provided an infrastructure to remain on track with the education modules:

> *I thought it was...nice to have that pretest and the posttest, just to keep you on point...* [Focus group 2, participant]

Education Modules: Brochure Content

Reinforcement and Summary Tool

Some participants found the brochure content within each education module to be a useful resource to summarize information relayed within the video series:

> *I thought the brochures are always a good way to sum up everything that they've talked about. So before doing the last quiz, I'd always like to just go through quick and read those brochures.* [Focus group 1, participant]

Time-Consuming

Although the content was viewed as useful and relevant, some participants found review of this information to be time-consuming and too much to digest as an addition to the other module features:

> *...at least I didn't really want to skip any of it, but it was a lot to consume at one time...and this is interesting, so I don't really want to stop, but it's taking my time...it was a lot of reading, but it was good, but it was just a lot to digest at once.* [Focus group 2, participant]

Technical Difficulties With Access

Participants noted that access to the brochure content was cumbersome as the content was not housed within the app itself and required redirection to PDF files within a separate screen.

Recipes

Inspired Action Toward Healthy Eating

Several participants enjoyed heart healthy recipes on the app and shared experiences at the individual and church level of how they incited healthy eating. One participant shared how his family modified their traditional holiday practices toward healthy dietary change through smaller portion sizes:

> *...this past Thanksgiving, me and my wife, we even changed our whole ... traditional Thanksgiving; we did something totally different. We usually get the turkey ...and was going to put it in the oven or deep fry it or however they do it. We did a small turkey breast, a little turkey breast…we just made everything smaller. And then we just did smaller portions…everything was done and we was good. We didn't throw a lot out. We didn't waste a lot of money. And we were a lot healthier.* [Focus group 2, participant]

At the church level, participants held a church potluck to try out recipes in order to introduce each other to healthier options. They wanted to know if they could integrate healthier ingredients into their daily lives. Many enjoyed the dishes as they maintained flavor without added salt or butter:

> *...so when we did bring it to our church, we all got to taste different recipes, and it was changing the way of looking at life where I don't have to have all of this salt, ...so it just gave me a new way of looking at different seasonings or butter...it's a more healthier version of it, but I was like, hey, I could use this. So I do like that and it still had flavor...we still enjoyed it. We had greens that was cooked in different things and they taste good!* [Focus group 2, participant]

Better Understanding of Benefits of Healthy Eating

Participants discussed that eating healthier can sometimes be more expensive, but they felt the value of eating healthier to improve overall health outweighed the extra costs:

> *...then here's the thing too,...everything that's healthy for us, it costs more money. But we waste money on things we don't need anyway...So why not spend a little money on something that's going to help our bodies...If you eat a burger for a buck every day...You'll be going to the hospital for a heart attack; but if you eat a salad every day, it might cost you more, but you're healthier.* [Focus group 2, participant]

Sharing Board

Motivational to Healthy Lifestyle Change

Participants used the sharing board posts to connect with others and found the posts to be very encouraging and motivating to maintain healthy behaviors.

One participant shared:

> *Those...posts that a lot of people made, to me, were very encouraging...kind of like testimonials to a degree, so it helped me...try to get my game back up closer to everybody's...* [Focus group 1, participant]

Support Network

Participants also found the sharing board to be a support network to better support others through personal struggles. One participant revealed empathy for another participant through prayer:

> *They would tell what was going on in their life. And so I was actually able to feel for them...I mean, we're calling this a faith thing, so I would pray for other folks cuz I can see that they're going through things.* [Focus group 2, participant]

Information Exchange Between Participants

Participants enjoyed sharing and learning from each other through a variety of communication modalities on the sharing board (eg, text, pictures, videos):

> *...somebody posted a recipe or someone...cuz people were adding pictures...of things that they cooked...and some people posted recipes. It was amazing how many people would say you can find a large bag of green peppers for $2 at XYZ.* [Focus group 1, participant]

For those who used it less often, they reported that they still enjoyed reviewing the posts and in hindsight wished that all participants would have used the feature more often:

> *I thought the sharing board was good. I wish I would have used it more, and I wish everybody else would have used it.* [Focus group 2, participant]

Testimonials

Preferred Heart Disease Survivors or Those Making Healthy Lifestyle Changes

Participants appreciated the testimonials from the church pastors and past FAITH! participants but initially thought they would feature those with an experience of CV disease or those who have made significant lifestyle changes. They felt that hearing stories from them would inspire them to reflect on their own risk for CV disease. One participant shared:

> *...it might be good to have, people who may have experienced a heart issue and maybe changed their life...and someone that could encourage you to engage. It probably would be more effective to [make one say] "I really need to think about this more."* [Focus group 1, participant]

Self-Monitoring (Diet and PA)

Fostered Personal Accountability Toward a Healthy Lifestyle

Overall, participants found the self-monitoring feature useful as it fostered personal accountability toward a healthy lifestyle. One participant shared how the feature helped to "keep track" of diet and PA patterns:

> *...some of the people really like tracking and they did it religiously...they prefer to track...*
>
> *to stay true to the expectation of what you were doing, and then you could also see where you were falling short.* [Focus group 1, participant]

Theme 3: App Format

General

Fulfilled Expectations for Continued Engagement

Overall, the participants enjoyed using the app, with several directly expressing that they would want to continue with the digital formatting of the intervention:

> *We got enough but we want more!* [Focus group 2, participant]

Participants also felt that the interactive multimedia delivery modality was appropriate with the goal of increasing awareness of healthy lifestyle change:

> *They were very informative. The way they presented it, it was easy to understand, very insightful, especially for me because this is an area that I really don't pay attention to...I realized I had to change my diet; and then once I realized that, then I started listening to these apps and these doctors, I really enjoyed them. I really, really enjoyed them; I really did.* [Focus group 2, participant]

The participants emphasized that the education modules were essential components of the platform. They also found the homepage inviting, colorful, and eye-catching. Arranging simple icons on the homepage was viewed as a great technique to organize module topics:

> *These little icons, I thought, were very good, too, for the links. You know, like physical activity, you had the little man walking in healthy living.* [Focus group 1, participant]

Diversity of Health Care Professionals Within the Education Modules

Participants also took notice of the diversity of health care professionals included within the education module videos that included multidisciplinary individuals (eg, cardiologists, endocrinologists, nurses, dieticians).

Attentiveness to Nuanced Cultural Perspectives

Importance of Linking Faith to Health for the AA Community

The participants commended the study team for incorporating biblical scriptures and spiritual messaging within the app as

religious involvement is of high importance to AAs and showed humility to this prioritized AA faith community. They appreciated the emphasis on connecting spiritual and physical health for healthy lifestyle changes, as described by this participant:

> *I really liked the fact that the scriptures and things like that were there because it seemed like, okay we're tying faith together with healthy living...I thought that was really awesome; and the little faith icon in the corner, it's a nice touch that was there...* [Focus group 1, participant]

CV Health Disparities Affecting AAs

The vast majority of participants acknowledged the importance of placing emphasis within the modules on the CV health disparities burden among AAs. They felt that the positive messaging strategies were delivered in an appropriate manner to not place offense or blame on this group but to inform them of their elevated risk for CV disease. This was encompassed in a statement from one participant with many nodding in agreement:

> *...not pushing one culture over another but still letting you know that this culture is more at risk, and I thought they did that, for lack of a better word, very tactfully, very swoopy where you didn't feel offended or saying that this was speaking against your culture—you people get this and you people are targets for this. I didn't feel like it was being pointed out, but I also understood that you were being addressed.* [Focus group 2, participant]

Implications of Visual Representations of AAs

In general, the group felt that the selected photographs of AAs included in the app were accurate reflections of the AA community's experience. This was of significance for the group as this influenced their acceptability of the app:

> *I liked that it was representative of the community that we were...that I'm in. I always look for that in things like apps or magazines...anything that's print or digital media, I always look for am I represented or reflected in what's being presented to me. I think that was huge. That was very positive.* [Focus group 2, participant]

A concern surfaced from a male participant regarding the placement of wording over one of the AA men depicted on the home page visual. The man had a darker skin tone/complexion than the other individuals, and it was felt that this was offensive and, in a sense, reinforced the societal discrimination against and ostracism toward AA men. An AA man in the group exclaimed:

> *I just wish I could see the dark-skinned brother up there (laughs). I just had a problem with the writing on the brother's face... I wanted to see his face, and I can't see it, and it's like, okay...it would stick out, like every time I opened that app, it bugged me, that's all.* [Focus group 1, participant]

Theme 4: App Implementation

Facilitators for Use

Participants identified several facilitators of their engagement with the app features. They placed emphasis on the education modules and their utility for app use.

Positive Messaging Supported Engagement

A consistent topic among participants was that the intentional use of positive and encouraging messaging throughout the education modules supported their desire to view the entire series:

> *They gave us positives even though we're going through situations, they said "if you just make one change", so it was encouraging. I liked how they encouraged us to make a small change.* [Focus group 2, participant]

Focus on Benefits of Healthy Lifestyles

The app as a whole increased awareness about and facilitated healthy behaviors among the participants. Participants reported that having this overarching focus infused into the app motivated them to become more physically active and to make healthier food choices:

> *It definitely made me more aware. I now do 10,000 steps a day…try to get in more vegetables; I don't always meet that goal to the vegetables, but I do get the fruit in cuz I like those little mandarins; I eat about four or five of those a day (laughs). But it definitely made me more aware of a lot of things; the tracking of the things that we do just made me so much more aware.* [Focus group 1, participant]

> *Cuz at one time, I thought, ooh, I walked 2000 steps today; I walked a whole mile (laughs) right ... you sound like me; if you walked in a store, it would be like, ooh, that was a walk (laughs). And now, I'm like…10,000 steps, oh my goodness; oh look at me!* [Focus group 1, participant]

Simple Navigation

Furthermore, a simple navigation layout on the app including a homepage and clear tabs (for tracking and the sharing board) was key to using the app features. Participants noted that it was easy to follow the education module curriculum on a weekly scheduled basis:

> *Navigation-wise it was very simple. So one key thing that seemed to work for me is if I was like in a particular area and I wasn't sure where I was going to go, I could look at the top and say, oh, tracking, sharing, you know, should I go back to the homepage. You know, if I was in a module and I wanted to switch to tracking, those links were, to me, they seemed to be available no matter where I clicked. So navigating, I could always get back and forth to the main page where I was...* [Focus group 1, participant]

Visual Display of the Education Module Progress

This was further reinforced by the inclusion of checkmarks to show completion of the education modules as detailed by one participant:

> *... I also liked the ability to say that you've completed the module by selecting "done". Once you clicked "done," there was a checkmark there, so it already told you, yeah, you did it...you don't remember—did I already look at that (laughs)?* [Focus group 1, participant]

Education Module Variety of Activities Appealed to Differing Learning Styles

As a reflection of the initial development of the education module content, participants appreciated the variety of activities within the modules (videos and quizzes) and that they appealed to different learning styles:

> *I loved the way it was set up because not everybody has a long memory like me. I had to do just a little bit at a time. I thought the design was great because, I mean, you do the pre-quiz, watch the videos and learn... and then do the post-quiz, and that's a summary of that module. The objective was to learn more about heart health, so I liked having them.* [Focus group 1, participant]

The education modules and their central feature, videos were viewed as essential app components, as they facilitated learning by the user. One participant shared a positive comment about the succinct "to the point" nature of the modules:

> *Short and sweet but direct to the point. I thought the videos really made the app...to be honest. I mean I thought that because I'm a visual person; so having someone talk to you without you having to read a book of information was convenient. And they were easier than I was thinking they were going to be (laughs).* [Focus group 1, participant]

Overview of CV Risk Factors at the Start of Education Modules

The order of the education modules was of importance as participants felt that having the "Introduction to Risk Factors" module first among the series of education modules was key to setting the stage for the purpose of the intervention, which in turn promoted continued engagement:

> *I thought risk factors was important to be first cuz... to me, it engaged me into the application itself. It's like that first exposure you have to something; you know, when you're testing out a new app or you're looking at something new, if you don't have a good impression on that first one...you might be a little jaded about it...I don't really want to go back to it...it opens your eyes right away. I thought that having that be one of the first things was engaging, so then I wanted to learn more.* [Focus group 1, participant]

Consolidation of CV Health Information Through Mobile Technology

It was also advantageous to consolidate CV health information from a trusted source on the app over having to search the internet, which was seemingly overwhelming:

> *...pooling all the information together in one spot because I know that you could probably search the web and find all this information. I thought that was just awesome because they talked about so many aspects of things that can cause heart problems and it was just all in one spot versus if you have to go out and find this information, you might be in several different websites. So I thought that was great.* [Focus group 1, participant]

> *You may see these things or hear about it on commercials and stuff but just to be able to have something in your hand and, you know, the world today is all tech-savvy.* [Focus group 2, participant]

Barriers to Use

Participants identified several app features that presented barriers to app usage.

Cumbersome Data Entry and Log-In Process

One of the most commonly mentioned barriers was the cumbersome nature of the self-monitoring/tracking feature, which required manual data entry of daily PA and diet patterns by the user. The app's lack of autosave for the tracking feature presented the greatest challenge. Participants also commented on the multi-step log-in process required by the user to access the app. Although this was intended as a one-time requirement for users at the first long-in, oftentimes, users were required to repeat this process as a security measure or when the user was idle or using different internet networks.

Inability to Download Apps on Other Personal Mobile Devices

Participants were provided with tablet devices for use throughout the intervention phase of the study, which had a direct link to the web-based app. As participants enjoyed having the device available through mobile technology, they also found the inability to download the app on other personal mobile devices as a barrier:

> *The downside was I couldn't really download anything cuz it was on the app, the iPad that you guys gave us...cuz I wasn't able to keep the material or print it off because it wasn't available for me on my own personal iPad.* [Focus group 2, participant]

Theme 5: App Impact

The impact of the app on participants' personal healthy lifestyle change and community was intensively discussed.

Positive Changes to Dietary Patterns

Accordingly, participants mentioned specific manners by which the app incited positive changes to their individual dietary patterns:

> *I think about this even today the fruit and the vegetable intake, I really am more conscientious of that and even when I go to the store, I find myself buying more. I go to the fruit and the vegetables, and my cart seems to have more of that in it than it did before.* [Focus group 2, participant]

Better Awareness of Long-Term Benefits and Motivation to Make Healthy Lifestyle Changes

Participants also highlighted how the app provided them with a better awareness of the long-term benefits of maintaining a healthy lifestyle. They expressed how they viewed the information provided by the app as vital and practical to apply within their daily lives:

> *...if I continue this way, I'm going to reap better benefits but that information is so vital that you have that information going into the grocery store that this is what I need to buy. Yes, that's cheaper and I'd get more of that, but this is much healthier and it's going to reap better benefits for me in the long run.* [Focus group 2, participant]

Similarly, participants positively expressed that the app provided them with motivation to start healthy lifestyle changes:

> *...once I started focusing in and how this program showed me just to make slight changes....I started changing my eating habits before I even started going to the gym, and I started losing before I even did anything at the gym.* [Focus group 2, participant]

Team-Based Lifestyle Changes Among Couples and Across Generations

Several participants shared how they noticed that there were several team-based lifestyle changes among couples engaged with the app:

> *... having a spouse doing it along with them, I think that really encourages because both of those couples were really engaged in terms of the physical activity. I think the one couple...tracked the most steps...over a million steps.* [Focus group 1, participant]

One participant shared the details of how he and his wife were integrating healthy behaviors as a team:

> *Me and my wife would go out to dinner; we would get one plate and share it. We would get one entrée, one thing, one meal, and we would cut it in half; we'd tell them to bring us two plates. So we started doing things like that, and that's what we still do now. So that helps out, and it saves money...* [Focus group 2, participant]

One of the cascading effects noted from the app was how it inspired an intergenerational healthy lifestyle change among family members. A sense of role modeling of healthy behaviors was observed by younger generations and provoked a desire among them to adopt the same behaviors:

> *I had to get a youth membership for one of my grandsons because I was going, and he wanted to go along with, and I only have so many guest passes, and he used them all up; so then I had to get a Y membership for him (laughs).* [Focus group 2, participant]

Positive Influence on the Patient-Provider Relationship

Participants identified the positive influence that their participation in the program as a whole had on their relationships with their health care providers. Several participants shared how they were more informed and prepared during their regular check-ups. The information also increased their attention to and understanding of their prior discussions with their health care providers about their CV risk factors. They also were enthusiastically looking forward to sharing their progress toward improving their CV risk factors with their providers:

> *I told my doctor about it. I took a physical here two weeks ago, and I was telling her, I'm in this Mayo program, in this faith-based program, and it's wonderful!* [Focus group 2, participant]

> *...it made me more knowledgeable about things that I just took for granted and didn't pay attention to…like my doctor told me… I want you to drop weight. He said, when you come back here next year, you know, just show me some improvement as it is. So when I go back to him, he's going to like what he sees 'cause I've lost almost 20 pounds. So he's going to be like, you did good. I liked it because it was something that I took for granted then that I'm really paying more attention to now.* [Focus group 2, participant]

Health Promotion Within the Church Congregation

Another key element that emerged was that the app enhanced health promotion within the church congregation. This was described as communicating the health information learned from the app to weekly worship services with programming for adults and children:

> *Each Sunday, we bring a health topic to church, and I've noticed how people take notes to eat healthy foods.*

> *One other thing we started as a result of this between our Sunday school service and our regular worship service...we have a snack time. We have children that come...they haven't had breakfast or maybe not even dinner the night before…and then teaching them the importance of eating proper foods, and there are a lot of fruits and vegetables and things like that in there...[Focus group 1, participant]*

Theme 6: Suggestions for App Improvement

Participants had a number of valuable suggestions to improve the app with a focus on certain features.

Visuals to See Progress of Diet and PA Self-Monitoring

In particular, participants suggested the use of a visual rewards system or dashboard summary within the app self-monitoring and tracking system to allow users to see their personal progress as it relates to their diet and PA. One participant provided a detailed suggestion:

> *With my Fitbit, when I reach a goal, I get this little MEEEEEEEE, and it's like that ... explosion of celebration and it would be nice if, on here, when you put in your fruits and veggies, if you've made your five that there was something, like maybe a little star. I mean, it's more of a visual that—hey, I'm on track; I'm doing good!*
>
> *...on the calendar that it would show...an apple for the fruit or a banana or something. Some visual that you did it that day. You made it that day, yes.* [Focus group 2, participant]

Another participant highlighted the need for a weekly summary of diet and PA to increase app engagement by providing the user with useful information:

> *...because the tracking is great, but if you had a summary for the week, how many fruits and vegetables I've eaten, or how many steps have I done for this week...So the more productive the app is, I think the more people will jump on it and want to use it.* [Focus group 1, participant]

Automatic Syncing Function From Other Diet and PA Apps

Participants also suggested integrating an automatic syncing function from PA monitors to upload tracking data directly to the app throughout the day. Participants stressed the inconvenience of having to manually input tracking data and the requirement to complete this "all at once." Syncing with other diet and PA apps at any preferred time during the day would alleviate the need to have to recall your routine and specific patterns at the end of the day. To illustrate this suggestion, one participant shared:

> *So if there were integrated apps... say for instance, you're using some really popular app that allows you to track your calories and your food and stuff...if the faith app could pull information from another app or take that as input without you having to select it over here and go tuck it in there.* [Focus group 1, participant]

Additional Functions for Education Modules and Sharing Boards

Suggestions for additional content to the educational modules included topics related to genetics and CV disease risk. Participants also suggested the inclusion of closed-captioning for viewing content within the education modules, which would also allow them to view videos without sound in the appropriate setting. This feature would also support the needs of those individuals with hearing impairment:

> *I like seeing what they're actually saying and put into like it's a talk or into words or whatever...a closed-caption. Cuz I know sometimes if I'm at work, I don't have the volume all the way up or something.* [Focus group 1, participant]

Participants indicated their intention to revisit the education modules and sharing board as a means to reinforce concepts learned from the presenters and to review insights posted from their peers. To accomplish this goal, a search function for topics within features was suggested:

> *I'd be having conversations with someone, and I couldn't go back, and I couldn't find it. The keyword search...that seems like the way to do it. Cuz there were some pretty interesting threads in there too.* [Focus group 1, participant]

Individual Tailoring of the App to Encourage App Use and Increase its Relevance

Participants also suggested that personally tailored reminders (via email or text messages) be sent to participants when there was a lapse in use of the app but not necessarily to those actively engaging with the app. This would help minimize the need for automated email reminders:

> *...a little reminder that, hey you haven't cleared your module or you haven't looked at this new content that we have out there...would be good, but that would be intuitive of the app itself and tailored for the person using it.* [Focus group 1, participant]

It was suggested that the app allowed participants to configure whether they preferred email or text messages and to include an "on/off" setting.

Finally, participants suggested individual tailoring of the app to specific CV risk factors and for women's health. One suggested delivery modality included succinct, personal messages to users outside of the education modules related to major CV risk factors such as hypertension or diabetes. One participant discussed this in the context of heart attack warning signs in women:

> *... even for heart attacks, women—their symptoms are totally different than men, so maybe having a module about that women, certain ages, watch for certain signs cuz this could be a heart attack for you, where in men it's...and I know a lot of times when you go to the ER, if you present certain symptoms, they don't think about a woman having a heart attack.* [Focus group 2, participant]

Discussion

Principal Findings

In this formative evaluation, the FAITH! App was perceived as a culturally relevant and acceptable delivery modality for promoting and facilitating positive CV health behaviors for CV disease prevention among AA adults. The main themes that emerged were that the intervention successfully prompted healthy behavioral change through cultural tailoring, multimedia education modules, and social networking. Challenges to healthy behavioral changes related to the intervention primarily revolved around technical malfunctions with the diet and PA self-monitoring features. This formative evaluation contributes to a small but growing body of the literature providing evidence to support mHealth lifestyle interventions to foster sustained behavior change. Taken together, our results provide support for the willingness and eagerness of AAs for the use of mobile devices for health promotion.

A preliminary finding of our formative evaluation was the importance of considering unique cultural influences, as these can be facilitators/barriers to intervention engagement. Few mHealth interventions have adopted tailoring strategies to include content specifically optimized to the sociocharacteristics of AAs [30]. Our parent study is the first to document the development of an mHealth app with faith-based content for CV health promotion to the AA faith community [18]. As maintenance of a healthy religious/spiritual life is central to our prioritized audience [38], our connection of faith and healthy lifestyle through spiritual messaging and biblical scripture was harmonious. It has been previously shown that positive messaging through scripture may heighten the acceptability and use of mHealth interventions by AAs [39]. Our cultural tailoring strategies through both superficial (visual imagery of AAs) and deep (the Black Church) structures also likely increased the receptivity to adapting positive behavioral change strategies [40]. Within our cohort, this was concretely demonstrated by participants' reports of the organization of potluck events within the churches to sample healthy recipes. This has strong implications in activating change in cultural norms within the Black Church around unhealthy eating [41], thereby improving major CV risk factors such as obesity and diabetes, which are highly prevalent within this group [42].

This study adds to previous work showing the importance of understanding how behavioral theory constructs incite behavioral change in mHealth interventions [8,43,44]. Few studies have similarly explored these behavioral pathways through qualitative approaches. CareSmarts, a theory-based, mobile phone–based intervention was associated with improvements in diabetes self-management among AAs through self-efficacy, social support, and health beliefs [44]. Similarly, our participants' expressions of healthy lifestyle change supported our underlying theory-driven intervention development model. In line with the social construct theory model, participants were encouraged by a sense of connectedness or commitment to a group that inspired their adherence to positive health behaviors [45]. Several participants compared themselves with others through their interactions on the sharing board, which increased and maintained their motivation toward healthy lifestyle change. Interestingly, participant commentary also suggested that diet and PA behaviors were learned and reinforced in the context of the family unit (spouses and grandparents to grandchildren) [46]. In accordance with earlier studies, this influence of their behaviors on family members is reflective of the family model of reciprocal determinism [47-49]. Furthermore, participants within our study reported that their health beliefs were shaped by the content of the interactive education modules, which in turn enlightened them on their perceived CV risk. This likely further spurred behavior change.

Participants provided several suggestions for improvement to the app that could further strengthen health behavior change. Among these were streamlining the app self-monitoring features, prompts to encourage app use, and personalization based on an individual's CV risk. On the basis of this valuable feedback, there are plans to integrate these suggestions into the next iteration of the FAITH! App and make the intervention accessible on smartphones. Participants' feedback also suggests that efficacious approaches should aim to strike a balance between the need for individualized and collective social support for more meaningful and beneficial user experiences. Similar themes advocating for personalization to the individual's needs were identified by AA gatekeeper stakeholders involved in the development of an mHealth intervention for patients with hypertension [39]. Consistent with our participants, they emphasized the need to include churches in the launch of mHealth interventions. Although these suggestions are closely aligned with a recent systematic review suggesting that personalization and monitoring are effective behavioral change techniques commonly used in mHealth interventions, none of the 21 studies were focused on the preferences/needs of AA end users [43]. This presents a major challenge in drawing conclusions about the most effective features to incorporate into mHealth interventions. The intrinsic advantages of mHealth interventions are their flexibility for delivery in a wide range of settings and their easy adaptability to content to meet the unique needs of specific populations, even at the individual level. Future work is underway to further refine and investigate these app components for AAs within a larger randomized controlled trial.

Strengths and Limitations

This study is among only a few community-based studies that have performed a comprehensive evaluation through mixed methods of a mHealth intervention among AA adults. This study is also novel in that it describes the in-depth formative evaluation process of a CBPR study aimed at promoting CV health using app-based technology among the AA faith community. As such, our CBPR model provides access to valuable perspectives from an often overlooked, underresourced group at high risk for CV disease. Furthermore, our approach to health promotion may be used as a model to support the AHA 2030 Impact Goals to improve the population's CV health and well-being while increasing life span, particularly for AAs [50]. Our qualitative findings align with our previously published quantitative results showing improved CV health behaviors (increased daily fruit and vegetable intake and weekly moderate-intensity physical activity) [26]. Thus, they reinforce the impact that our health promotion strategy had on individuals with the greatest CV disease risk.

Nevertheless, we had a very small sampling (9/50, 18%) of parent study participation in the focus groups, possibly introducing recruitment and selection bias. Furthermore, there is a possibility of overestimation of acceptability of the app by participants due to social desirability bias, or those who did not participate in the focus groups may not have found the app to be satisfactory. We implemented strategies to mitigate social desirability bias through rapport-building techniques, pre-fieldwork training with our data collector, and minimization of power differentials [51]. Finally, our study findings may lack generalizability to other AAs residing in other regions of the United States or to other racial and ethnic minority groups. These limitations must be weighed against the opportunity to utilize this novel approach to health promotion in a community-based cohort of AAs.

Conclusions

This formative evaluation found that the FAITH! App mHealth lifestyle intervention had high reported satisfaction and impact on the health-promoting behaviors of AAs, thereby improving their overall CV health. These findings reinforce the acceptability of mHealth interventions among AAs. Culturally tailored, community-driven mHealth interventions have the potential to support lifestyle behavioral change for CV disease prevention among AAs. Without attention to upfront participatory design followed by rigorous formative evaluation approaches, we may miss the opportunity for the use of innovative mHealth strategies to address health disparities in marginalized populations.

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Conflicts of Interest

None declared.

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Abbreviations

AA: African American
AHA: American Heart Association
CBPR: community-based participatory research
CDC: Centers for Disease Control and Prevention
CTSA: Clinical and Translational Science Awards
CV: cardiovascular
eHEALS: eHealth literacy scale

FAITH!: Fostering African-American Improvement in Total Health
mHealth: mobile health
NCATS: National Center for Advancing Translational Sciences
NIH: National Institutes of Health
PA: physical activity

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Original Paper

Technology-Enabled Solutions for Australian Mental Health Services Reform: Impact Evaluation

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Abstract

Background: Health information technologies (HITs) are becoming increasingly recognized for their potential to provide innovative solutions to improve the delivery of mental health services and drive system reforms for better outcomes.

Objective: This paper describes the baseline results of a study designed to systematically monitor and evaluate the impact of implementing an HIT, namely the InnoWell Platform, into Australian mental health services to facilitate the iterative refinement of the HIT and the service model in which it is embedded to meet the needs of consumers and their supportive others as well as health professionals and service providers.

Methods: Data were collected via web-based surveys, semistructured interviews, and a workshop with staff from the mental health services implementing the InnoWell Platform to systematically monitor and evaluate its impact. Descriptive statistics, Fisher exact tests, and a reliability analysis were used to characterize the findings from the web-based surveys, including variability in the results between the services. Semistructured interviews were coded using a thematic analysis, and workshop data were coded using a basic content analysis.

Results: Baseline data were collected from the staff of 3 primary youth mental health services (n=18), a counseling service for veterans and their families (n=23), and a helpline for consumers affected by eating disorders and negative body image issues (n=6). As reported via web-based surveys, staff members across the services consistently *agreed* or *strongly agreed* that there was benefit associated with using technology as part of their work (38/47, 81%) and that the InnoWell Platform had the potential to improve outcomes for consumers (27/45, 60%); however, there was less certainty as to whether their consumers' capability to use technology aligned with how the InnoWell Platform would be used as part of their mental health care (11/45, 24% of the participants *strongly disagreed* or *disagreed*; 15/45, 33% were *neutral*; and 19/45, 42% *strongly agreed* or *agreed*). During the semistructured interviews (n=3) and workshop, participants consistently indicated that the InnoWell Platform was appropriate for their respective services; however, they questioned whether the services' respective consumers had the digital literacy required to use the technology. Additional potential barriers to implementation included health professionals' digital literacy and service readiness for change.

Conclusions: Despite agreement among participants that HITs have the potential to result in improved outcomes for consumers and services, service readiness for change (eg, existing technology infrastructure and the digital literacy of staff and consumers) was noted to potentially impact the success of implementation, with less than half (20/45, 44%) of the participants indicating that their service was ready to implement new technologies to enhance mental health care. Furthermore, participants reported mixed opinions as to whether it was their responsibility to recommend technology as part of standard care.

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KEYWORDS

evaluation methodology; mental health; health care reform; technology; mobile phone; community-based participatory research

Introduction

Mental Health Services Reform

Despite more than two decades of effort toward mental health services reform, the Australian system remains to be fraught with shortcomings, including service fragmentation [1], limitations in access [2], and deficient accountability based on outcomes [3]. With an eye toward system reform, the Fifth National Mental Health and Suicide Prevention Plan [4] specifically highlights the need to foster and facilitate enablers for effective system performance and improvement. To that end, health information technologies (HITs) are increasingly being recognized as a way to support and drive mental health services reform, enabling the delivery of evidence-based interventions via the internet to complement or augment traditional face-to-face and existing web-based services to improve health outcomes [5]. For example, cognitive behavioral therapy (CBT) approaches have been incorporated into several apps and websites, including MoodMission [6] and CBT-i Coach [7], to help consumers better self-manage their health and well-being, provide psychoeducation about areas of concern or difficulty, and enhance traditional face-to-face care.

The results of a recent systematic review highlighted the benefits of HITs on the quality and efficacy of health care, partly by facilitating adherence to guidelines or protocol-based care with the aid of embedded electronic decision support functions [8]; however, several facilitators and barriers have been identified that may impact the success of implementation [9]. As summarized thoroughly in LaMonica et al [10], service-level factors include negative staff attitudes; staff members' resistance to change; and changes to work practices, such as increased workload [11,12], as well as the importance of leadership from senior organizational and local service management to champion the HIT [12,13]. In relation to health professionals, co-designing and configuring the HIT to fit their needs helps to foster buy-in and acceptance [12-14]. Furthermore, successful implementation is facilitated by effective education and training of health professionals, which nurtures self-efficacy and capacity in the context of continuous on-the-ground support [12-15]. The involvement of consumers with lived experience and their families in the co-design process and the consideration of consumer preferences for and disparities in the use of technology are also critical factors for successful implementation. Finally, the adaptability, flexibility, and fit of the technology for the service and its model of care [14,15] should be considered.

Rapid and Iterative Evaluation and Refinement of HITs

As Mohr et al [16] outline in their Accelerated Creation-to-Sustainment model, when implementing an HIT, it is crucial to evaluate and optimize usability, acceptability, and effectiveness to ensure that it meets the clinical objectives to facilitate successful implementation in the service. Traditional clinical science approaches to the development and implementation of interventions rely on a linear process, including basic science, intervention creation or adaptation, efficacy testing in both research and clinical settings, effectiveness research in community settings, and dissemination [17]. Although the outcomes of each step in this process are indeed valuable, this progressive, staged model can result in delays of up to 17 years for research translation into clinical practice [18]. In contrast, Mohr et al [16] argue against time-consuming pilot and/or clinical trials and rather highlight the superior benefits to be gained from examining the challenges associated with optimization of both the HIT and the implementation plan within a target clinical setting.

As explained in our implementation science strategy [10], our group employs evaluative processes to continuously design, develop, and refine HIT-enabled solutions during implementation. In this case, an HIT-enabled solution refers both to the HIT as well as to the service model in which it is embedded [19]. Our iterative approach ensures that the HIT-enabled solution is adapted for the changing needs of the stakeholders, including consumers with lived experience and their supportive others, as well as the service based on real-world feedback from target users. It is our belief that gathering feedback from all user groups as they utilize the HIT as part of routine clinical practice will facilitate its iterative refinement and optimization and identify the required workforce and structural service-level changes that are required to improve access to and the delivery of quality care. We expected feedback to include technical difficulties as well as comments in relation to user experience and clinical aspects of both the HIT and the associated service model. Importantly, it is generally accepted in digital mental health research that HITs will be iteratively designed, developed, and refined during implementation, with the ultimate aim of integrating an optimized yet adaptable HIT within a service, such that it is seen as a vital piece of standard care, enabling and maintaining ongoing service improvement and system reforms.

The InnoWell Platform

In 2017, the Australian Government Department of Health (DOH) and InnoWell (a joint venture between the University of Sydney and PwC, Australia) entered into a 3-year funding agreement to deliver Project Synergy (2017-2020). Through a series of collaborative research trials, Project Synergy's objective is to develop and implement innovative HITs (including the InnoWell Platform) to enable improved mental health service delivery in Australia, facilitating better outcomes for people with lived experience, supportive others, health professionals, and service providers [9,20]. The funding agreement provided for the establishment of a research and development group as well as a product and technology group for the development of the InnoWell Platform.

As described in detail by Davenport et al [21], the co-designed InnoWell Platform was developed through Project Synergy (by InnoWell) to collect, score, store, and report clinical data back to consumers and their health professionals to promote person-centered care, self-management, early intervention, shared decision making, and routine outcome monitoring (Textbox 1, which is a variation of the description of the InnoWell Platform previously published by Hickie et al [9]). All consumers presenting for care to a service utilizing the InnoWell Platform as part of standard service delivery are offered the opportunity to use the InnoWell Platform. The InnoWell Platform utilizes multiple sources of information to develop a comprehensive understanding of a consumer's needs and to track progress over time, including web-based self-reported psychometric measures assessing a range of biopsychosocial domains (ie, psychological distress, suicidal thoughts and/or behaviors, social and occupational functioning, depressed mood, sleep-wake cycle, social connectedness) from both consumers and their health professionals as well as objective behavioral data collected via third-party integrations (eg, Fitbit). The multidimensional assessment results are reviewed collaboratively by the consumers and their health professionals to promote shared decision making and collaborative care and to facilitate routine outcome monitoring, clinical review, and coordinated care to ensure that all consumers receive the right care, first time.

Textbox 1. Description of the InnoWell Platform as listed on the Australian Register of Therapeutic Goods (ARTG ID 315030; software as a medical device, class 1).

"The InnoWell Platform is a customisable digital tool that assists assessment, monitoring and management of mental health issues, and maintenance of wellbeing. It does this by collecting personal and health information from consumers and their service providers. This information is stored, scored, and reported back to consumers and their health professionals to promote collaborative care. The clinical content is determined in collaboration with the service provider who invited the consumer to use the Platform. Importantly, the Platform does not provide stand-alone medical or health advice, diagnosis, or treatment. Instead, it guides and supports (but does not direct) consumers and their health professionals to decide what may be suitable care options. Importantly, all care aligns with the existing clinical governance (eg. policies and procedures) of the service provider."

Objectives

The primary objective of this study is to gather data through web-based surveys, semistructured interviews, and workshops with staff from the mental health services implementing the InnoWell Platform (eg, health professionals, service managers, and administrators) to evaluate and monitor the impact of embedding the HIT as part of standard service delivery, including (1) digital literacy and competence of the service staff in relation to implementation of the HIT in the service; (2) changes in the service associated with implementation of the HIT-enabled solution; and (3) the quality, usability, and acceptability of the solution. Importantly, the baseline data related to the design, development, and implementation of the InnoWell Platform as part of standard care in Australian mental health services are used to inform the ongoing development of both the HIT as well as the service model in which it is embedded, including implementation processes, for improved user adoption and future sustainment. Additional evaluation data will be captured longitudinally via service audits, user testing, and observational logs; however, reporting on these findings is beyond the scope of this paper.

Methods

Study Design

This is a prospective study employing web-based surveys, semistructured interviews, and workshops to identify potential barriers and facilitators for the implementation of an HIT (ie, the InnoWell Platform) and to measure the ongoing impact of implementing the HIT-enabled solution in participating mental health services within Australia. Importantly, before initiating the impact evaluation, the InnoWell Platform is configured for each participating service, ensuring that the solution meets the needs of all end users, from people with lived experience and their supportive others accessing care through to health professionals, service managers, and administrators, using well-established research and development co-design methodologies (such as service mapping, participatory design, knowledge translation, user testing, and rapid prototyping) [9,10,20-22].

Participating Services and Participants

All staff involved in the implementation of the InnoWell Platform in the service, including health professionals, service managers, and administrators, from *headspace* centers in Port Macquarie, Coffs Harbour, and Lismore; the Butterfly Foundation's National Helpline; and Open Arms–Veterans and Families Counselling (Sydney) were invited to participate in the impact evaluation study. Staff from the funding and/or governing bodies of the services (ie, service providers and/or primary health networks [PHNs]) who were associated with implementation were also invited to participate. This wide-ranging recruitment is critical to ensure that data are captured from stakeholders at all levels of participating services. Information about research activities, including web-based surveys, semistructured interviews, and workshops, was distributed via email to eligible participants by an implementation officer embedded within the services. In some services, awareness of the impact evaluation was also generated by the display of posters and flyers with details about the research activities. To avoid any perceived coercion, recruitment was passive such that a potential participant needed to contact a member of the study team (using details provided on all study advertisements) who then forwarded the Participant Information Sheet and Consent Form. This study was voluntary, and the participants chose to participate in as many or as few of the research activities as they chose.

Participant Procedures

Qualitative and quantitative data were collected via the web-based data capture application, REDCap (Vanderbilt University; Multimedia Appendix 1), semistructured interviews (Textbox 2), and a workshop (Textbox 3) with staff at

participating services at baseline (ie, preimplementation of the InnoWell Platform). The methods were aligned with the study objectives. Specifically, digital literacy and competence were explored through both web-based surveys and semistructured interviews. As this is reported at the individual level, it was not included in the workshop agenda. All methods were used to investigate the potential quality, usability, and acceptability of the InnoWell Platform as well as the anticipated impact of its implementation on the service. Unique to the semistructured interviews were questions regarding education and training topics that may be of use to the participants and to the consumers of their respective services.

Textbox 2. Excerpt of the baseline impact evaluation semistructured interview questions.

Topic: Use of the InnoWell Platform

Now, tell me what you think about the implementation of the InnoWell Platform in your service.

- What do you anticipate the impact to be on your practice (eg, more resources for consumers, increased collaboration with consumers regarding treatment planning, increased engagement in care from consumers, changes to efficiency of care, increased case load)?
- Why do you think this change will happen? How do you think this will happen?
- What do you anticipate the impact to be on your service (eg, more resources for consumers, improved team decision making, reduced wait times, improved access)?
- Why do you think this change will happen? How do you think this will happen?
- What do you anticipate the impact to be on your consumers (eg, more resources for consumers, improved ability to self-manage care, increased engagement in care from consumers)?
- Why do you think this change will happen? How do you think this will happen?

Textbox 3. Excerpt of the baseline impact evaluation workshop agenda.

Topic: Implementation within your service

Group discussion

- When thinking about the implementation of the InnoWell Platform in your service, what do you think will work well for you, the service, and/or your consumers?
- Why do you think this will work well?
- How do you think this will impact you, the service, and/or your consumers?
- What do you see as the value of this change/impact for you, the service, and/or your consumers (eg, time savings, financial savings, etc)?
- What might facilitate (eg, functionality, usability, sufficient training, necessary hardware, etc) the use of the solution for you, the service, and/or your consumers?
- What do you worry will

  not

  work well for you, the service, and/or your consumers?
- Why do you think this will be problematic?

These data collection methods were designed specifically for the purposes of this study and were not piloted before use. Importantly, before engaging in this study, all participants had received training on the InnoWell Platform, including both its functionality and clinical benefits. The participant procedures are repeated every 3 months for the duration of the implementation, the length of which is determined and agreed upon by InnoWell and the participating services; however, reporting on the longitudinal impact evaluation data is outside the scope of this paper.

A template of the web-based survey questions is provided in Multimedia Appendix 1. The surveys were adapted from an eHealth readiness scale developed by Phillips et al [23,24] to assess the readiness of health care teams to effectively and efficiently deliver care using HITs. Semistructured interview questions (Textbox 2) and the workshop agenda (Textbox 3) were designed to identify potential barriers and facilitators to successful implementation not previously uncovered during the preimplementation co-design process (LaMonica et al [10] provide information on the phased implementation strategy). In addition, the longitudinal collection of these data throughout implementation will facilitate revisions over time on the basis of a retrospective review and constructive feedback from services in which the InnoWell Platform is implemented and from the consumers who engage with the solution.

Data Analysis

The participant sample size is limited by the number of service staff within each mental health service; however, appropriate statistical analyses were conducted and reported based on the sample size for each service, and only aggregate data across services were used for the multidimensional statistical analyses.

Descriptive statistics were used to analyze all aspects of the web-based survey data. Given that the overall sample size was small (n=50), response options were collapsed for some analyses, combining *strongly agree* and *agree* as well as *strongly disagree* and *disagree*. Bivariate analyses using Fisher exact tests were used to evaluate group differences based on participating services, and a reliability analysis was conducted to evaluate the internal consistency of the web-based survey. The alpha level was <.05. SPSS version 24 (IBM Corp) was used for all analyses.

As only one workshop was conducted, a basic content analysis of the scribe notes was conducted by 2 researchers (HL and KB) to identify key service-level barriers and facilitators to implementation. In accordance with the qualitative data analysis processes used by our group [9,20,22], references were tallied, and those references with 3 or more independent tallies were considered to be a consistent theme. Semistructured interviews were audiorecorded, transcribed, and anonymized. Interpretation of the qualitative data from the semistructured interviews followed established thematic techniques [25]. Transcripts were reviewed by 2 research health professionals (HL and AM) to develop a coding framework outlining all key concepts. Transcripts were coded in NVivo 12 software using this framework. The coding followed an established iterative process of reading, coding, exploring the pattern and content of coded data, reflection, and discussion. Similarities and differences in opinion were examined, and differences were resolved through discussions to reach consensus on the coding framework. Themes were then organized by implementation barriers and facilitators for each identified group: (1) consumers accessing the service for support, (2) health professionals working at the service, and (3) the service. The research health professionals checked the themes against each other and back with the original transcripts to ensure that all relevant references had been collated. This process resulted in a thematic framework that was internally coherent and consistent.

Ethics

This research required multiple ethics approvals by various human research ethics committees (HRECs) because of the diverse organizational structures governing each of the mental health services involved in the impact evaluations. The governing bodies of some mental health services required applications to be submitted through their own internal HRECs (ie, the Department of Defence and Veterans' Affairs HREC project number 056-18), whereas others preferred that the required applications be submitted through the University of Sydney HREC (project numbers 2018/849 and 2018/962).

Results

Participants

A total of 50 staff members from 3 *headspace* centers (Port Macquarie, Coffs Harbour, and Lismore; n=18), Butterfly Foundation's National Helpline (n=8), and Open Arms–Veterans and Families Counselling (Sydney; n=24) who were trained to use the InnoWell Platform as part of standard service delivery consented to participate in the impact evaluation study. As this study was voluntary, those who consented were not mandated to complete any of the research activities, which resulted in differing rates of participation. Most participants (47/50, 94%) completed the web-based survey. In addition, most participants from Open Arms–Veterans and Families Counselling (17/24, 71%) also participated in the workshop and thus were not inclined to engage in a semistructured interview. In contrast, the variable work schedules of the staff at the Butterfly Foundation's National Helpline were more conducive to participation in the survey (6/8, 75%) and a semistructured interview (3/8, 38%) as opposed to a workshop. With regard to the *headspace* centers, participants were heavily engaged in the co-design of the InnoWell Platform (studies by LaMonica et al [10] and Davenport et al [21] provide more details) as well as education and training sessions in relation to how to use the InnoWell Platform simultaneously with this study and noted that they did not have the capacity to engage in the semistructured interviews. In addition, given the geographic spread of the participants in these centers, a group-based workshop was not feasible; therefore, use of the web-based surveys was key to ensure participation from this group (18/18, 100%). Importantly, despite variable participation rates in each research activity, methodological triangulation ensured that data capture was comprehensive and inclusive of all relevant stakeholders.

Web-Based Survey Outcomes

A total of 47 participants completed the web-based survey at baseline, representing diverse roles in the services (Table 1).

Table 1. Participants' (n=47) roles across services.

Role	Participants, n (%)
General psychologist	12 (26)
Social worker	10 (21)
Counselor	6 (13)
Service managers and administrators	4 (9)
Mental health nurse	2 (4)
Youth worker	2 (4)
Dentist	1 (2)
General practitioner	1 (2)
Other	9 (19)

Cronbach alpha was calculated for the 27 Likert-scale survey questions and indicated that the survey was acceptably reliable (α=.86). As shown in Table 2, the participants endorsed considerable value associated with using technology as part of their work and consistently *agreed* or *strongly agreed* that HITs have the potential to improve outcomes for consumers. Importantly, most respondents indicated that the proposed technology (ie, the InnoWell Platform) was appropriate for their services' consumers and that service staff were willing to implement the HIT for its intended purpose. Importantly, there was no notable difference in participants' perceptions of the role of the technology in mental health care or the appropriateness of the HIT on the basis of the participating service (Table 2).

Table 2. Differences in aggregated web-based survey responses from participants based on the participating service.

Question[a]	Strongly disagree or disagree, n (%)	Neutral, n (%)	Strongly agree or agree, n (%)	*P* value
I see the benefit of using technology as part of my work (n=47)	7 (15)	2 (4)	38 (81)	.55
How do you feel about this statement: "My organisation is making the best use of technology for mental health care" (n=47)	12 (26)	8 (17)	27 (57)	.48
Technology has made mental health care change too fast (n=46)	21 (46)	19 (41)	6 (13)	.58
My service feels it is part of our professional role to actively recommend technologies for mental health care and provide assistance to consumers (n=46)	6 (13)	15 (33)	25 (54)	.50
Our consumers' capability to use technology is aligned with how technology will be used in their mental health care (n=45)	11 (24)	15 (33)	19 (42)	.39
My service has a work culture that actively encourages the integration of technologies (n=45)	4 (9)	17 (38)	24 (53)	.83
My service's policies reflect a belief that technologies can improve consumer outcomes by providing more efficient and effective services (n=45)	4 (9)	14 (31)	27 (60)	.88
On average, consumers appear to have a positive experience with using technology as part of their mental health care (n=45)	5 (11)	19 (42)	21 (47)	.21
My service is ready to implement new technologies to enhance mental health care (n=45)	14 (31)	11 (24)	20 (44)	.98
The proposed technology (ie, InnoWell Platform) is appropriate for the consumers who are cared for in the service (n=45)	8 (18)	12 (27)	25 (56)	.08
There is a willingness within the service to implement the technology for its intended purpose (n=45)	2 (4)	12 (27)	31 (69)	.47

[a]Percentage totals for each row do not always sum up to 100% due to rounding error.

Most participants indicated they were *veryaware* (7/27, 26%) or *somewhat aware* (18/27, 67%) of HITs that support or directly provide mental health care, indicating a wide range of sources for learning about these types of technologies (Table 3).

Table 3. Participants' (n=47) sources of learning about technologies for mental health care.

Source	Participants, n (%)
Colleagues	34 (72)
Personal research	26 (55)
Professional development organizations	26 (55)
Training sessions conducted by the service	25 (53)
Websites	22 (47)
Consumers	20 (43)
Manager	16 (34)
Social media	15 (32)
Friends and family	13 (28)
Supervisor	13 (28)

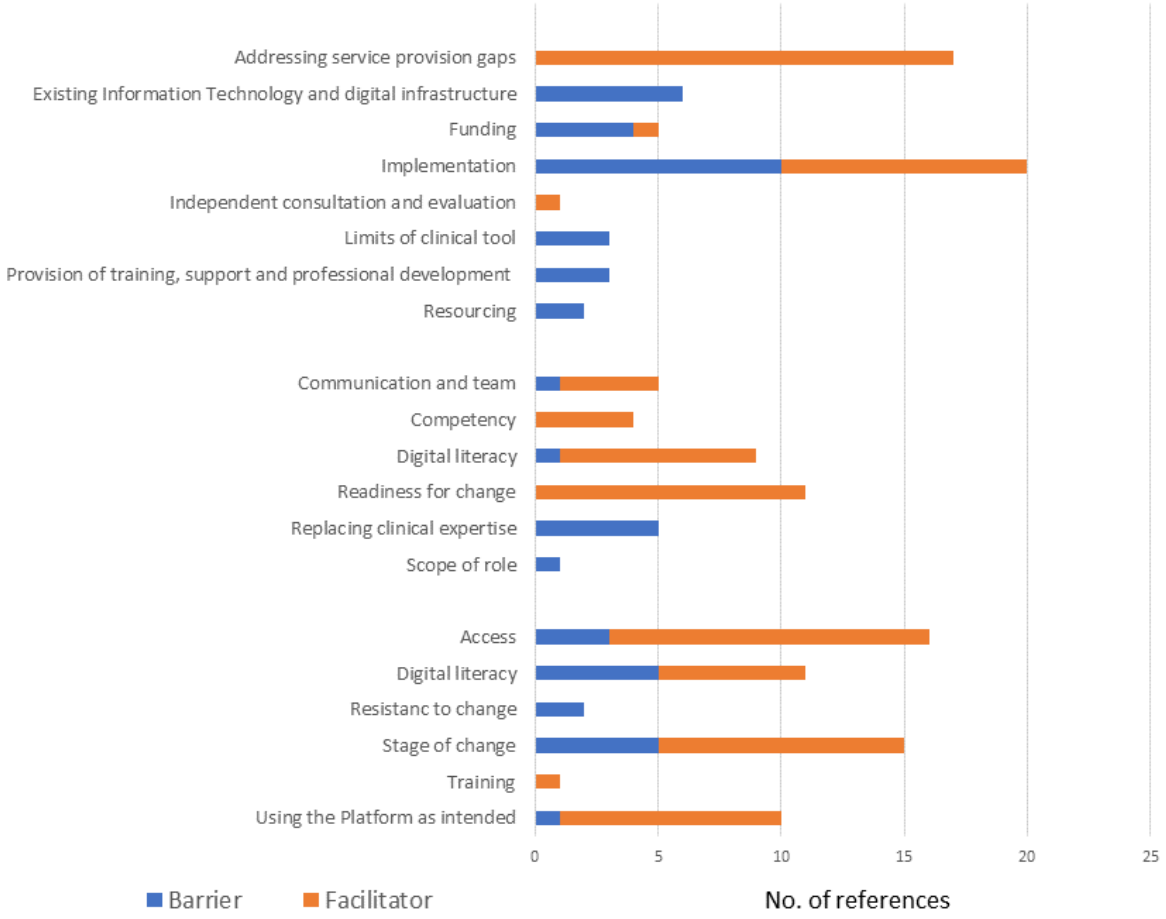
The frequency with which participants tried different technologies as part of their role was highly variable (Never: 6/47, 13%; Not very often: 16/47, 34%; and Sometimes: 25/47, 53%). The primary reasons for not trying technologies as reported by the 22 participants who responded "Never" or "Not very often" included a lack of time to experiment (6/22, 27%),

technological limitations of the service (5/22, 23%), and a lack of interest from consumers in relation to using technology as part of their mental health care (2/22, 9%), with the participants being given the option to choose all reasons that applied for this question.

Semistructured Interviews

Given the 16-hour workforce schedule (7 days a week), the 60-min semistructured interviews (n=3) were the preferred method of providing qualitative feedback for health professionals from the Butterfly Foundation's National Helpline. Qualitative themes were organized to reflect the barriers and facilitators of the implementation of the InnoWell Platform within the service. These barriers and facilitators contained 3 groups: (1) *consumer*, which included implementation factors (barriers or facilitators) that impacted the consumers of the service; (2) *health professional*, which included implementation factors that impacted the health professionals working at the service; and (3) *service*, which included implementation factors that were considered at a service level. The barrier and facilitator themes for each group (*consumer, health professional*, and *service*) are presented in Figure 1, with illustrative quotes provided in Multimedia Appendix 2. As displayed in Figure 1, facilitators to implementation were referenced more frequently (52 references) than barriers (39 references). A reference refers to the selection of content from the interviews that has been coded. References can be coded under more than one theme; in this case, they are counted as more than one reference. It should be noted that the sum of the references of the parent theme (ie, barriers) reflects the number of unique references for that theme. As references may have been coded to more than one subtheme (ie, digital literacy and readiness for change), the sum of references for each subtheme will not equate to the sum of references for the parent theme.

Figure 1. Codes and themes.



Consumer Barriers and Facilitators

For consumers accessing the service, the most commonly reported barrier and facilitator themes are related to *access* and *staging.* In terms of *access*, all participants felt that technology could promote better access for consumers to services, particularly in rural and regional areas, but such technologies might not be accessible in certain services, such as in hospital settings. The theme of *digital literacy* also overlapped with the theme relating to *access*, with all participants feeling that the InnoWell Platform might be more accessible to (and adopted by) young people, who were digital natives, whereas those "...who are a bit older...don't use internet" and "...they would need some time to adapt" (interview 1). One participant felt the provision of "some sort of *training* that is accessible, probably free, that's easy and not time consuming" would be important for consumers to help them to use the InnoWell Platform (interview 1). *Staging* related to both the consumer's clinical stage of help-seeking and their stage of change (as per the transtheoretical model [26]), with potential benefits noted for

both consumers who had previously received treatment and those who had not yet sought help as it might be "...a lot less invasive or intrusive or confronting" (interview 3).

Using the InnoWell Platform as intended was a common facilitator theme but was only referenced once as a barrier. All participants envisioned that technology could complement the support a consumer received by being a "...one-stop shop for resources" (interview 3) and by being used as a communication tool for services and for seeking help. However, 1 participant cautioned that it was important to be aware that some may "...twist things to make it appear they're okay to themselves" (interview 1).

Health Professional Barriers and Facilitators

Although the main implementation barrier identified for health professionals generally related to concerns that the tool could *replace clinical expertise*, participants denied this as a personal concern, noting that the InnoWell Platform may "...enrich the counseling side of things" (interview 1), "...free up the counselors" (interview 2), or "...supplement a counseling practice, in so far as helping them support people ahead of the contact with the therapist" (interview 3). Interestingly, all participants commented that they felt that they had a high level of *digital literacy* and *competency* in their role and were *ready for change*; however, 1 participant noted that the use of new technologies was outside the *scope of their role* in the service. Good *communication and team* environments were seen as vital to implementation. This feedback was not only from service management but also from colleagues as it created a culture of support, with one participant highlighting "I think it's everybody. It's just the culture" (interview 3).

Service Barriers and Facilitators

At the service level, the main barriers were associated with the interrelated themes of *implementation*, *existing information technology (IT) infrastructure*, *funding*, and *resourcing*. The first 2 participants had major concerns about the current funding situation, the "clunky" (interview 1) existing infrastructure—highlighting that "...we are pretty over extended as it is" (interview 1). All participants felt that technology could *address service gaps* "...quite well, especially (for) those who live regionally and (are on) waitlists" (interview 1). In fact, *addressing service gaps* was the main facilitator theme at the service level highlighted by participants. The third interview, however, took place immediately after the introduction of new IT systems, commencement of new funding, and the early implementation of the InnoWell Platform. This participant had very positive views of *implementation* and felt that the service was being quite "innovative...trying to include or integrate technology as part of what they offer..." (interview 3). Positive views were attributed to the InnoWell Platform being supported through proper resourcing, implementation, planning, and training.

Workshop Themes

Owing to highly variable work schedules (ie, 16-hour schedule) and the distance between participating services, the baseline workshop was only conducted at Open Arms (Sydney) with 17 participants, including health professionals, service managers, and administrators. The 90-min workshop was titled, *Anticipating what is to come: Implementation of the InnoWell Platform within the Open Arms (Sydney) Centre*, and the agenda (Textbox 2) focused on identifying potential barriers and facilitators to successful implementation of the technology.

The primary theme (15 tallied references) that emerged from the workshop related to an immediate need to clarify or establish procedures to facilitate implementation of the HIT and to allocate responsibility to staff for new tasks resulting from that implementation. For example, participants were asked to clarify the following:

- "What are the (consumer) allocation processes within the InnoWell Platform?"
- "How is the decision made whether the InnoWell Platform is offered to individuals or not?"
- "How will (the InnoWell Platform) interface with national intake?"
- "How are we keeping track of how many (consumers) are being offered and saying yes/no?"
- "What happens when consumers leave the service but re-engage again a few months later?"
- "Who will assess eligibility for the service?"

At the end of the workshop, the service leadership agreed to put in place the following mitigation strategies before implementation: the development of a tracking system to log consumer uptake of the InnoWell Platform, clarification of eligibility screening criteria and procedures, updated intake assessment requirements for consumers who had previously accessed care through the service, data requirements for the electronic medical records, timelines for allocating consumers who completed their intake in the InnoWell Platform to a health professional, standard procedures for responding to moderate-to-high levels of suicidal thoughts and/or behaviors identified in the InnoWell Platform, and procedures for contacting consumers with incomplete data in the InnoWell Platform. No other themes emerged from the content analysis.

Discussion

Benefits of the Evaluation

HIT-based innovation efforts are increasingly recognized as a way to support and drive mental health services reform for improved quality and clinical outcomes. Integral to this process is the need to continuously evaluate the quality, acceptability, and usability of these HIT-enabled solutions, encompassing both the technology itself and the service models in which they are implemented. Evaluation provides the necessary information to further develop and refine the HIT as well as to understand the interactions with and impact of the HIT by the mental health service staff (health professionals, service managers, and administrators) to reform or refine the service model. Our impact evaluation, including web-based surveys, semistructured interviews, and a workshop, facilitated the rapid iterative development of the HIT and the service model in which it was embedded and is consistent with a usability engineering approach to software evaluation.

Importantly, our findings highlight the value of our impact evaluation methods as a means to discover potential barriers to implementation. Although our group employs a 4-phase, evidence-driven implementation science strategy designed to systematically guide the successful implementation of HITs in mental health services [10], several potential barriers remained unrecognized and unmitigated. As part of this strategy, all participating sites are included in a thorough co-design process, often cited as a primary strategy to facilitate successful implementation [11-13], to ensure the appropriateness and acceptability of the HIT-enabled solution for the service, including consumers, health professionals, and service administrators. Despite using established strategies to mitigate potential barriers to implementation, our data highlight several factors yet to be addressed. For example, specifically as a result of this research, service-level processes were developed by a participating service before the implementation of the HIT-enabled solution with the aim of minimizing workflow disruptions for impacted staff, a well-known risk to successful implementations. This included establishing procedures and allocating responsibility to staff for new tasks resulting from the implementation, such as determining the eligibility for access to the InnoWell Platform based on desired clinical services (eg, individual therapy vs family counseling), monitoring consumers' engagement with the InnoWell Platform (ie, completion of the web-based multidimensional assessment) to determine when they are ready to be allocated to a health professional, and overseeing the allocation of consumers to a health professional based on the clinical need identified through the InnoWell Platform.

The unique use of methodological triangulation (ie, mixed methods) ensured that data collection was comprehensive and inclusive of all stakeholders to drive an enhanced understanding of the potential impacts of implementation. The triangulation of data has previously been used to evaluate the implementation of HITs among health service professionals [27,28]. This method not only allows for a richness of qualitative and quantitative data capture [29] but also ensures that outcomes are measured at all levels of the health services, including all key stakeholders. In relation to the latter, the use of mixed methods in this study was invaluable as it facilitated the participation of staff members from different service models (ie, a web-based helpline operating on a 16-hour schedule vs traditional face-to-face counseling services operating during normal business hours), thus ensuring both breadth (via the surveys) and depth (via the semistructured interviews and workshop) of evaluation from a broad range of participants. Not surprisingly, the rate of participation (47/50, 94% of consented participants) was highest for the web-based survey, with participation in the workshops and semistructured interviews being largely dictated by the service model and schedule. The application of methodological triangulation in this case was important to determine whether the InnoWell Platform was likely to be effective and whether further co-design was required to improve the alignment of the HIT with the service's goals for reform. In future research, the methods will be further strengthened by the inclusion of service audits, user testing, and observational logs.

Barriers to and Facilitators of Implementation

There was consistent agreement across services regarding the potential benefits of technology as part of mental health care service provision, with most respondents on the web-based surveys indicating that they believed that technologies could improve outcomes by providing more efficient and effective services (27/45, 60% of the participants chose "agree" or "strongly agree"). This aligns with existing literature highlighting the potential for HITs to improve consumer outcomes. For example, several trials have shown that a personal health record can significantly improve outcomes and increase the use of routine preventive medical services [30-32]. A personal health record shifts the management of health data from health professionals and/or services to the consumer, enabling active participation in care. They frequently include decision support tools to help consumers manage chronic health conditions and are able to integrate with other data sources, such as electronic medical records, to support coordinated, person-centered care [33].

It was also agreed that HITs have the potential to improve access, particularly for consumers in regional, rural, and remote areas, and address gaps in service provision. Increasing funding for these types of services also signals a growing acceptance of HIT-enabled models of care [34,35]. Within the health sector, it is agreed that technology can help consumers overcome access barriers, including time constraints, transportation problems, and cost [36]. Consideration of the *digital divide*, however, is critical to ensure that those who may not have easy access to technology (eg, internet, smartphone) or the skills required to use it (eg, older adults) are not excluded from receiving mental health care delivered via HITs. To that end, our results indicate that the digital literacy of consumers is both a potential barrier to and facilitator of implementation, with some respondents questioning whether consumers had the required digital literacy to engage with the InnoWell Platform as part of their care (11/45, 24% of the participants chose "disagree" or "strongly disagree"; 15/45, 33% chose "neutral"; and 19/45, 42% chose "agree" or "strongly agree"). As the study participants worked in services providing care to varied consumer groups in different regions of Australia (urban and regional), it is possible that sociodemographic factors, such as age, gender, and socioeconomic status, may explain the latter finding. Data from a substudy of the Bettering the Evaluation and Care of Health program indicate that there is an inverse relationship between age and internet usage for web-based health information. Furthermore, socioeconomically disadvantaged patients were found to be less likely to use the internet, access health information on the web, or obtain health information related to a condition being managed by their general practitioner [37]. Recommendations to bridge the digital divide include (1) technology subsidies for low-income consumers, (2) user-friendly technologies appropriate for consumers with physical and intellectual disabilities, and (3) demonstrations and training opportunities for consumers who might otherwise not have the opportunity to learn how to use available technologies [38].

The digital literacy of health professionals was also noted to be an important factor to consider during implementation. Although

the health sector is rapidly embracing technology as an integral part of effective work practices and service provision, the digital literacy of health professionals may not be sufficient to maximize the potential of HITs. For example, a study of 10,000 nurses in Australia found low levels of use of computer-based applications as well as poor confidence in using such tools. Strikingly, less than 40% of respondents in the study indicated that they "frequently" or "always" used HITs (eg, accessing patient records and results) as part of their work [39]. Furthermore, a recent systematic review found low levels of digital literacy among pharmacists in Australia, Canada, and the United States [40]. To realize the full potential of HITs, investment is urgently needed in the training and professional development of health care staff to ensure competence and confidence in using HITs, the latter of which has shown to improve engagement with technology [41].

Importantly, most participants believed that the InnoWell Platform was appropriate for their consumers (25/45, 56% of the participants chose "agree" or "strongly agree"); however, nearly one-third of the respondents did not believe that their service was ready to implement the HIT (14/45, 31% of the participants chose "disagree" or "strongly disagree"). Participants emphasized the need to establish clear processes for implementation, particularly in relation to how the InnoWell Platform will integrate with or change current workflows, including screening consumers for service eligibility, creating digital case files in existing electronic medical records, allocating consumers to health professionals, and responding urgently to risk identified via the HIT. These concerns align with existing literature, which highlights several factors that can impact organizational readiness to adopt new technologies, including (1) leadership both at the executive and local level to help ensure alignment between the technology and the service mission as well as to foster organizational support for the HIT-enabled solution [12-15], (2) misalignment between conventional service models and workflows with the HIT-enabled solution [42], (3) limitations in the availability of appropriate resources (eg, information and communications technology) and personnel [12,15], and (4) required interoperability with other existing technology systems used within the service [12].

Our results also showed that the readiness of health professionals to adopt this type of HIT as part of their practice may be a key facilitator for implementation. Most respondents indicated a willingness to implement the HIT-enabled solution (31/45, 69% of the participants chose "agree" or "strongly agree"), likely reflecting the benefits of the proceeding co-design process as a means to foster buy-in and acceptance among the health professionals involved in this study. With that being said, staff members' resistance to change and negative staff attitudes are consistently reported in the literature as potential barriers to implementation [11,12]. Furthermore, HITs can be perceived as impersonal as they reduce the need for face-to-face interactions with consumers [43]. Effective education and training in the context of continuous on-the-ground support is a critical mitigation strategy [12-15]. Similarly, establishing a clear communication strategy to support consistent messaging to staff, service users, and other key stakeholders is key to a successful implementation [12].

Limitations

This study has some limitations in relation to sample size, which are important to note. In particular, as a product of differing service models, only 3 semistructured interviews were conducted with participants from the Butterfly Foundation's National Helpline, and only a single workshop was run with participants from Open Arms (Sydney). Although the aim had been to utilize all methodologies across participating services, the consistency in the themes identified suggests that this did not notably skew or impact the findings. Rather, we present formative results that will be further explored in future research projects, both at the outset of new implementations as well as longitudinally, as described in the Future Directions section.

Future Directions

Future services participating in this impact evaluation research may include services for children and their families, specialist youth mental health services, adult staged-care services, older persons mental health, and general practice, allowing for the collection of evaluation data of greater depth and breadth. Furthermore, as mentioned in the Methods section, the impact evaluation data described herein will be collected quarterly for the duration of the implementations and will be complemented by service audits, user testing, and observational logs. These longitudinal data will (1) facilitate ongoing iterative co-design and refinement of our HIT-enabled service model; (2) provide valuable insights into the impact of the implementation on consumer outcomes, health professional practices, and key service-level performance indicators, such as safety, satisfaction and acceptability, appropriateness, efficiency, accessibility and equity, effectiveness, continuity and coordination, and competence and capability; and (3) support the evaluation of social return on investment (ie, the social, environmental, and/or economic value) of our HIT-enabled service model [44].

Conclusions

The implementation of HIT-enabled solutions in services is inherently disruptive as they bring change to conventional practice for all stakeholders (eg, health professionals, service managers, and administrators). Despite the extensive co-design methods used in the preimplementation phase [10], our impact evaluation methods allowed for the identification of barriers and facilitators that had not otherwise been uncovered, providing a critical opportunity for mitigation to reduce the potential for implementation failure. Notably, the results of an American Medical Informatics Association Workshop highlighted that failures in the implementation of HITs were largely driven by managerial rather than technical factors [45]. Ongoing collaboration and research and development between researchers and participants (eg, health professionals, service managers, and administrators) to facilitate the iterative co-design and development of the HIT and, perhaps more importantly, the service model in which it is embedded are critically important components for the success of implementation and sustainability for mental health services reform.

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Authors' Contributions

The authors IH and TD were integral in securing funding to support the study. The study was designed by TD and HL, with subsequent revisions and contributions by KB. All data analyses were conducted by HL, AM, and KB. All authors contributed to and have approved the final manuscript.

Conflicts of Interest

Professor IH was an inaugural commissioner on Australia's National Mental Health Commission (2012-2018). He is the Co-Director, Health and Policy at the Brain and Mind Centre (BMC), University of Sydney. The BMC operates an early-intervention youth service at Camperdown under contract to *headspace*. He is the Chief Scientific Adviser to, and a 5% equity shareholder in, InnoWell Pty Ltd. InnoWell was formed by the University of Sydney (45% equity) and PwC (Australia; 45% equity) to deliver the Aus $30 million (US $21.6 million) Australian Government–funded Project Synergy (2017-2020), a 3-year program for the transformation of mental health services and to lead transformation of mental health services internationally through the use of innovative technologies. The other authors have nothing to disclose. The source of funding does not entail any potential conflicts of interest for the other members of the Project Synergy research and development team nor for any other members of the governing bodies, such as PHNs and lead agencies, and health services involved in the study.

Multimedia Appendix 1
Web-based survey template.
[DOCX File , 116 KB - formative_v4i11e18759_app1.docx]

Multimedia Appendix 2
Codes and themes.
[DOCX File , 20 KB - formative_v4i11e18759_app2.docx]

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Abbreviations

BMC: Brain and Mind Centre
CBT: cognitive behavioral therapy
DOH: Department of Health
HIT: health information technology
HREC: human research ethics committee
IT: information technology
PHN: primary health network

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Original Paper

Early-Stage Feasibility of a Mobile Health Intervention (Copilot) to Enhance Exacerbation-Related Self-Management in Patients With Chronic Obstructive Pulmonary Disease: Multimethods Approach

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Abstract

Background: There is an emergence of mobile health (mHealth) interventions to support self-management in patients with chronic obstructive pulmonary disease (COPD). Recently, an evidence-driven mHealth intervention has been developed to support patients with COPD in exacerbation-related self-management: the Copilot app. Health care providers (HCPs) are important stakeholders as they are the ones who have to provide the app to patients, personalize the app, and review the app. It is, therefore, important to investigate at an early stage whether the app is feasible in the daily practice of the HCPs.

Objective: The aim of this study is to evaluate the perceived feasibility of the Copilot app in the daily practice of HCPs.

Methods: A multimethods design was used to investigate how HCPs experience working with the app and how they perceive the feasibility of the app in their daily practice. The feasibility areas described by Bowen et al were used for guidance. HCPs were observed while performing tasks in the app and asked to *think aloud*. The System Usability Scale was used to investigate the usability of the app, and semistructured interviews were conducted to explore the feasibility of the app. The study was conducted in primary, secondary, and tertiary care settings in the Netherlands from February 2019 to September 2019.

Results: In total, 14 HCPs participated in this study—8 nurses, 5 physicians, and 1 physician assistant. The HCPs found the app acceptable to use. The expected key benefits of the app were an increased insight into patient symptoms, more structured patient conversations, and more tailored self-management support. The app especially fits within the available time and workflow of nurses. The use of the app will be influenced by the autonomy of the professional, the focus of the organization on eHealth, costs associated with the app, and compatibility with the current systems used. Most HCPs expressed that there are conditions that must be met to be able to use the app. The app can be integrated into the existing care paths of primary, secondary, and tertiary health care settings. Individual organizational factors must be taken into account when integrating the app into daily practice.

Conclusions: This early-stage feasibility study shows that the Copilot app is feasible to use in the daily practice of HCPs and can be integrated into primary, secondary, and tertiary health care settings in the Netherlands. The app was considered to best fit the role of the nurses. The app will be less feasible for those organizations in which many conditions need to be met to use the app. This study provides a new approach to evaluate the perceived feasibility of mHealth interventions at an early stage and provides valuable insights for further feasibility testing.

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KEYWORDS

mobile health; mHealth; mobile app; COPD; exacerbation; self-management; self-care

Introduction

Background

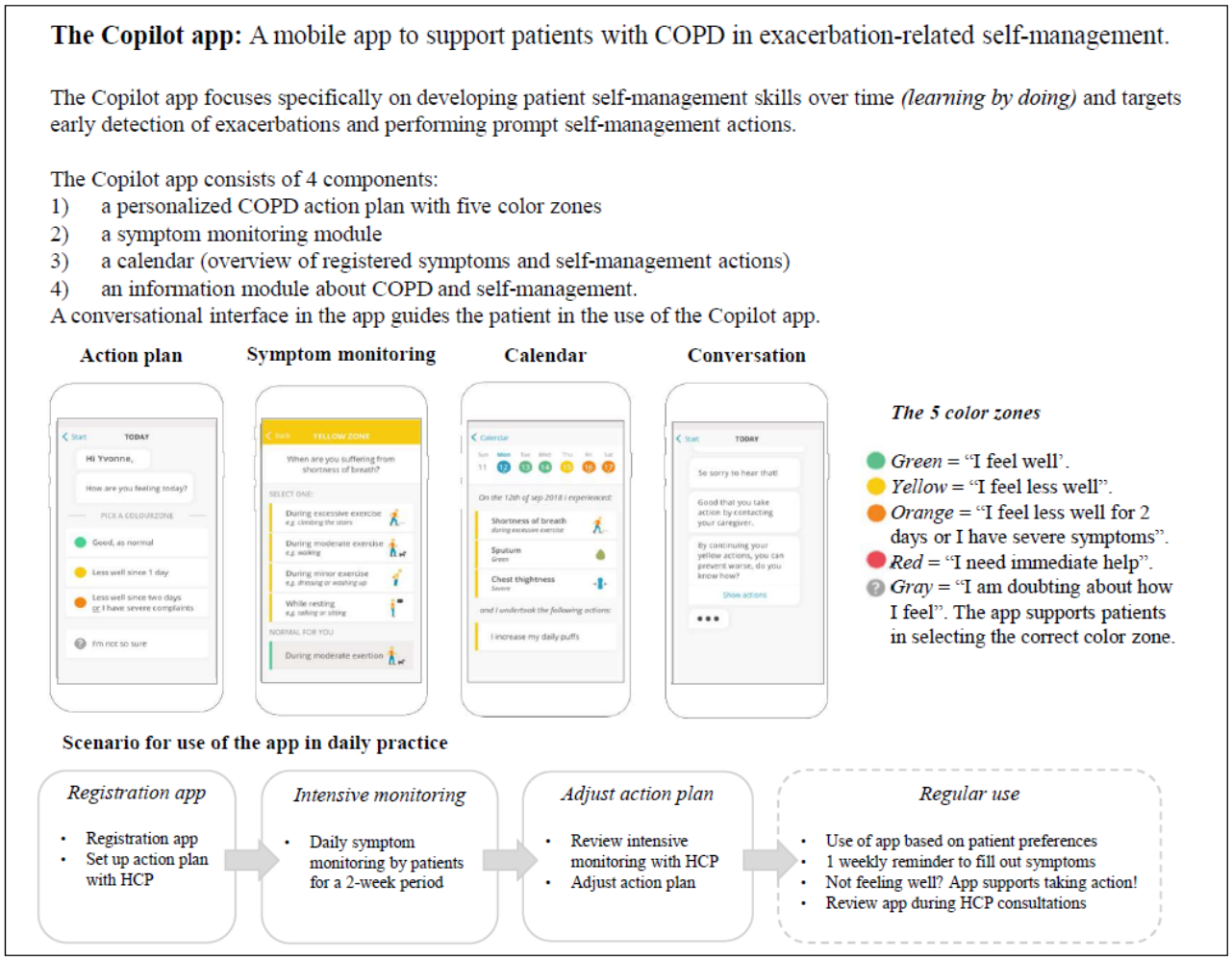
Chronic obstructive pulmonary disease (COPD) is a highly prevalent disease and a major cause of mortality worldwide [1,2]. Exacerbations are important events during the course of COPD because they accelerate the decline in lung function [3], negatively affect quality of life [4,5], and lead to increased mortality and high socioeconomic costs [6,7]. Self-management is important to reduce the impact of COPD exacerbations on both patients and society. Self-management is defined as "an individual's ability to detect and manage symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic condition" [8]. Over the past years, research has increasingly focused on exacerbation-related self-management interventions, as they have shown to have positive effects on quality of life and hospital admissions [9,10]. In this context, the use of mobile health (mHealth) is considered to be promising to engage patients in their own health and to change health behaviors [11-13].

Current eHealth and mHealth interventions often focus on telemonitoring strategies to reduce the impact of exacerbations [14-19]. Although positive outcomes were found for telemonitoring, the results are thus far inconclusive because of the poor quality of the studies and the heterogeneity among the studies [15,18,19]. The inconclusive results might also be explained by the lack of focus on enhancing self-management skills, as the decision-making process is mostly professional based. mHealth interventions aimed at facilitating, supporting, and sustaining self-management in patients with COPD have shown to improve quality of life and levels of activity; however, no firm conclusions could be drawn from them [13]. Recently developed mHealth interventions focusing on self-management have shown variable results. Farias et al [20] showed that using telehealth technologies to enhance adherence to a COPD action plan resulted in faster exacerbation recovery and decreased number of COPD-related emergency department visits and hospitalizations. Another mHealth tool that supports self-management of exacerbations showed no positive effects on exacerbation-free time, health status, and health care utilization [21]. However, given the proven effectiveness of self-management interventions in patients with COPD, it could be expected that mHealth interventions supporting patients in self-management can be effective in reducing exacerbation impact.

Recently, an evidence-driven mHealth intervention has been developed in the Netherlands to support patients with COPD (the end users) in exacerbation-related self-management—the Copilot app. The Copilot app is a mobile app that targets the early detection of exacerbations through self-monitoring and performing prompt actions by using individualized action planning. The Copilot app consists of 4 components: (1) a personalized COPD action plan, (2) symptom monitoring, (3) an overview of registered symptoms and undertaken self-management actions, and (4) an information module about COPD and self-management. The Copilot app focuses specifically on developing patient self-management skills over time (*learning by doing*) without real-time monitoring by health care providers (HCPs). Nevertheless, the HCPs are important stakeholders as the Copilot app requires a case manager role from HCPs. The role of the HCPs is to provide the app to patients, instruct patients on how to use the app, set up a personalized action plan together with a patient, and evaluate the patient's condition based on registrations in the app during consultations. The app can be provided by HCPs across health care settings. The Copilot app was developed by following a user-centered design that included several phases of usability testing [22]. The usability of the Copilot app for patients was considered to be good [22]. More information about the Copilot app is provided in Figure 1.

An important next step is to investigate whether the Copilot app can work within the daily practice of HCPs by evaluating how HCPs perceive the feasibility of the Copilot app [23]. Evaluating feasibility within the daily practice of HCPs at an early stage helps to determine whether the Copilot app is appropriate for further testing and to identify what changes are needed and how they might occur [23]. Although patients with COPD and HCPs are both crucial stakeholders in feasibility evaluation, adequate personalization of the app and evaluation of the patient's condition by HCPs is essential for safe and effective self-management by patients using the Copilot app [24,25]. Therefore, early feasibility evaluation in the daily practice of the HCPs should precede further longitudinal feasibility testing among patients. On the basis of this step, essential design input for optimization of the Copilot app can be generated and a substantial part of the feasibility problems in the daily care by HCPs can be eliminated before further testing.

Figure 1. The Copilot app. COPD: chronic obstructive pulmonary disease; HCP: health care provider.



Objectives

The aim of this study is to evaluate the perceived feasibility of the Copilot app in the daily practice of HCPs.

Methods

Study Design

A feasibility study with a multimethods design was used to investigate how HCPs experience working with the first version of the Copilot app and how they perceive the feasibility of the app in their daily practice. On the basis of the work by Bowen et al [23], feasibility areas relevant for this early-stage feasibility evaluation were used for guidance. This study evaluates how HCPs react to the Copilot app (acceptability); the extent to which the Copilot app is likely to be used by HCPs (demand); the extent, likelihood, and manner in which the Copilot app can be used by HCPs as planned and proposed (implementation); the extent to which the app can be used by HCPs in their routine daily practice considering the available resources (practicality); and the extent to which the Copilot app can be integrated within the context of Dutch health care settings (integration) [23]. A one-time interactive session was conducted to observe how HCPs interacted with the app. HCPs were observed while performing tasks with the app and asked to *think aloud* to verbalize initial perceptions and feelings toward the app, clarify their process of decision making, and express experienced problems [26,27]. Afterward, a standardized usability questionnaire was used to investigate how HCPs perceived the usability of the app, and semistructured interviews were conducted with HCPs to further explore how they perceive the feasibility of the app. The study was conducted in primary, secondary, and tertiary care settings in the Netherlands from February 2019 to September 2019. The study was approved by the Medical Ethics Research Committee of the University Medical Centre Utrecht (18/831).

Study Population

A purposive sample of HCPs who have a case manager role in COPD care was selected from primary, secondary, and tertiary care settings in the Netherlands. Case management was defined as physicians or nurses who provide ongoing and/or follow-up self-management support during patient consultations [28]. Eligible HCPs were pulmonologists, general practitioners, respiratory nurses, respiratory nurse specialists, physician assistants, and primary care nurses, with a minimum work experience of 1 year and employment at their present organization for at least one year. The 1-year cutoff point was considered relevant in providing meaningful insights into the feasibility areas. The maximum variation in profession and work setting was pursued to select a sample that adequately represents the HCPs providing self-management support in Dutch COPD

care and to increase the likelihood of capturing different perspectives in the findings. On the basis of the guidance for evaluating the use of apps in general, a minimum of 10 HCPs were approached [27]. HCPs were included until saturation was reached for acceptability, demand, and implementation. Practicality and integration vary greatly across various health care organizations; therefore, it was not considered feasible to achieve saturation in these areas of focus using this study design. Therefore, data collected on practicality and integration are only described in this study.

Recruitment and Informed Consent

HCPs were approached by email or telephone to participate in this study by 2 researchers (YK and TH). Four HCPs were approached based on their expressed interest during participation in previous studies related to the development of the app, whereas others were recruited through local COPD networks. The HCPs received an invitation to participate in the study by email. A reminder was sent after 1 week in case of nonresponse. In case of continued absence of a response, the HCPs were contacted within a week by phone to determine their interest to participate in the study. The HCPs willing to participate received further study information and an informed consent form. An appointment was scheduled at the place of employment of the HCPs, and the informed consent form was signed during the appointment. Recruitment started initially with 5 HCPs to initiate data analysis. Further recruitment was determined based on ongoing data analysis and data saturation for acceptability, demand, and implementation.

Data Collection

Data were collected during a single, 1-hour session following a stepwise procedure. The stepwise procedure is described in the following sections.

Step 1: Interactive Session (Observations and the Think Aloud Method)

Before starting the interactive session, participants were informed about the study procedure and received further information about the Copilot app, the scenario for use of the app in daily practice, the intended role of both HCPs and patients, and the developmental stage of the app (Multimedia Appendix 1). Furthermore, the researcher walked through the 4 components of the app together with the participants. The participants were then asked to read a fictional patient case together with a set of tasks developed by the research team (Multimedia Appendix 2). These tasks focused on personalizing the action plan, adjusting the action plan, and evaluating the overview of registered symptoms and actions in the app. The participants were asked to perform these tasks in the app and were instructed and stimulated to *think aloud* while performing these tasks [26,27]. Almost all HCPs used the first version of the Copilot app. In the final interview, an updated version of the Copilot app was used, in which minor changes were made to improve usability. No major changes were made to the content and functions of the app; therefore, the influence of these changes on study outcomes was considered to be minor.

Step 2: The System Usability Scale

After working with the app, participants were asked to fill in the validated 10-item System Usability Scale (SUS) to obtain an overall view of the usability of the app for HCPs [29]. Each item was scored on a 5-point Likert scale, and all items were converted to a total score (range 0-100; a score >70 is considered to be acceptable) [29,30]. Although investigating usability was not the objective of this study, usability problems could have been experienced by participants who worked with the first version of the Copilot app. The perceived usability by HCPs was considered to be an important factor that could influence the adoption of the app by HCPs in daily practice and was therefore evaluated roughly in this study as well [31].

Step 3: Semistructured Interview

A semistructured interview was conducted to investigate perceptions toward the feasibility of the Copilot app in daily practice. A topic list was developed based on the 5 areas of focus and their related outcomes of interest [23]. Questions that were formulated by Bowen et al [23] to illustrate the areas of focus and the outcomes of interest were used as a basis for formulating interview questions. The topic list is further detailed in Multimedia Appendix 3. During and directly after the interviews, memos were created to describe observations, reflect on methodological issues, and capture initial thoughts related to theoretical concepts. Insights gained during the interviews were introduced in subsequent interviews, leading to data saturation.

Step 4: Baseline Questionnaire

After finishing the interview, participants were asked to fill in a questionnaire to collect baseline characteristics.

The stepwise procedure of data collection is further detailed in Table 1 and Multimedia Appendix 1.

Table 1. Stepwise data collection procedure related to the areas of focus and outcomes of interest.

Method and area of focus	Outcome of interest
Step 1: interactive session	
Implementation[a]	Degree of execution of tasks and success or failure of execution of tasks
Step 2: SUS[b]	
Acceptability[c]	Satisfaction with the app
Demand[d]	Intention to use the app
Implementation	Degree of execution of tasks
Step 3: interview	
Acceptability	Satisfaction with the app, perceived appropriateness, and fit within the organizational culture
Demand	Perceived demand and intention to use the app
Implementation	Degree of execution of tasks, success or failure of execution of tasks, and factors affecting implementation ease or difficulty
Practicality[e]	Expected benefits and burden for end users and ability of HCPs[f] to carry out tasks in their routine daily practice
Integration[g]	Perceived fit with local care infrastructure at the patient and organizational level and perceived sustainability at the patient and organizational level
Step 4: baseline questionnaire	Profession, age, work experience, size of organization, amount of patient consultations for COPD[h] in a week, average time available for patient consultations, disease severity of patients with COPD in daily care, current use of written action plan, current use of mobile health

[a]Implementation: the extent, likelihood, and manner in which the Copilot app can be used by health care providers as planned and proposed.

[b]SUS: System Usability Scale.

[c]Acceptability: how the health care provider reacts to the Copilot app.

[d]Demand: To what extent is the Copilot app likely to be used by the health care provider.

[e]Practicality: To what extent the Copilot app can be used by health care providers in their routine daily practice considering the available resources.

[f]HCP: health care provider.

[g]Integration: to what extent can the Copilot app be integrated in Dutch primary, secondary, and tertiary care settings.

[h]COPD: chronic obstructive pulmonary disease.

All sessions were conducted by 1 researcher (YK or TH) who guided the interactive sessions and conducted the interview. The whole procedure was video recorded to observe the hand interaction of participants with the app and to audio record verbalizations during the interactive session and the interview. In addition, the researcher made notes on observed user problems and relevant verbalizations of the participants while they were working with the app. Before starting the data collection, 2 pilot sessions with professionals in COPD care were conducted to investigate whether participants understood the procedure and questions, to determine whether the questions resulted in relevant answers, and to determine whether the stepwise data collection procedure fitted in a 1-hour session. Findings of the pilot sessions were used to modify data collection procedures by reducing the set of tasks that HCPs had to perform, by adjusting the information about the app and study procedure, and by merging interview questions that resulted in similar answers. The results of the pilot sessions were not included in this study. Practical issues that arose during the study resulted in iterations in the data collection guideline (Multimedia Appendix 1).

Data Analysis

Data from the interactive sessions and semistructured interviews were analyzed according to a thematic analysis as described by Braun and Clarke [32]. Video recordings were reviewed for usability issues and categorized according to the type of problem. All video recordings, including both the *think aloud* comments of the interactive sessions and the interviews, were transcribed verbatim. In total, 13 hours of video recordings were transcribed verbatim, resulting in 230 pages of transcription. Data analysis was supported by NVivo 11.0 software (QSR International Pty Ltd Version 11). The analysis took place in a cyclic process, alternating data analysis with data collection. Data were analyzed by 2 researchers (YK and TH) and were discussed with a third researcher (SV).

First, the 2 researchers independently read the transcripts to obtain an overall picture and noted initial ideas on relevant themes. Second, the transcripts were reread in more detail, and initial codes were linked to meaningful paragraphs by both researchers and discussed afterward to reach consensus. Next, identified codes were brought under potential themes and were reviewed for correspondence to the coded paragraphs, generating a thematic map of the analysis. Finally, potential themes were further refined, and clear definitions were generated for each theme. The third researcher was involved from the stage at which potential themes were reviewed, by coding a selection of data and participating in discussions on the final definition of themes. Interpretation of the data was discussed with experts

in the fields of nursing science, self-management, and mHealth (JT, MS, and LS), which contributed to the credibility of the study [33]. Memo writing supported the data analysis process. The confirmability of the study was enhanced by peer review of the methodological quality by an external expert on qualitative research (SV) [33].

Data from the SUS and the baseline questionnaire were analyzed with SPSS 25.0 (IBM Corporation) using descriptive statistics.

Results

Baseline Characteristics of the Participants

A total of 14 HCPs (9 females and 5 males) participated in this study, including 8 nurses, 5 physicians and 1 physician assistant recruited from 5 primary, 7 secondary, and 2 tertiary care settings. The baseline characteristics of the participants are presented in Table 2. A total of 11 HCPs currently used written COPD action plans in their daily care to some extent, varying from barely using action plans to integrating action plans in regular care. A total of 10 HCPs had experience with the use of digital technology in COPD care; however, in most cases, technology was only used occasionally or within a study context. Maximum variation was achieved for profession, work setting, age, work experience, patient category most frequently seen by the HCP based on disease severity, number of patient consultations for COPD during a week, and organization size.

Table 2. Baseline characteristics of the participants.

ID	Age range (years)	Profession	Setting	Work experience (years)	Patient category[a] based on GOLD[b] stage	Patient consultations per week	Consultation duration (minutes)	Organization size[c]	Use of written action plan	Set up action plan (minutes)	Use of digital technology in COPD[d] care
R01	30-39	Respiratory nurse	Hospital	2	3-4	20	30	251-1000	Yes	30	No
R02	50-59	Primary care nurse	General practice	30	2-3	15	45	26-50	No	N/A[e]	Apps
R03	50-59	Respiratory nurse	Hospital	6	3-4	28	20	>1000	Yes	15	Telehealth
R04	40-49	Respiratory nurse	Hospital	12	3-4	21	30	101-250	Yes	30	Telehealth
R05	30-39	Pulmonologist	Hospital	7	3-4	15	10	>1000	No	N/A	eHealth and apps
R06	50-59	Respiratory nurse specialist	Hospital	20	3-4	70	20	>1000	Yes	10	No
R07	40-49	General practitioner	General practice	7	1-2	4	10	101-250	Yes	10	eHealth
R08	60-69	Pulmonologist	Hospital	34	3-4	50	15	251-1000	Yes	20	eHealth
R09	40-49	Pulmonologist	Rehabilitation clinic	2	3-4	25	20	251-1000	Yes	0[f]	No
R10	50-59	Physician Assistant	Rehabilitation clinic	30	3-4	10	30	251-1000	Yes	15	No
R11	50-59	Primary care nurse	General practice	12	2-3	2	30	<10	Yes	10	eHealth
R12	40-49	General practitioner	General practice	10	1-2	4	10	11-25	Yes	30	eHealth and apps
R13	60-69	Respiratory nurse specialist	Hospital	14	2-3	20	30	>1000	Yes	30	Apps
R14	30-39	Primary care nurse	General practice	3	1-2	3	60	11-25	No	N/A	eHealth

[a]Patient category most frequently seen by the health care provider, based on Global Initiative for Chronic Obstructive Lung Disease stage.

[b]GOLD: Global Initiative for Chronic Obstructive Lung Disease.

[c]Organization size determined by the number of employees.

[d]COPD: chronic obstructive pulmonary disease.

[e]N/A: not applicable.

[f]The health care provider uses an action plan during consultations but does not set up an action.

The themes that emerged from this study are described in the following paragraphs and illustrated by quotes of the HCPs. Q references in the text refer to quotes of specific themes that are provided in the textboxes at the end of each paragraph. An overview of the themes is provided in Table 3. The themes are categorized based on the areas of focus, and the perceived benefits and risks of using the app in daily practice are described separately.

Table 3. Overview of the themes.

Area of focus	Themes
Acceptability of the app and perceived demand	• High satisfaction • User friendly • Relevant for daily practice • App fits well within the organizational culture • High level of interest
Perceived benefits and risks of using the app in daily practice	• A useful tool for patients to support self-management behavior • Patients being the owner of the app could enhance patient control • Improvement for patients compared with the use of written action plans • More in-depth and structured patient conversations • More insight into actual experienced symptoms • More tailored treatment and self-management support • Increase uniformity in self-management support by HCPs[a] • Enhance collaboration between HCPs within and across health care settings • Concerns about the safety of the app • Patients substituting HCP contact with the app • The app could be distracting from interacting with patients • Contribute to an increase in treatment burden
Factors that could influence the use of the app in daily practice	• Patient skills, opportunity, and motivation • The fit with the available time and workflow of HCPs • The autonomy of the professional • The focus of the organization on eHealth and self-management • Costs associated with the use of the app • Compatibility of the app with the current systems and eHealth initiatives
The extent to which the app can be used in current daily practice	• The app being in line with the GDPR[b] rules • Clear instructions about the app for both patients and HCPs • Sufficient time during consultations • Approval of using the app within the organization • Having a plan for implementation of the app • Access to a fast Wi-Fi connection • Good coordination between HCPs in collaborating organizations with regard to their roles and responsibilities • A separate HCP portal would have added value • Concerns about the privacy sensitivity of an HCP portal • HCPs having access to the app could undermine or diminish self-management behavior of the patient
Integration of the app across Dutch health care settings	
How to integrate the app into daily practice	• The app is feasible to integrate into their daily practice and in already existing paths of care • Flexibility in the moment of introducing the app to patients and evaluating the app • Could be used as guidance during patient consultations • Replace the use of written action plans for the app • Sustainable in Dutch COPD[c] care
The role of health care professionals	• A shared responsibility between nurses and physicians • The selection of eligible patients for the app should be the responsibility of HCPs • Role in installing and personalizing the app • Evaluate patient skills and use of the app

[a]HCP: health care provider.

[b]GDPR: General Data Protection Regulation.

[c]COPD: chronic obstructive pulmonary disease.

Acceptability of the App and Perceived Demand

When the HCPs were asked about their first impressions of the app, the HCPs spoke about the usability aspects of the app and the relevance of the app for daily practice. Overall, *high satisfaction* about working with the app was expressed by ratings of 7 or higher on a 10-point numeric scale. These high ratings were attributed to finding the app *user friendly* because of its ease of use, intuitive navigation, design simplicity, attractive layout, and receiving positive feedback when using the app (Q1). Although HCPs needed time to familiarize themselves with the app, working with the app was perceived to be easy to

learn. The high level of satisfaction and the app being perceived as user friendly was also supported by an average score of 83.8 (SD 15.1) on the SUS, indicating good usability of the app.

Furthermore, almost all HCPs believed that the app would be *relevant for daily practice* (Q2). HCPs recognized the content of the app, and particularly nurses found the app in line with the current self-management support. The calendar function in the app was considered to be most relevant for HCPs as it provided a compact, rapid, and clear overview of registered symptoms and actions. The action plan was largely in line with the current written action plans used by HCPs. The gray zone for decision support in determining the correct color zone (Figure 1) and the focus on personalizing the green zone based on registered symptoms were considered to have added value compared with written action plans. However, 8 HCPs preferred further tailoring of the yellow and orange zones (Figure 1) by adding more personalized signals for symptom deterioration. The information module was considered to be clear and relevant, although information could be presented more attractively and could be extended with more detailed information about self-management actions. Most HCPs were positive about the symptom monitoring module, as indicating symptoms fits well with how patients would describe their symptoms. A total of 3 HCPs found the symptom monitoring module to be more convenient than the currently used questionnaires in COPD care, such as the Medical Research Council dyspnea scale and the Clinical COPD Questionnaire [34,35], whereas 6 HCPs expressed a wish to add those questionnaires to the app.

A total of 11 HCPs expressed that the *app fits well within the organizational culture* as their organizations are open to digital innovations in health care because of the fit with the current environment in which health care digitalization is rapidly evolving. However, some organizations neither prioritize nor facilitate digital innovations yet. Almost all HCPs had a positive attitude toward using the app in daily practice because of opportunities to improve the quality of self-management support (Q3). When discussing colleagues' attitudes toward using mHealth, 3 HCPs believed that physicians would be hesitant and resistant toward these innovations on account of time constraints in their profession.

The majority of HCPs expressed a *high level of interest* in using the app, scoring an 8 or higher on a 10-point numeric scale. HCPs explained these ratings by their personal interest and enthusiasm for innovations and the fit with their needs and demands for health care improvement, such as more structured self-management support for patients with COPD (Q4). All HCPs expressed having the intention to use the app in their own practice, except for 1 general practitioner who believed the app will not fit with the current workflow and related time constraints.

Quotes of HCPs (Q references in the text) related to acceptability of the app and perceived demand are provided in Textbox 1.

Textbox 1. Quotes related to acceptability of the app and perceived demand.

Quotes of health care providers related to acceptability of the app and perceived demand:

- Q1: "I find it very useful, it is accurate and well-arranged and I find the lay-out very pleasant, actually. You're not distracted by small letters or something on the side edge of the screen. I think it's very clear." (R10)
- Q2: "I believe the app is clinically relevant, yes. It is very much based on the questions we are asking nowadays, based on the Medical Research Council dyspnea scale and the Clinical COPD Questionnaire. I recognize those questions in the app, but it is more logically translated to the daily practice of the patients themselves in my opinion" (R14)
- Q3: "I think these sort of initiatives for a large part have the future and…and that it can make it easier for people, and that it will help. So I am very, very enthusiastic." (R05)
- Q4: Interviewer: "How interested are you in using the app and why?" R11: "I think an 8 or 9, because self-management is returned to the person who has the disease. Also because currently, there is nothing. The culture is finally shifting as we discover, oh yes...the patient has to do it. What we have been doing with patients with diabetes for years already." (R11)

Perceived Benefits and Risks of Using the App in Daily Practice

The HCPs believed that there would mainly be benefits of using the app in daily practice at the patient, HCP, and organizational levels and only a few potential risks. Almost all HCPs found the app *a useful tool for patients to support self-management behavior* as it can help patients to create awareness of their stable symptoms and signals of symptom deterioration and could then support taking prompt and adequate actions. More than half of the HCPs believed that *patients being the owner of the app could enhance patient control* of the disease by becoming less dependent on their HCP and being in control when receiving support from HCPs across health care settings (Q5). The 4 HCPs explicitly mentioned that the app would be an *improvement for patients compared with the use of written action plans* as patients carry the app with them all the time and an app stays clean and readable.

The HCPs perceived many benefits of using the app for their own practice. Most importantly, 11 HCPs believed the app could lead to *more in-depth and structured patient conversations*, as the conversations would be more initiated by patients and, therefore, be more tailored to the specific needs and preferences of the patients (Q6). HCPs experience that patients often have difficulties with recalling experienced symptoms and performed actions and tend to underestimate or exaggerate their symptoms. The calendar in the app would provide *more insight into actual experienced symptoms* when patients are at home and prevents that HCPs have to dig for information. This could save valuable time and lead to more meaningful contact between HCPs and patients. The calendar could contribute *more tailored treatment and self-management support* by HCPs as the output could be

used by physicians to evaluate medication treatment and by nurses to match patient needs with relevant self-management support (Q7-8). In addition, 5 HCPs believed that the app could *increase uniformity in self-management support by HCPs*. Nowadays, self-management support by HCPs is often inconsistent between HCPs within and across health care organizations. Some HCPs mentioned that the app could provide more guidance in providing self-management support and could also facilitate making clear agreements on which HCPs are assigned as contact persons for a patient (Q9). Moreover, most HCPs agreed that the app could be used by various HCPs throughout and across health care settings, including those without a case manager role, and could *enhance collaboration between HCPs within and across health care settings*. Although some HCPs expressed having good contact with HCPs in other health care organizations and clear agreements about their roles and responsibilities, others expressed experiencing limited collaboration between HCPs in primary, secondary, and tertiary care. Some HCPs expressed that the patient being the owner of the app would facilitate the patients themselves being able to show the agreements made about their treatment with an HCP in one setting to HCPs in other settings. This could result in more continuity of care (Q10). Most HCPs found it difficult to reflect on the potential benefits of the app on an organizational level. A few HCPs mentioned that the app could potentially reduce health care costs by preventing hospital admissions or reducing the duration of hospital admissions.

Most HCPs perceived limited risks associated with the use of the app in daily practice. However, some HCPs expressed *concerns about the safety of the app* as there is potential for making mistakes during manual registration of medication into the app. In addition, 1 nurse specialist was concerned about the misinterpretation of the color zones by patients. Furthermore, 1 general practitioner expressed that *patients substituting HCP contact with the app* could be a risk, as patients might be less likely to involve their HCP when they have the app to guide them. Especially during a stable phase, a patient might think that the HCP contact is redundant because their app indicates that all is well. Moreover, 1 pulmonologist felt that using *the app could be distracting from interacting with patients*, which could form an obstacle for the HCPs role (Q11). Finally, 1 HCP from tertiary care expressed that the app could *contribute to an increase in treatment burden* for patients as they are already treated in multidisciplinary teams with a variety of (digital) interventions (Q12).

Quotes of HCPs (Q references in the text) related to the benefits and risks of using the app in daily practice are provided in Textbox 2.

Textbox 2. Quotes related to the benefits and risks of using the app in daily practice.

Quotes of health care providers related to the benefits and risks of using the app in daily practice:

- Q5: “I think patients will be more equipped to say: ‘These are my symptoms, and when if I have this then something really needs to be done’. And I think that especially in a situation when the orange zone is going towards red, that patients will be heard by HCPs, especially by the ones they don’t know well. A substitute general practitioner or emergency doctor or so...It gives them confidence that they know.” (R10)
- Q6: “Now you have a specific topic to discuss. Usually it’s small talk, but now patients will know in advance, ‘okay, we will discuss this.’ So also they will prepare in advance. So yes, I think it could be positive.” (R01)
- Q7: “I think, in the end, it could also save time because patients could clearly express their questions and problems. Based on that overview you could better target your consults and adequately meet patient needs.” (R03)
- Q8: “Look, if someone’s calendar is continuously ‘green’, you can say, ’well, that looks really good!, maybe we should cut back or adjust some medication. Let’s see if that is possible’. So that is all profit.” (R08)
- Q9: “Maybe more uniformity in how HCPs work, since the app would require a specific method of working. Currently, we all work in our own individual way (...) When you look at colleagues’ notes, you notice variation in reporting due to differences in focus. There is no consistency. So the app could stimulate that as well.” (R06)
- Q10: “By having the action plan on the phone the responsibility is given to the patient. When he comes into contact with other HCPs (...) you can say: ‘Look, the patient has it on his phone!’ And not only for us outpatient clinic but also for the nursing ward they can say: ‘Hey, what has the patient done? What happened?’” (R04)
- Q11: “You don’t have the time to fill out the app during a consult. In those 10 minutes you already have to type in a lot in the electronic patient file, and you have to talk to your patient and examine your patient as well. That doesn’t work. Looking patients in the eyes and listening to their lungs is most important for patients.” (R05)
- Q12: “If I put myself into the patients position, I think, ‘Now I have an app for exacerbations, and the food intake app and move monitor app. That is quite a lot.’ That’s the only thing that makes me hesitant, the treatment burden.” (R10)

Use of the App by HCPs and Factors That Could Influence the Use of the App in Daily Practice

Observed Use of the App by HCPs

During the interactive session, all HCPs clearly understood the tasks they had to perform in the app and they were able to perform those tasks well. HCPs who had experience with written action plans expressed that setting up the action plan in the app corresponds with the current workflow of setting up a written action plan and could even improve this workflow. All HCPs were able to set up and adjust the action plan and review registered symptoms and actions in the calendar function of the app. Support from the researcher was needed when usability issues were observed. These issues were mostly related to the registration of medication, setting up the yellow zone of the action plan, and saving registrations.

Factors That Could Influence the Use of the App in Daily Practice

By asking HCPs about their perceptions toward using the app in their daily practice, HCPs reflected on factors that could facilitate or hinder using the app as intended at the level of patients, HCPs, and the organization. All HCPs believed *patient skills, opportunity, and motivation* influence the use of the app (Q13-14). The proliferation of mobile device use and improvement in the digital skills of patients were believed to facilitate the use of the app in a large patient population. However, low health literacy, avoiding confrontation with illness, limited digital skills, lack of access to the internet, and loss of interest in the app on the long term were considered to be threats for continued use.

The fit with the available time and workflow of HCPs was perceived to be an important factor that would influence the use of the app in daily practice. HCPs' perceptions toward this fit were influenced by the traditional division between the roles of nurses and physicians. Most HCPs mentioned that the app fits within the available time and workflow of nurses as they already have an important role in providing self-management support (Q15). A total of 6 HCPs believed that the app does not fit within the available time and workflow of physicians as they have a main focus on medical treatment in the limited time they have available for patients (Q16). Two physicians even felt that using the app could result in more work as they would be obligated to focus on issues that normally would not come to light. For physicians, it was important to determine whether the app would improve their work efficiency (Q17). Furthermore, *the autonomy of the professional* in implementing innovations and scheduling extra time for consultations, if needed, was perceived to facilitate use of the app in daily practice (Q18). Moreover, 2 HCPs in primary care mentioned that primary care nurses might not feel comfortable with adding medication prescriptions to the app, which could hinder the use of the app as intended.

The *focus of the organization on eHealth and self-management* was considered to be an important facilitator for implementation of the app, as this would also facilitate the existence of innovation teams within organizations that could support HCPs in the use of digital innovations (Q19). Furthermore, some HCPs mentioned that *costs associated with the use of the app* would influence the use of the app in an organization, as innovations should not be too expensive and should ideally lead to a reduction in health care costs. Finally, some HCPs expressed that the *compatibility of the app with current systems and eHealth initiatives* in their organization is important, as a mismatch with current systems could hinder the use of the app in an organization (Q20).

Quotes of HCPs (Q references in the text) related to performance of tasks in the app and factors that could influence the use of the app in daily practice are provided in Textbox 3.

Textbox 3. Quotes related to performance of tasks in the app and factors that could influence the use of the app in daily practice.

Quotes of health care providers related to performance of tasks in the app and factors that could influence the use of the app in daily practice:

- Q13: "We have a lot of older generations here. That could be complicated for them. But sometimes it takes me by surprise when someone of 90 has a tablet and iPhone. I am often surprised because you think, 'Oh no, they will not do that', and then all of the sudden, there is their phone!" (R04)
- Q14: "I do wonder if someone will actually work with it. Because there are also people who do not constantly want to be reminded about their illness and prefer to hide it." (R01)
- Q15: "The content, we also work with that when we make plans. So it is in agreement with the work procedure we do without the app, what we do on paper now." (R03)
- Q16: "Right now I am already thinking, for a doctor, for the consultation time available, this is too complicated, it takes too long. I am already thinking: 'I have to continue. I don't have that much time.' Look, now I am not even talking with the patient." (R05)
- Q17: "For patients, it would be an obvious improvement, but it will not directly be an improvement in efficiency for us." (R05)
- Q18: "To an extent, I am free to provide that kind of care of which I believe is necessary or has added value." (R14)
- Q19: "Yes, we are actually ready for implementation at this time since we are currently working on all kinds of innovations, also innovations that support patients to be in control over their disease." (R03)
- Q20: "I am not sure whether the app matches with the integrated care system we are currently using, since you have to focus a part of your consultation on the app where we normally follow our integrated care system that provides a certain structure for a consult." (R14)

The Extent to Which the App Can be Used in Current Daily Practice

By asking HCPs how the app would fit within the current daily practice, 3 HCPs explained that the app could already be used in daily practice considering the available conditions, time, and resources. However, the majority of HCPs mentioned conditions that should be met before being able to use the app in daily practice. An important condition that should be met is *the app being in line with the General Data Protection Regulation (GDPR) rules*, as HCPs asked questions about privacy issues (Q21). In addition, some HCPs explained that the app should function technically well on various devices so that patients can use the device they prefer.

On patient and HCP levels, most HCPs expressed a need for *clear instruction about the app for both patients and HCPs*, such as written information or a demo about the app, to have sufficient knowledge about how the app should be used and to show patients how the app works (Q22). Especially for HCPs without the experience of working with written action plans, instruction on how to set up an action plan that includes

medication prescription is important. Furthermore, for HCPs specifically, there should be *sufficient time during consultations* to be able to work with the app. On the basis of this study, HCPs expected to need approximately 30 min to install the app and to personalize the action plan for the patient. They believed this would probably take longer in daily practice as they would have to communicate with patients at the same time. Therefore, some HCPs explained that their consultation time should be extended. Most of these HCPs expressed that they would have the opportunity to schedule some extra time for consultations. Two HCPs emphasized the importance of embedding the app into current workflows to realize sustained use over time.

Many HCPs insisted that *approval of using the app within the organization* was considered to be an important condition that must be met before being able to use the app in daily practice (Q23). Having an organizational mandate to implement the app was considered to contribute to the allocation of time and resources. Overall, HCPs working in larger organizations believed acquiring management support to be more difficult and time consuming than HCPs working in smaller organizations. Moreover, 2 HCPs working in larger organizations expressed that *having a plan for implementation of the app* would be important to mobilize people in an organization to start working with the app. Furthermore, a practical issue mentioned was that organizations need to have *access to a fast Wi-Fi connection* to be able to quickly download and use the app in daily practice. Finally, HCPs emphasized the importance of *good coordination between HCPs in collaborating organizations with regard to their roles and responsibilities* in the use of the app. A total of 7 HCPs indicated that training and instructional material for HCPs across health care settings would help to create awareness about the app among HCPs and about their role in using the app (Q24).

On the basis of the question whether HCPs would prefer to have access to a separate HCP portal to set up an action plan and review patients' registrations on their own computer, 8 HCPs expressed that *a separate HCP portal would have added value* for their daily practice. These HCPs, mostly physicians, believed that a separate portal would be more user friendly and efficient, would be helpful in preparing patient consultations, and would enable HCPs to review the app during consultations by telephone. Furthermore, it could reduce the administrative burden and could support collaboration between HCPs in an organization when the HCP portal is integrated into local information technology systems. *Concerns about the privacy sensitivity of an HCP portal* influenced the perceptions of the HCPs on having a separate portal. On one hand, 2 HCPs expressed that they would not feel comfortable if they had to work on the patient's device itself, as this is a private device. On the other hand, some HCPs expressed that a connection with a separate portal or patient system could entail privacy risks as well. A separate HCP portal was less important for nurses. Three nurses argued that *HCPs having access to the app could undermine or diminish self-management behavior of the patient.* It could give patients the feeling of being monitored by their HCP, which emphasizes an external locus of control (Q25). Nonetheless, most HCPs perceived a separate HCP portal as an important condition that must be met to stimulate use of the app in daily practice.

Quotes of HCPs (Q references in the text) related to the extent to which the app can be used in current daily practice are provided in Textbox 4.

Textbox 4. Quotes related to the extent to which the app can be used in current daily practice.

Quotes of health care providers related to the extent to which the app can be used in current daily practice:

- Q21: "It is important to know what will happen with the data. Will data be used for further research? What will happen with it? Will data be stored somewhere? Or will it only be available for patients themselves?" (R04)
- Q22: "Of course training for HCPs is necessary, but also to show patients the app. That you have an app with a an example of a patients and that you can show what you can do with it. Then the patient can decide to use the app or not. And yes.. an instructional flyer, with preferably a demo as well. Preferably on a desktop or on mobile device, that would work most handy because that is what they will work with." (R02)
- Q23: "We have an agreement that new studies or implementations must be approved of by the management team. On the one hand, it always costs a little bit of time. On the other hand, you know when its approved then everybody has to abide by it. Then it will be supported by all location managers." (R07)
- Q24: "We do collaborate with primary care, although this is not really translated into detailed care. If we were to implement the app, we also should inform primary care organizations about the app and that patients may come to their consults with the app instead of a written action plan." (R06)
- Q25: "No, no...then you actually affirm or emphasize the external locus of control. The patient becomes passive, 'I am being taken care of.' And that is what we don't want anymore!" (R06)

Integration of the App Across Dutch Health Care Settings

How to Integrate the App Into Daily Practice

Overall, the HCPs from primary, secondary, and tertiary care settings felt that *the app is feasible to integrate into their daily practice and in already existing paths of care* as the app could be easily adapted to the specific context of health care organizations. The HCPs believed that the app could be introduced in annual COPD checkups in primary care; clinical care paths, outpatient follow-up care, and pulmonary rehabilitation programs in secondary care; and pulmonary rehabilitation programs in tertiary care (Q26). Most HCPs emphasized the importance of *flexibility in the moment of introducing the app to patients and evaluating the app* to be able to integrate the app into their workflow. Individual organizational factors, such as a specific path of care or division

between HCP roles, would determine the specifics of how the app is to be integrated. The HCPs explained that the app *could be used as guidance during patient consultations.* HCPs currently using written action plans intended to *replace the use of written action plans for the app*. Nonetheless, for them, patient preferences and skills would determine whether a written action plan could be replaced by the app. Most HCPs felt that the use of the app would be *sustainable in Dutch COPD care* because of the fit within national COPD guidelines and current paths of care and their wish for more structured self-management support (Q27). However, 3 HCPs mentioned that the need for the app could decrease over time when the self-management skills of patients have been improved.

The Role of Health Care Professionals Toward Using the App

Although all HCPs indicated that working with the app best fits the role of the nurses because of their current role in providing self-management support, most HCPs considered the use of the app to be *a shared responsibility between nurses and physicians* (Q28). As nurses and physicians have a shared responsibility in the care for patients with COPD, this also applies to the use of the app in daily practice. Overall, introducing the app to patients and initiating and evaluating the action plan was considered to best fit the role of the nurses. However, some HCPs explained that physicians could have a role in prescribing and evaluating medication treatment in the action plan, which depends on the autonomy of the nurses with regard to medication prescription. HCPs expressed that reviewing the calendar of the app could be integrated in the consultations of both the nurses and physicians.

Most HCPs felt that *the selection of eligible patients for the app should be the responsibility of HCPs.* Although 4 HCPs expressed the intention to provide the app to all of their patients, most HCPs believed that not all patients will be eligible for the app. Therefore, they would select patients based on their assumptions about patient skills and motivation to use the app. A few HCPs explained that the motivation to use the app could be related to the severity of the disease. HCPs expected that patients with severe COPD and frequent exacerbations would be more motivated for exacerbation-related self-management compared with patients with an early stage of COPD who prefer to avoid confrontation with the disease. Therefore, most HCPs mentioned that they would provide the app to patients who frequently have exacerbations (Q29). Furthermore, most HCPs believed they would have an important *role in installing and personalizing the app* together with a patient, although 2 HCPs believed patients could do this initially by themselves. Finally, 6 HCPs mentioned that they would *evaluate patient skills and use of the app* so that they could provide support in using the app when needed, thereby guaranteeing safe and effective use by patients over time (Q30).

Quotes of HCPs (Q references in the text) related to integration of the app across Dutch health care settings are provided in Textbox 5.

Textbox 5. Quotes related to integration of the app across Dutch health care settings.

Quotes of health care providers related to integration of the app across Dutch health care settings:

- Q26: ‘The app could actually fit in the current path of care we have in in this hospital, in which we also discuss self-management. It would fit with that. (...) It would be a new element to integrate, but it could be used as a supportive tool.” (R13)
- Q27: “The action plan can always be improved. And I think this app is an improvement. So in my opinion, it is future proof.” (R09)
- Q28: “The primary care nurses could start with filling out the patients name and symptoms. And if they do not feel comfortable with filling out medication, they can instruct the patient to bring the app with them to the yearly consult with the general practitioner who can fill out that part.” (R07)
- Q29: “The app can be useful for everyone, but I think it would be very useful for those patients that have clear symptoms and feel disabled, especially for those who frequently experience exacerbations. So if patients have frequent exacerbations I would be more inclined to offer the app to patients. However, I think I would have assumptions, unconsciously, about patients digital skills as well that could influence this decision.” (R07)
- Q30: “During the consult in which the symptom monitoring is evaluated you could as well evaluate how patients have used the app so far. You could let patients practice for example with how they could adjust the app. They have to learn how to use a new instrument.” (R6)

Discussion

Principal Findings

This early-stage feasibility study provides insight into the perceptions of Dutch HCPs with a case manager role in COPD care regarding the use of the Copilot app in daily practice. Overall, the HCPs were able to work with the app and found the app acceptable to use in daily practice. The app could be used as guidance during patient consultations and could replace the use of written action plans in COPD care. Many benefits and only a few risks were expected regarding the use of the app in daily practice at the patient, HCP, and organizational levels. The app was considered to best fit the role of the nurses. Physicians were expected to have a marginal role in working with the app because of time constraints and misfit with their workflow. Other key factors that could influence the use of the app were the autonomy of the professional, the focus of the organization on eHealth, costs associated with the app, and compatibility with the current systems used. There are various conditions that must be met to be able to use the app in daily practice. The level of importance of these conditions varied between professions and contexts and may be attributed to organizational factors or fundamental differences in needs between physicians and nurses. The app was considered to be feasible to integrate into existing care paths of primary, secondary, and tertiary health care settings. Individual

organizational factors must be taken into account when integrating the app in daily practice.

Some of the findings of this study are in line with those of other studies. Two recent studies focusing on the adoption of mHealth by HCPs also identified usefulness, ease of use, perceived benefits, autonomy of the professional, and integration with other systems as facilitators for the adoption of mHealth by HCPs [31,36]. Similar to our results, these studies considered disruption to workflow, lack of time, increased workload, cost issues, and privacy and security issues as key adoption barriers [31,36]. Gagnon et al [31] pointed out that the use of mHealth could be disruptive during visits as it could influence the interaction between patients and health care professionals; this was identified in our study as well and was perceived as a risk for the use of the app in daily practice. Furthermore, a study focusing on the adoption of new technology by physicians found that high initial physician time costs, uncertain financial benefits, and lack of electronic exchange between systems were key physician-related barriers [37]. These studies indicate that nurses may hold the key to successful implementation of the Copilot app because of their role, the fit with their workflow and available time, and numerous advantages for their daily practice. Moreover, these studies strengthen our findings on the importance of meeting specific conditions to use the app in daily practice. According to our results, a separate portal for HCPs and integration with current systems could potentially facilitate the use of the app, especially for physicians. However, HCPs' perspectives toward system integration differ, which was also observed in conversations with HCPs during the development of the Copilot app [22]. On the basis of the literature, it could be expected that interoperability is important for integration of the app across health care settings [31].

The findings of this study show that factors influencing future implementation and integration of the app into health care organizations are context dependent. Recently, much emphasis has been placed on the importance of taking into account the context in intervention research aiming at changing behaviors, to increase the likelihood of developing appropriate, implementable, effective, and sustainable interventions [38]. On the basis of HCPs' perceptions that the app is feasible to implement and integrate into Dutch health care organizations, taking context into account in the development of the app seemed to have resulted in sufficient flexibility in the design of the app to work across a range of contexts [22,38].

Strengths and Limitations

A strength of this study was the maximum variation in settings and HCPs resulting in a broad range of perspectives, thereby increasing the transferability of our findings to similar settings in the Netherlands [33]. Furthermore, the credibility and confirmability of this study were enhanced by using data and researcher triangulation [33]. The feasibility framework described by Bowen et al [23] ensured that feasibility was evaluated by considering several important areas of focus to determine if the app can work within the constraints of daily practice. Although not the focus of data saturation, data collected on integration and practicality gave a general impression of contextual differences on how to integrate the app and which HCP role is perceived to be most suited.

A limitation of this study was the variation in the course of the interactive sessions and interviews because of time constraints and unforeseen circumstances within the HCPs' workflow. In some cases, this resulted in limited in-depth interviews and underexposure of some topics. However, systematic reflection on these methodological issues and subsequently adapting the guideline of the session resulted in more in-depth data collection as the study proceeded. Furthermore, a relatively large part of the study population had experience with digital technology to some extent. This may have resulted in a more positive perception toward the use of technology as familiarity with mHealth and technologies in general is considered to facilitate the adoption of mHealth [31]. Finally, this early-stage feasibility study evaluated the Copilot app within an artificial context, consisting of 1 interactive session with a fictional patients' case. It could be discussed whether perceptions of feasibility would be different in the case of actual implementation of the app in the daily practice of the HCPs. Nonetheless, HCPs have experienced working with the app by simulating the use of the app in daily practice.

Implications for Practice and Future Research

The findings of this study are important for HCPs in COPD care and for researchers focusing on the development and evaluation of mHealth interventions. The study shows that the Copilot app is considered to be relevant and acceptable to use in the daily practice of the HCPs. The app could result in various benefits for patients, HCPs, and health care organizations and has high potential for successful implementation and integration across Dutch health care settings. Important lessons can be learned from this study with regard to practicality, which we described in this study as conditions that have to be met to use the app in daily practice. To use the app in daily practice, it is important that clear instruction about the use of the app is provided to both patients and HCPs, that there is sufficient time during consultations, and that approval to use the app within organizations is realized. In addition, good coordination about the use of the app between HCPs in collaborating organizations is needed. Adequate training and support for HCPs regarding the use of the app is important for implementation and integration of the app in daily practice, as using the app requires behavior change from HCPs. Essential in changing HCPs' behaviors is that they have the capability, motivation, and opportunity to use the app in daily practice [39]. Training and support should therefore focus on motivating HCPs to use the app and enhancing HCPs' knowledge and skills needed to use the app, with a specific focus on the use of action plans [40]. Finally, a separate portal for HCPs is an important condition that must be met in some organizations to stimulate the use of the app in daily practice. Contextual factors across health care settings will determine the specific conditions that should be met to be able to use the app in daily practice.

For researchers and developers focusing on the development and evaluation of mHealth interventions, this study provides insight into a new approach to evaluate the feasibility of mHealth interventions at an early stage. This approach has been

shown to be a thorough and relatively quick way to investigate perceptions toward feasibility. The methods used in this study provided rapid insight into influencing factors and conditions regarding feasibility, thereby allowing researchers and developers to adapt mHealth interventions by moving backward or forward quickly. Evaluating feasibility at an early stage helps to determine whether mHealth interventions are appropriate for further feasibility testing with end users over a longer time period.

Further research on the Copilot app should focus on longitudinal feasibility testing of the Copilot app with both patients and HCPs to investigate the delivery and acceptability of the intervention, compliance with the intervention, and recruitment of patients and to investigate limited efficacy. In a next phase, the effect of the Copilot app on relevant patient outcomes and health care use should be evaluated. This evaluation should include an assessment of how context influences the effectiveness of the app [38]. Understanding how the app relates to context is critical to understand how the app works and for whom, what influences implementation success and failure, whether the app can be successfully adapted or scaled-up from one context to another, and to what extent effects could be generalized to other contexts [38]. To achieve this, a thorough process evaluation using qualitative and quantitative methods from a system lens is recommended [38,41,42].

Conclusions

This early-stage feasibility study shows that the Copilot app is feasible to use in the daily practice of Dutch HCPs and is considered to best fit the role of the nurses. The app is perceived to be acceptable to use and relevant for the daily practice of HCPs. The app can be used as guidance during patient consultations and could replace the use of written action plans in COPD care. Many benefits and only a few risks were expected regarding the use of the app in daily practice at the patient, HCP, and organizational levels. The app will be less feasible in organizations where relatively many conditions need to be met. The app is considered to be feasible to be integrated into primary, secondary, and tertiary health care settings in the Netherlands. Individual organizational factors must be taken into account when integrating the app in daily practice. This study provides a new approach to evaluate the perceived feasibility of mHealth interventions at an early stage and provides valuable insights for further feasibility testing. Future research should focus on longitudinal feasibility testing of the Copilot app by both patients and HCPs.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Stepwise procedure of data collection.
[PDF File (Adobe PDF File), 261 KB - formative_v4i11e21577_app1.pdf]

Multimedia Appendix 2
Fictional patient case and assignment for health care providers.
[PDF File (Adobe PDF File), 181 KB - formative_v4i11e21577_app2.pdf]

Multimedia Appendix 3
Topic list for the semistructured interview.
[PDF File (Adobe PDF File), 163 KB - formative_v4i11e21577_app3.pdf]

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Abbreviations

COPD: chronic obstructive pulmonary disease
GDPR: General Data Protection Regulation
GOLD: Global Initiative for Chronic Obstructive Lung Disease
HCP: health care provider
mHealth: mobile health
SUS: System Usability Scale

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Original Paper

Integrating a Web-Based Self-Management Tool (Managing Joint Pain on the Web and Through Resources) for People With Osteoarthritis-Related Joint Pain With a Web-Based Social Network Support Tool (Generating Engagement in Network Involvement): Design, Development, and Early Evaluation

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Abstract

Background: Joint pain caused by osteoarthritis (OA) is highly prevalent and can be extremely debilitating. Programs to support self-management of joint pain can be effective; however, most programs are designed to build self-efficacy and rarely engage social networks. Digital interventions are considered acceptable by people with joint pain. However, many existing resources are not accessible for or developed alongside people with lower health literacy, which disproportionately affects people with OA.

Objective: This study aims to design and develop an accessible digital self-management tool for people with joint pain and integrate this with an existing social network activation tool (Generating Engagement in Network Involvement [GENIE]) and to explore the feasibility of these linked tools for supporting the management of joint pain.

Methods: The study was conducted in 2 phases: a design and development stage and a small-scale evaluation. The first phase followed the person-based approach to establish guiding principles for the development of a new site (Managing joint Pain On the Web and through Resources [EMPOWER]) and its integration with GENIE. People with joint pain were recruited from libraries, a community café, and an exercise scheme to take part in 3 focus groups. EMPOWER was tested and refined using think-aloud interviews (n=6). In the second phase, participants were recruited through the web via libraries to participate in a small-scale evaluation using the LifeGuide platform to record use over a 1-month period. Participants (n=6) were asked to complete evaluation questionnaires on their experiences. The NASSS (nonadoption, abandonment, scale-up, spread, and sustainability) framework was used to explore the feasibility of the sites.

Results: The focus groups established guiding principles for the development of the tool. These included ensuring accessibility and relevance for people with OA-related joint pain and recognizing that joint pain is the reason for seeking support, trust, social facilitation, and goal setting. Think-aloud interviews identified issues with user experience and site navigation and the need for professional input for referral and goal setting, confusion, and tensions over the role of GENIE and site connectivity. Participants

expected the sites to be specific to their pain-related needs. EMPOWER was accessed 18 times; 6 users registered with the site during the evaluation study. Participants mostly explored information pages on being active and being a healthy weight. Only one participant undertook goal setting and 4 participants visited the GENIE website.

Conclusions: Using the NASSS framework, we identified the complexity associated with integrating EMPOWER and GENIE. The value proposition domain highlighted the technical and conceptual complexity associated with integrating approaches. Although identified as theoretically achievable, the integration of differing propositions may have caused cognitive and practical burdens for users. Nevertheless, we believe that both approaches have a distinct role in the self-management of joint pain.

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KEYWORDS

joint pain; osteoarthritis; internet; self-management; social networks

Introduction

Background

Joint pain secondary to osteoarthritis (OA) causes disability for many people and can be associated with a loss of independence [1,2]. In the United Kingdom, a 7-year consultation (2004-2010) determined a prevalence of 8.75 million people with OA aged above 45 years [3]. The prevalence of OA increases with age, with substantial associated human and economic costs [4]. Given the projected increase in older adults across the European Union by 2080 [5], this impact is expected to grow. OA disproportionately affects lower socioeconomic groups [6]. Such groups have been found to have low levels of health literacy, which is associated with poorer health outcomes [7].

Self-management is defined as both the action of a person to actively engage with their own health treatment and a program for delivering health-promoting information to people with chronic conditions [8,9]. Active engagement with self-management is an essential part of everyday life for people living with a long-term condition (LTC) [9], such as OA. Therefore, it is relevant to understand how support for self-management could be optimized. Programs or interventions to support the daily management of LTCs can be effective. Small improvements in symptom control, including pain, have been reported in people with OA following self-management programs, although these effects may not translate into improved quality of life [10]. Barriers to effective OA self-management programs, reported by patients in primary care [11], include a lack of information from health care professionals, beliefs that OA cannot be improved, and negative perceptions about program formats. A key recommendation in most self-management programs for OA is to increase physical activity [12]. Although both face-to-face and digital interventions can effectively support the promotion of physical activity [13,14], digital interventions are accessible to a broader range of people [15] and acceptable as a method for supporting the self-management of joint pain [16]. Furthermore, digital tools for managing chronic conditions have been found to increase awareness and build capacity for people to better manage their condition [17].

Self-management interventions often combine multiple interacting components to improve health and well-being and commonly include behavioral change approaches [18]. Interventions that are designed using behavior change theory are considered effective at improving outcomes for people [19,20]. However, using this approach alone focuses only on an individual's motivation to self-manage. Other approaches that use a social network approach, which seeks to improve engagement with existing network members and resources and build new connections in the community to meet the needs of individuals, also enhance self-management [18,21,22]. However, to date, these have not been included in OA self-management programs. A relational approach to self-management, focused on the interdependence between individuals and network-level processes, can assist in changing behavior, managing day-to-day practicalities, and sharing experiences [22]. Consequently, there is considerable potential for this approach to improve the effectiveness of self-management programs for people living with OA. An example of a facilitated network-centered approach is provided by a web-based tool called GENIE (Generating Engagement in Network Involvement) [23]. GENIE is an evidence-based intervention that aims to reconstruct existing relationships and build new connections through valued activities to develop a diverse social network. GENIE is most effectively delivered through a one-to-one interaction by a trained facilitator and includes 4 distinct stages [22,23]: (1) mapping an individual's social network using concentric circles, (2) exploring activity and support preferences, (3) linking network members to their preferences, and (4) providing access to information on local resources linked to an individual's preferences.

Deductive approaches to developing health care interventions are commonly used [24,25]. However, it is important to explore the needs of people living with the condition to ensure that the intervention is effective and acceptable to those who will ultimately use it [26]. One approach to achieve this is the *person-based approach* (PBA) [27].

Aims and Objectives

This study aims to describe the development of a new web-based self-management intervention using the LifeGuide software, developed at the University of Southampton, which integrates a traditional evidence-based approach to supporting self-management, such as My Joint Pain (MJP) [28] with social network support using GENIE. The objectives of this study are as follows: (1) to design and develop, alongside user-led groups, a digital, personalized self-management program accessible to people with lower health literacy and joint pain; (2) to link this digital, personalized self-management program with the social network GENIE tool; and (3) to conduct an early evaluation of

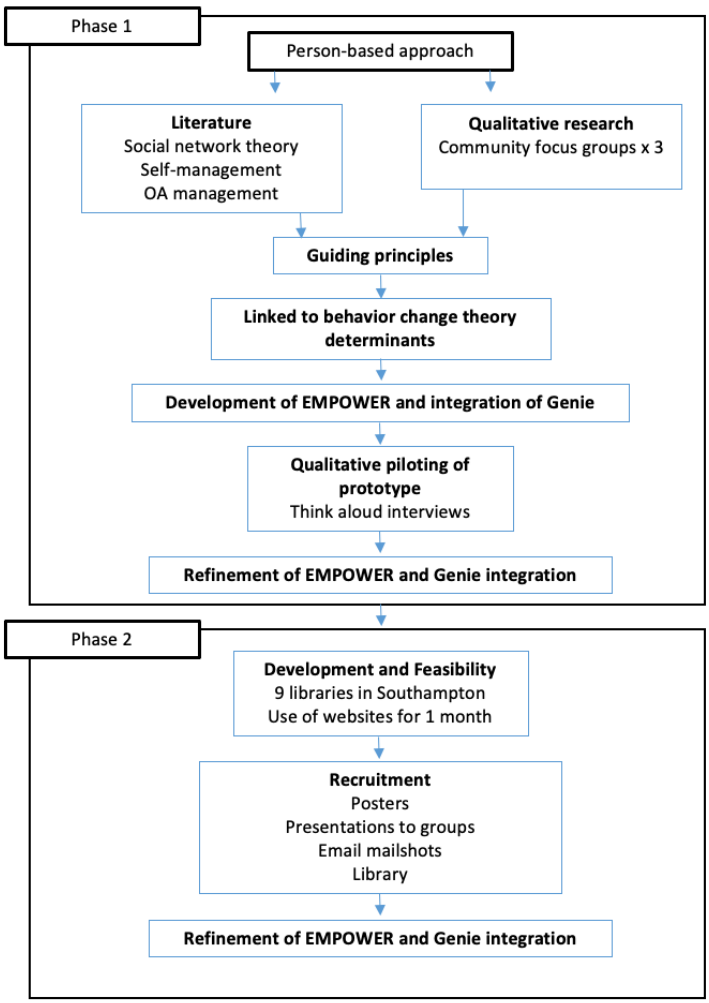
the self-management program and its integration with GENIE for people with joint pain.

Methods

Study Design

The study was divided into 2 phases: (1) design and development, including focus groups and think-aloud interviews and (2) a small-scale early evaluation of the intervention using LifeGuide software (Figure 1). Underpinning our design and development approach was the use of appropriate behavior change theory and the literature on social networks. These methods are discussed in the following sections.

Figure 1. The person-based approach used for the design and development of the web-based intervention in phase 1 and small-scale evaluation using LifeGuide software. EMPOWER: Managing joint Pain On the Web and through Resources; Genie: Generating Engagement in Network Involvement; OA: osteoarthritis.



Ethics

Ethical approval to conduct the study was granted by the Faculty of Environmental and Life Sciences ethics committee at the University of Southampton (Ref. 40268.A1, 48286).

The PBA

The PBA provides a systematic way to integrate theory with the lived experiences of people with LTCs to develop usable and engaging interventions [29]. In this project, the PBA was used to identify guiding principles for the development of the intervention by using and linking data collected from participants to relevant theories and existing research. Once prototypes were developed, qualitative approaches were used to further refine the intervention.

Phase 1: Design and Development

To design and develop a new digital self-management tool, we invited people with joint pain to take part in focus groups to review and provide feedback on an existing web-based joint pain self-management tool for OA [28] alongside GENIE [30]. Participants were subsequently invited to participate in think-aloud interviews to review the newly created tool.

LifeGuide Software

The new digital self-management tool was developed using the LifeGuide software, which is an open-source software that enables the development of web-based resources without the need for programming experience. It was developed at the University of Southampton and has previously been used

alongside the PBA for self-management interventions for asthma [31], hypertension [32], and weight loss [33].

MJP

MJP [28] is a web-based resource for people with OA-related joint pain. Developed by Arthritis Australia, it provides information to support the management of joint pain. The MJP asks participants to indicate the location of their pain on a visual body map and answer questions so that the content of the site can be tailored and made relevant to the individual. Participants can return to the site for follow-up visits to further individualize their management plan [28]. MJP was reviewed by the study participants, as it represented an up-to-date and novel web-based tool for people with OA [28]. However, the site requires a high level of health literacy, particularly in relation to the level and quantity of information provided [15,16]. Consequently, it was important to understand whether a more accessible site could be developed for UK-based users.

Recruitment

We recruited a convenience sample of people with joint pain from a variety of backgrounds and with different health literacy levels from community organizations in Southampton, United Kingdom. We used posters, presentations to groups, and drop-in sessions to support recruitment into the study. All participants were provided with a participant information sheet (PIS) that was designed to be accessible, with a reading level of <12 years [34]. A simplified and more visual information sheet also accompanied the full PIS. All participants signed a consent form before taking part and verbally consented before data collection. All study materials were reviewed by a patient and public involvement representative (JL) and a health literacy advisor (CB) before use. Participants were eligible to take part if they were aged >50 years and had self-reported joint pain. This age group was chosen because of the age-related increase in the prevalence of OA [4,35]. Self-reported joint pain reflects the fact that many people living in the United Kingdom with OA-related joint pain do not have a confirmed OA diagnosis [36].

Procedures

A total of 3 focus groups were conducted in community locations and at the University of Southampton in May and June 2018. Participants provided demographic information (age, gender, years of full-time education, highest level of education, and most recent occupation) and answered a question on health literacy (How confident are you at filling out medical forms by yourself? [37]). This health literacy question was found to be predictive of inadequate health literacy when compared with a larger validated measure—the Short Test of Functional Health Literacy in Adults [38]. Each focus group lasted 1 hour and was conducted by 2 members of the research team (a moderator [PC] and a note taker [CB or IV]) with experience of conducting focus groups. Participants were asked to review MJP and GENIE websites using their choice of a laptop or tablet. Immediately after viewing each site, participants were asked about their overall impressions. After viewing both sites, a further discussion, led by the moderator, was held using a topic guide. These focus group discussions provided information on the development of an initial version of the new digital self-management tool and its integration with GENIE.

Participants who had previously consented to participate in the think-aloud interviews were invited to review the initial version of the new tool. Think-aloud interviews were chosen to identify user responses to the content, style, and delivery of the new tool [27]. Before participating, each participant watched a short video demonstrating the think-aloud method. Interviews were conducted by one researcher (PC) at a time convenient to the user and were conducted either at the university or at the participant's home. The interviews were conducted in January and February 2019 using a predesigned interview schedule of tasks related to the key aspects of the site. There was no previous relationship between the participants and the researchers.

Focus groups and think-aloud interviews were digitally recorded and transcribed verbatim. Transcripts were read repeatedly to deepen comprehension by 2 researchers (PC and IV), coded and categorized using content analysis [39] by PC, and discussed with IV, AR, and JA to establish guiding principles for intervention development and amendments within the constraints of the technology and time.

Phase 2: Early Evaluation of the Integrated Tools

Following the modifications suggested by the interview participants, we conducted a small-scale early evaluation of Managing joint Pain On the Web and through Resources (EMPOWER) and its integration with GENIE. We used quantitative usability metrics, recorded in the LifeGuide platform and accessible to the research team, including the number and the time of visits to the site, time spent on each page and how a participant navigated through different pages, the use of various functions such as goal setting and email reminders, and text entered. We also aimed to establish the feasibility of the tools for use in a larger trial, based on the following criteria: acceptability, demand, implementation, practicality, integration, and limited efficacy [40]. A mixed methods approach is considered beneficial for developing digital interventions for people with lower levels of health literacy [41]. We aimed to recruit a diverse group of people from across the community through 9 local libraries in different city locations. However, no specific recruitment target was set, as we were interested in exploring recruitment feasibility for a future larger scale study. According to the English Indices of Deprivation, 5 recruitment locations were in the highest 2 deciles of deprivation. The others clustered around deciles 4, 5, and 6 [42].

We amended the age inclusion criteria to ≥18 years based on feedback during the development phase about being able to access such resources at an earlier age. EMPOWER was designed for people with OA; however, our development work indicated that many people will not have been given a formal diagnosis. We therefore used a symptomatic definition for recruitment, which was movement-related joint pain with morning stiffness that does not resolve within 30 minutes. Participants were also required to have access to an internet-enabled computer or tablet and be able to read English.

Recruitment

Recruitment was conducted using posters and library presentations and through an email newsletter to library users and city council staff. Potential participants had access to the study information sheet and instructions about how to find the EMPOWER site and take part. Participants were asked to confirm their eligibility and consent to participate in the study. Once registered, participants answered a series of demographic questions, including age, gender, OA diagnosis, and postcode (to explore deprivation indices). Participants were also asked to complete questionnaires on self-efficacy [43], health literacy [37,38], and the impact of joint pain symptoms [44].

Procedures

Participants had access to the full EMPOWER site for 1 month, including email reminders, external links, and an option to request a facilitated GENIE session. At the end of the month, registered participants received an email inviting them to return to EMPOWER to evaluate the content and feasibility of the tools, complete the health literacy question [37,38] and the impact of joint pain questionnaire [44], and attend an interview. EMPOWER was programmed to automatically show the evaluation questions when the participant signed into the site at the end of the month. Each registered participant received an e-gift voucher to thank them for participating. No changes were made to the interventions during the evaluation period.

To evaluate the complexity of the intervention, we drew on the first 4 domains of the NASSS (nonadoption, abandonment, scale-up, spread, and sustainability) framework [45]. This framework was developed through systematic reviews and case studies to identify appropriate domains, which were then tested with 10 programs across health and social care (Multimedia Appendix 1). The NASSS framework is considered particularly relevant for the evaluation of technological interventions [46]. Each domain can be classified as simple, complicated, or complex, with greater complexity representing a less chance for sustained adoption. Usability data were used to explore these domains.

Results

Phase 1: Design and Development—Focus Groups

In total, 11 people participated in the focus groups, which included groups of 5, 4, and 2. The participants were mostly women and aged 50 to 79 years. Just under half of the group reported that they had a secondary level of education (aged 12-16 years), whereas the others had a college (aged 16-18 years) or university education (>18 years). Most participants had higher health literacy levels (n=8; Table 1).

The results of the focus groups were divided into factors related to the usability of the sites and themes for intervention, development, and implementation. The following themes were identified: introductions or recommendations, flexibility, complementarity, tailoring, and important aspects of managing joint pain. Representative accounts are shown in Multimedia Appendix 2.

Table 1. Focus group and think-aloud interview participant demographics.

Participant	Age (years)	Gender	Years of full-time education	Highest educational level	Most recent occupation	Health literacy score[a]
P2[b]	70-79	Male	15	Secondary	Milkman	A little bit
P3	60-69	Female	10	Secondary	Nurse	Quite a bit
P5[b]	50-59	Female	12	College	Library supervisor	Quite a bit
P6[b]	60-69	Female	13	College	Craft tutor and child carer	Quite a bit
P7[b]	50-59	Female	19	University	Support worker	Extremely
P8	60-69	Female	12	College	Customer advisor	A little bit
P9	50-59	Male	12	Secondary	Road sweeper and toilet cleaner	A little bit
P10[b]	50-59	Male	11	Secondary	Information technology specialist	Quite a bit
P11	50-59	Male	6	College	Engineer	Extremely
P13[b]	50-59	Female	18	University	Community development officer	Extremely
P14	70-79	Female	12	Secondary	Receptionist and telephonist	Extremely

[a]Responses to health literacy question—extremely (likely high health literacy) to not at all (likely low health literacy).

[b]Participants took part in think-aloud interviews.

Introductions or Recommendations

Participants considered that contexts facilitating engagement with the websites could be associated with perceptions of trust in the site's content; for example, a recommendation from a general practitioner (GP) would provide reassurance that the site was suitable. GENIE was also considered to have potential as a proactive tool when introduced by a social housing officer. The sites' independence of commercial interests was important to participants.

Flexibility

Participants wanted self-management interventions to be sufficiently flexible to meet their needs at different times.

Although participants reviewed the MJP website before the GENIE website during the focus groups, there were mixed opinions about the order in which the sites could be used. Some participants liked the idea of using GENIE with a facilitator first. Others found it difficult to initially see how it could help to manage their joint pain. For this reason, some participants felt that joint pain should be the starting point, with a site such as MJP, and lead onto GENIE.

Complementarity

The two websites (MJP and GENIE) were perceived as complementary to one another. Participants liked being able to find information on how to manage their joint pain while also having the opportunity to find people and resources that might help in their own community.

Tailoring

Participants were asked a series of questions on the MJP website to tailor the information on the site but found that the results fell short of their expectations in terms of personalization and relevance due to similar recommendations across the group. Participants disliked having to sign up immediately to perform this tailoring process, preferring to browse the site first. However, this process did reassure others that their painful joint was displayed on a visual body map.

Important Aspects of Managing Joint Pain

Participants considered web-based resources helpful in alleviating pressure on the National Health Service (NHS) but suggested that GPs would need to be aware of the sites. They highlighted the role of others in self-management and the need for relevant resources for friends and family. Furthermore, because of feelings of loneliness and isolation, it was deemed important to connect with others who experienced similar issues. Other important features for managing joint pain were discussed, including maintaining activity (partly for distraction from pain) and acquiring information about practical resources and support. Tracking personal progress and gaining emotional support to cope with pain were also considered important.

Identifying Guiding Principles for Design and Development of EMPOWER and Its Integration With GENIE

The guiding principles for the new self-management tool (EMPOWER) and its integration with GENIE were generated from focus group themes and research literature on the self-management of OA and are as follows:

- Accessible for people with different levels of health literacy.
- Relevant to users need at different times.
- Self-management support strategies beyond medical advice.
- Pain as a starting point.
- Being able to track progress.
- Trust in the resource.

These guiding principles were developed into design objectives for the project. Intervention features informed by behavior change theories were chosen to meet these objectives (Table 2).

Table 2. Design objectives, intervention features, and background literature or theory linked to the guiding principles.

Design objectives	Intervention features	BCT[a] or previous literature
To ensure that the intervention is accessible for people with lower levels of health literacy	• Ensure that the site and content are accessible and understandable • Reduce complexity and jargon to enable the personal use of information • Provide options to support users to apply relevant information and put advice into practice	• Integrated model of health literacy [47]
To enable people with joint pain to gain advice and support that is relevant to them at different times	• Integration of web and community resources to provide information and advice when it is required • Links to community resources to connect web information with real-world application	• Integrated theory of health behavior change [48]
To encourage people with joint pain to think about and engage with support in terms of their wider social network	• Integration of the GENIE[b] tool with the new joint pain self-management tool (EMPOWER[c]) • Ensure that the benefits of social network support are highlighted	• Integrated theory of health behavior change [48]
To develop an approach that recognizes joint pain as the rationale for seeking support	• Ensure features and navigation through the sites that recognize joint pain as the motivation for accessing the intervention	• Self-determination theory (extrinsic motivation—identified regulation) [49,50]
To encourage people to set goals to promote action and maintenance of self-management behaviors	• Promote the creation of goals from information on the sites to develop behaviors for managing joint pain	• Health action process approach [51] • Goal setting theory [52,53]
To ensure that users consider the intervention to be trustworthy	• Provide references for all information • Provide information about the development of the intervention by people with joint pain, researchers, and health care professionals	• No specific BCT but background on trust and reputational mechanisms [54,55]

[a]BCT: behavior change theory.

[b]GENIE: Generating Engagement in Network Involvement.

[c]EMPOWER: Managing joint Pain On the Web and through Resources.

Developing the Intervention

A new joint pain self-management intervention was created, called EMPOWER. To develop an initial prototype, we first explored the potential to integrate EMPOWER with GENIE. However, technical programming constraints prohibited this, and it was necessary to find another method for integration. In accordance with guiding principle 4, we established EMPOWER as the starting point for users, acting as a resource for managing joint pain. The aim of EMPOWER was to facilitate the adoption of and engagement with self-management behaviors relevant to an individual, through information and engagement with network support. This was emphasized on the EMPOWER home page through links to joint pain information in EMPOWER itself and information about the benefits of social network support and GENIE facilitation. EMPOWER was also designed to prompt users to think about how members of their networks might help with self-management throughout the site. This included space on each page to record information about people or activities that might help, which was automatically transferred to the goal setting pages for integration into personal plans (Multimedia Appendix 3). Each page also included a link to the GENIE database of activities and groups, enabling users to identify local resources that could be relevant for making the changes individuals identified as important. These pages opened in a separate browser to ensure that the sites could be used interchangeably.

The content of EMPOWER was informed by focus group discussions, research evidence or guidelines, and in collaboration with Arthritis Australia. All content was reviewed by expert clinicians working in musculoskeletal services and the research team, including clinicians, sociologists, and a health psychologist. Video content provided by an existing GENIE project [23], Arthritis Australia [28], and the Chartered Society of Physiotherapy, United Kingdom, was considered beneficial by participants. Access to in-depth information was provided through public links to trusted third-party sites, including Versus Arthritis [56] and the NHS [57], which opened in separate browser windows.

Think-Aloud Interviews

A total of 6 participants took part in the think-aloud interviews. Participant demographic information is shown in Table 1. Interviews lasted between 20 and 60 minutes, reflecting the diverse needs and interests of participants in relation to joint pain. The following themes were identified: user experience, professional involvement, understanding GENIE, tensions between EMPOWER and GENIE, and pain and goal setting. Participants highlighted particular issues associated with the technical and conceptual integration of EMPOWER and GENIE.

This included confusion over whether any information entered on one site would influence the content of the other and a perceived conflict in approaches to self-management. Each theme is summarized below with illustrative accounts available in Multimedia Appendix 2.

User Experience

Participant feedback indicated that the overall navigation and integration of EMPOWER and GENIE needed improvement. Links to GENIE, which opened in separate windows, were confusing, particularly when participants were trying to return to EMPOWER. Most participants wanted EMPOWER to be more personalized and specific to their information needs. However, there were marked differences in opinion about the level of information provided. Differences were also reported about the site's appearance, with one participant reflecting that the site aesthetic was too formal and another considering that this formality improved the look of the site.

Professional Involvement

Different views about health care professionals' involvement in self-management and goal setting decisions were held. Some participants stated that it was important to draw on their own experience of managing joint pain, whereas others wanted a more prescribed approach. Furthermore, some participants were confused by perceived inconsistencies between some of the video content, which promoted the involvement of expert advice, and the wider self-management ethos of the sites.

Understanding of GENIE

Participants perceived that the role of GENIE was to locate groups and community content specifically linked to information within EMPOWER. However, although specific EMPOWER pages were linked to relevant GENIE pages, this was not sufficient to meet one participant's expectations. Involving other network members was considered important, although inner resilience was also integral to management. Options to record how your network could help on the EMPOWER pages were confusing and not used by most participants, suggesting that engaging with social networks for self-management requires a more facilitated approach.

Tensions Between EMPOWER and GENIE

The link between EMPOWER and GENIE required more explanation, as participants were confused about whether the content from both sites was automatically transferred to the other for use. In particular, given the physical impact of joint pain, one participant was concerned that linking up with local groups and activities recommended through GENIE may not be relevant. Others found it difficult to see how network members could influence their pain.

Pain

Expectations of the sites were linked to participants' joint pain needs. One participant expected more joint pain–specific content, whereas others wanted a greater focus on prevention to reduce the future impact of pain. Participants believed that given the varied nature of pain experiences, achieving relevance for all users would be difficult. Some of the participants did not recognize the term osteoarthritis.

Goal Setting

Goal setting was found to be potentially beneficial for some participants but only if linked with professional advice. One participant questioned the need for goal setting, whereas a further participant considered that the overwhelming amount of information made it difficult to select appropriate goals.

Refinement of EMPOWER and GENIE Integration

Amendments were made to EMPOWER and to its integration with GENIE following the think-aloud interviews. These included a new video on the EMPOWER home page, with explicit focus on improving the understanding of GENIE and its relevance within EMPOWER. User experience was also improved to ease tensions associated with navigating between EMPOWER and GENIE. Changes were made to the content and language used, such as replacing the term "network" with "people around you" (Multimedia Appendix 4) to improve users' understanding of social network support. A greater focus on the lived experience of people with joint pain was achieved through the inclusion of links to videos from the Healthtalk website [58]. The reported usability issues were improved through greater signposting to guide user navigation.

Phase 2: Early Evaluation of the Integrated Tools

The EMPOWER site was accessed 18 times for at least 10 seconds in the month it was available. Of the 17 eligible participants, 9 consented to participate in the study; however, only 6 registered and used the site's functions. Overall, 2 participants returned to the site twice within the month of the initial registration.

Registered Users

Table 3 displays the registered users' demographics. The participants were mostly female and aged 52 to 68 years. Overall, 3 participants reported a diagnosis of OA and indicated a greater impact of their symptoms on daily life. All participants reported joint pain in more than one joint, with 3 participants indicating pain in more than 5 joints. Most participants had a higher level of health literacy, whereas postcode data indicated that participants predominantly lived in areas with a lower level of deprivation (4/6, ≥5th decile [42]). Responses to the self-efficacy questionnaire showed a wide range of perceived self-efficacy (mean 5.5 [SD 2.1]; range 2.8-8.0).

Table 3. Registered participant demographics (phase 2).

Participant ID	Gender	Age	Osteoarthritis diagnosis	Impact of joint symptoms[a]	Health literacy[b]	Self-efficacy, mean (SD)[c]
P15	Female	54	No	Slightly	Quite a bit	7.7 (1.2)
P16	Female	66	No	Slightly	Extremelyc	8.0 (1.1)
P17	Male	68	Yes, physiotherapist	Moderately	Extremely	5.8 (1.9)
P18	Female	68	Yes, general practitioner	Severely	Quite a bit	3.3 (0.5)
P19	Female	68	No	Moderately	Extremely	5.3 (0.8)
P20	Female	52	Yes, doctor at surgery, scans, etc	Severely	Somewhat	2.8 (1.2)

[a]Full question: How much have your joint or muscle symptoms interfered with your work or daily routine in the last 2 weeks (including work and jobs around the house)? [44].

[b]Responses to health literacy question—extremely (likely high health literacy) to not at all (likely low health literacy).

[c]Self-efficacy measure [43] includes 6 items, scored from 1 (not at all confident) to 10 (totally confident).

Initial Visit

The 6 registered participants used the site for a mean duration of 21.6 minutes (SD 14.1) during their first visit (range 8.6-44.5). A total of 2 participants spent almost 3 minutes exploring the home page before moving on (likely viewing the GENIE information video), whereas the other participants moved on to register on the site almost immediately (6-13 seconds).

Overall, 2 participants, one with a diagnosis of OA and one without, viewed the "What is OA?" page first on the EMPOWER site, whereas 3 others chose to focus on issues that affected them (sleep, staying independent, and problem solving). The final participant opted to go to the goal setting page (*My goals*) first, discounting suggestions on the main menu to review information before setting goals. This participant (P20) chose not to visit any of the joint pain–related information pages during their initial visit, instead focusing on setting goals and visiting GENIE.

Data on the frequency of page views indicated that certain issues were more important than others. The *Being more active* and *Being a healthy weight and eating well* pages were the most visited, with one participant (P19) spending more time exploring this latter topic than any other. Information on medical management (accessed through *What is OA?*) was also of interest to 3 participants, with one user spending over 5 minutes exploring these 2 pages.

In total, 4 participants used the GENIE link button available in EMPOWER and used GENIE for 2 to ≥9 minutes before returning to EMPOWER. Multimedia Appendix 5 shows the process of going between the 2 sites. Participants did not use the option for recording "how could people around you help" and did not request a facilitated GENIE session. The EMPOWER site provided links to external sources of trusted information on the internet, but these were only used by one participant (Multimedia Appendix 5). Furthermore, links to videos from the Healthtalk website [57] providing real-life experiences of dealing with various issues were not used by participants.

Subsequent Visits

Overall, 2 participants returned to EMPOWER twice during the study, spending over 4 minutes (P15) and 19 minutes (P20) on the site and using GENIE. After logging in, these participants were given the opportunity to view their goals or go to the main menu. Both chose to view their goals initially, although only one of the participants had previously set a goal. This participant provided feedback on the progress of the previously set goals. Participants were invited to conduct evaluations of the intervention at the end of their month of use; however, these were not completed by any of the participants.

Discussion

Guiding principles for the EMPOWER site and its integration with GENIE were established. These were associated with ensuring that EMPOWER was accessible, trustworthy, and relevant for different people with OA. Participants suggested that pain was the reason for seeking support but wanted a digital tool to go beyond medical information and provide opportunities to track progress. Think-aloud interviews using EMPOWER and GENIE highlighted user experience issues, particularly around linking sites and the personalization of information. Participants were divided over whether they would need to involve health care professionals with setting goals on EMPOWER. A greater focus on preventing pain in the future was identified as important, although achieving a relevant approach for all was considered difficult. The connection between EMPOWER and GENIE required greater explanation, both technically and conceptually. Adaptations and usability issues were resolved before the early evaluation work was undertaken.

Early evaluation work identified that activity and weight management were particularly relevant for participants. Most participants visited GENIE from the EMPOWER site on their first visit and follow-up visits. Goal setting and links to external information sources were only used by one participant, whereas video case studies were not used. Unfortunately, participants did not undertake the evaluations at the end of the study, which limited our understanding of the context of these decisions. The reasons for this are unclear, but it is possible that there were technical issues with the site, although this function was widely

tested before going *live*. Digital evaluation (even with an email reminder) may have been too great an expectation, given the small number of additional visits to the site.

The domains of the NASSS framework (Multimedia Appendix 1) have been used to explore the intervention's complexity and potential for implementation using the available usability data. These are discussed in the following sections.

The Condition

OA can be considered complex, as many people do not have a diagnosis or are at different stages of managing the condition. OA was an unfamiliar term to some participants, which resulted in a change in the terminology used for recruitment. The EMPOWER home page was changed to accommodate this to meet the needs of those with lower levels of health literacy [59]. This approach was important, given that OA affects more people from lower socioeconomic backgrounds in which health literacy levels are also typically lower [6]. However, most of the recruited participants had high levels of health literacy. Although we aimed to recruit participants with diverse health literacy levels, we believe that our inability to do so may be symptomatic of the limited diversity of participants in health research more widely [60].

Pain was the primary reason for seeking support, and it was therefore important for participants to see the EMPOWER site before linking to GENIE. However, perceptions about the amount of information necessary to manage pain differed between participants. An association with aging may be one reason for this, as there are few perceived options for managing OA [61].

The Technology

Technical issues associated with integrating EMPOWER and GENIE caused usability problems for participants, although adjustments were made to improve navigation between sites, with page flow data showing that participants were able to navigate from EMPOWER to GENIE and back again. The dependability of the sites was otherwise satisfactory, although it was apparent that some links did not always open on the initial click. It is unclear, however, whether this was a site issue or whether it was related to a user's hardware or internet connection. Usability issues may reduce the effectiveness and potential of web-based interventions, and many self-management interventions are reported to have limitations in this area [62,63].

Although EMPOWER was developed to be independently usable, regardless of previous experience, the site emphasis was on goal setting to build efficacy for self-management behaviors. Goal setting is an effective strategy to support healthy behaviors, such as increased physical activity [64,65], which are recommended for the management of OA [12]. EMPOWER integrated the effective elements of goal setting and action planning, which are associated with the goal setting theory [51,52] and the health action process approach [51]. However, given that only one participant used this function in our evaluation, there may have been problems with the implementation of these functions or associated technical difficulties. Evaluating set goals is also a key part of goal setting [66], but few participants in this study returned to EMPOWER after the initial visit, potentially indicating ambivalence to this intervention. Finally, although there were frequent prompts to set goals, this may have assumed that individuals were able to develop, prioritize, and follow up on set goals. Given the participants' range of self-efficacy scores (Table 3), this may have been too great an assumption.

We also made assumptions about the capability of participants to use the internet. Although a user guide was provided on how to navigate to the EMPOWER site, potential participants may have decided not to take part because of the self-directed nature of navigating to and using the site.

The Value Proposition

The EMPOWER site was developed to support the self-management of joint pain for people with lower levels of health literacy. Previous research has identified that such interventions are also acceptable to those with higher levels of health literacy, with clear and accessible information preferred by individuals with both low and high health literacy [67-69]. The integration of EMPOWER and GENIE was considered valuable by encouraging users to move beyond a medicalized approach to self-management and think about what matters to them within their social practices and networks. Although this was theoretically informed and viable, there were technical issues and reported tensions related to mixed messages about self-efficacy. We suggest that this tension is caused by the underlying differences between the 2 sites. EMPOWER is a behavioral intervention, whereas GENIE is about social practices. The latter has been established to make a contribution that is not as immediate as needing to respond to and alleviate pain. Rather, it is designed to respond to the everyday demands of living life with a chronic condition [23]. In this context, GENIE supports people to seek activities that prevent or lessen the intensity of episodes over time (eg, through joining an activity group, which in turn may help to reduce episodes of acute pain).

EMPOWER was designed, based on user feedback, to be an initial point of contact for people seeking information and advice about joint pain. EMPOWER also promoted social engagement to support self-management by encouraging users to think about and record how their own social networks could help and to engage with GENIE. However, most participants did not engage with these features on the EMPOWER site. A facilitated approach has previously been found to encourage greater motivation and persistence to think about social network support using the GENIE site [23]. Such a facilitated approach was offered to participants using a simple electronic request on the EMPOWER site but was not taken up.

The tensions between the sites may have created practical and cognitive burdens for users, increasing the perceived complexity of the overall intervention. Although participants identified potential value in using a digital tool in collaboration with primary care, the increased complexity of the EMPOWER and GENIE intervention limits the potential for wide-scale future adoption [45].

The Adopter System

Some of the focus group and interview participants suggested that health care professionals should introduce the sites' resources and support goal setting. A lack of this input may have influenced the number of users registered during the evaluation phase. Previous studies have identified the importance of ensuring that new technologies contextually link with the existing health care environment [70]. In doing so, new interventions are more likely to be adopted and effective for their target population [71,72].

Limitations

We aimed to recruit a diverse range of people to take part in developing a new self-management intervention for people with OA. Although we achieved our recruitment target for focus groups and interviews, a lack of diversity was evident with respect to health literacy. We further aimed to improve this during the evaluation study by focusing on recruitment areas with the highest indices of deprivation. However, most participants in this study were from areas with the lowest level of deprivation. Although study materials were designed to be user friendly and readable, this had little effect on recruiting people with lower levels of health literacy. We considered the library setting appropriate for recruitment as a provider of community information and support, particularly related to using the internet [73]. However, it may have been more appropriate to set up a local patient and public involvement group to better understand the needs of the local population first. This approach has been reported to be beneficial, alongside a snowball sampling strategy for engaging *hard-to-reach* groups in the community [74].

We were also unable to recruit many older adults (aged ≥75 years) to take part in the studies. Although people in this age category typically use the internet less than other age groups, data from the Office for National Statistics show increased use year-on-year [75], which we hope would translate into study participation. Consequently, the findings of this study cannot be generalizable.

During the focus groups and interviews, participants were asked to explore the websites in a way that was relevant to them. However, this may not have been representative of daily use, impacting on the validity of the results and subsequently the development and integration of the sites.

In the evaluation study, although the site was accessed 18 times during the data collection period, this only translated into 6 registered users. Although issues related to the technology and adopter system have been discussed as barriers to recruitment, some of the library locations were less engaged or were only open part-time, which may also have had an influence. Digital feedback forms were not completed by any participant, even with email reminders. It may have been prudent, therefore, to offer nondigital alternatives, such as postal questionnaires or telephone interviews, which may have been more acceptable. However, this would have required participants to provide their address and/or telephone number and may have influenced their decision to take part in the study.

Given the successes and limitations of this study, future work should incorporate close community partners working to understand the needs of the local population. In doing so, a more representative sample may be achieved, particularly in relation to levels of health literacy. Both health information and social network approaches are important for supporting self-management. However, future work should seek to clarify how best to integrate and implement these approaches in terms of digital or nondigital approaches and in the context of the wider health care system.

Conclusions

This study has demonstrated the complexity associated with developing an accessible digital tool that combines self-efficacy and social network activation to support the variety of needs of people with joint pain. The NASSS framework provided a useful mechanism for evaluating and explaining the nonadoption of the intervention. Considerable complexity was associated with the integration of the EMPOWER and GENIE resources, both technically and conceptually. We identified tensions between the 2 resources caused by differences in their approach to self-management. Although EMPOWER aims to support change in self-management behaviors, GENIE focuses on building collective efficacy through engagement with valued activities. Recognition of joint pain as the prime reason for seeking support was considered important as was an association with health care professionals for some participants. However, connecting with the offline world was also considered beneficial through engagement with people and community resources for support. We therefore conclude that although an integrated approach was not adopted, both types of intervention have a role in the self-management of people with joint pain.

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Authors' Contributions

PC contributed to the design, data collection, analysis, technical development of EMPOWER, and drafting of the manuscript. IV contributed to the conception and design of the project, data collection, interpretation of data, and revision of the manuscript. AR

contributed to the conception and design of the project, theoretical underpinnings, and revisions of the manuscript. CB provided input on health literacy, undertook data collection, reviewed the EMPOWER site, and made revisions to the manuscript. NW contributed through content development and review of the EMPOWER site and revisions to the manuscript. JL contributed to the development of participant materials, content of EMPOWER, and review of the manuscript. JA contributed to the conception and design of the project, interpretation of data, development of the EMPOWER site, and review of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The 7 domains of the nonadoption, abandonment, scale-up, spread, and sustainability framework for the implementation of technology in health and social care, reproduced with permission and licensed under Creative Commons Attribution cc-by 4.0.
[PNG File , 90 KB - formative_v4i11e18565_app1.png]

Multimedia Appendix 2
Focus group and think-aloud interview representative accounts.
[DOCX File , 16 KB - formative_v4i11e18565_app2.docx]

Multimedia Appendix 3
Example Managing Joint Pain on the Web and Through Resources (EMPOWER) page during development showing the text input field for users to record how people around them could help.
[PNG File , 183 KB - formative_v4i11e18565_app3.png]

Multimedia Appendix 4
Example of changes made following the think-aloud interviews.
[PNG File , 227 KB - formative_v4i11e18565_app4.png]

Multimedia Appendix 5
Links between Managing Joint Pain on the Web and Through Resources (EMPOWER) pages and Generating Engagement in Network Involvement (GENIE).
[PNG File , 381 KB - formative_v4i11e18565_app5.png]

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Abbreviations

EMPOWER: Managing joint Pain On the Web and through Resources
GENIE: Generating Engagement in Network Involvement
GP: general practitioner
LTC: long-term condition
MJP: My Joint Pain
NASSS: nonadoption, abandonment, scale-up, spread, and sustainability
NHS: National Health Service
OA: osteoarthritis
PBA: person-based approach
PIS: participant information sheet

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Original Paper

Surveillance of Cardiovascular Risk Factors in the Fifth Military Sector Health Center, Ngaoundéré, Cameroon: Observational Study

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Abstract

Background: Noncommunicable diseases (NCDs) are the leading causes of death worldwide. They were responsible for 40 million of the 57 million deaths recorded worldwide in 2016. In Cameroon, epidemiological studies have been devoted to NCDs and their risk factors. However, none provides specific information on their extent or the distribution of their risk factors within the Cameroonian defense forces.

Objective: The objective of our study was to assess the cardiovascular risk of a Cameroonian military population compared with that of its neighboring civilian population.

Methods: We conducted a cross-sectional study that involved subjects aged 18 to 58 years, recruited from October 2017 to November 2018 at the Fifth Military Sector Health Center in Ngaoundéré, Cameroon. Data collection and assessment were done according to the World Health Organization (WHO)'s STEPS manual for surveillance of risk factors for chronic NCDs and the Alcohol Use Disorders Identification Test. Five cardiovascular risk factors were assessed: smoking, harmful alcohol consumption, obesity/overweight, hypertension, and diabetes. The risk was considered high in subjects with 3 or more of the factors. Univariate analysis and multivariate logistic regression were carried out according to their indications.

Results: Our study sample of 566 participants included 295 soldiers and 271 civilians of the same age group (median age 32 years versus 33 years, respectively; *P*=.57). The military sample consisted of 31 officers and 264 noncommissioned officers (NCOs). Soldiers were more exposed to behavioral risk factors than civilians, with a prevalence of smoking of 13.9% versus 4.4% (*P*<.001) and excessive alcohol consumption of 61.7% versus 14.8% (*P*<.001). They also presented with a higher cardiovascular risk than civilians (odds ratio 2.7, 95% CI 1.50-4.81; *P*<.001), and among the military participants, the cardiovascular risk was higher for officers than for NCOs (51.6% versus 14.0%, respectively; *P*<.001).

Conclusions: Cameroonian soldiers are particularly exposed to cardiovascular behavioral risk factors and consequently are at higher risk of NCDs.

Trial Registration: ClinicalTrials.gov NCT04315441; https://clinicaltrials.gov/ct2/show/NCT04315441

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KEYWORDS

prevention; noncommunicable disease; cardiovascular diseases; cardiovascular risk; soldiers

Introduction

In the last three decades, infectious diseases such as human immunodeficiency virus/acquired immunodeficiency syndrome and others were the leading causes of mortality in sub-Saharan countries. However, with increased life expectancy and the adoption of harmful lifestyles, noncommunicable diseases (NCDs) have emerged among the leading causes of morbidity as well as early death in these countries.

NCDs were responsible for 41 million of the 57 million deaths recorded worldwide in 2016 [1,2]. Low- and middle-income countries were affected by 28 million of these deaths, 82% of which were considered premature because they occurred in people younger than 70 years of age [1,2]. The four main NCDs responsible for the deaths were cardiovascular diseases (CVDs), diabetes, cancer, and chronic respiratory disease, with CVDs (ischemic heart disease, ischemic stroke, and peripheral vascular disease) being responsible for the greatest number of deaths. Ischemic heart disease, responsible for 9.4 million deaths, ranked first among the causes, followed by strokes, which were responsible for 5.8 million deaths. Other circulatory diseases, responsible for 1 million deaths, were the tenth leading cause of death worldwide in 2016 [1].

The NCD epidemic is gaining so much momentum that the military population, which seemed to be spared from these pathologies, is as exposed today as the general population, and sometimes even more so, with the consequences of a deleterious effect on their operational capacity and a high rate of absenteeism [3,4]. The effective response to this public health challenge requires prior identification of the level of exposure of populations in order to implement actions to reduce the risk factors. Several nations have therefore assessed the extent of NCDs in their military populations [3-8].

In Cameroon, epidemiological studies have been devoted to NCDs and their risk factors [9-15]. However, none of them provides specific information on their extent and/or the distribution of their risk factors within its defense forces.

Thus, the objective of our study was to assess the cardiovascular risk of a Cameroonian military population compared with that of a civilian population.

Methods

Study Design

We carried out a descriptive and analytical cross-sectional study.

Study Area and Population

The study involved the soldiers of the Ngaoundéré garrison and the neighboring civilian population. Ngaoundéré is the capital city of the Adamawa Region of Cameroon, with 298,016 inhabitants and a surface area of 62,000 km^2.

Participation in the study was proposed to all soldiers who came to the Ngaoundéré Fifth Military Sector Medical Center for the annual re-engagement medical visit during the period from January 1, 2017, to November 13, 2018. For inclusion in the study, the participant had to consent and be between 18 and 58 years of age—representing the ages for enrollment and retirement, respectively, for Cameroonian soldiers. The civilian populations were recruited during two free cardiovascular risk factor screening campaigns carried out from January 2017 to November 2018. These campaigns were also open to soldiers who wished to participate.

Medical Examination, Data Collection, and Definition of Variables

A questionnaire, developed from the World Health Organization (WHO)'s STEPS Manual for surveillance of risk factors of NCDs, made it possible to collect sociodemographic information (eg, age, gender, and military rank), information on habits related to healthy living (alcohol consumption and smoking in particular), and information on the medical history of study participants. An additional tool—the Alcohol Use Disorders Identification Test (AUDIT), developed by the WHO—was used to assess the participant's level of alcohol consumption [16]. Anthropometric data such as height and weight were collected to determine BMI.

Blood pressure was measured using an electronic blood pressure monitor. The individual was seated and rested for 15 minutes before a measurement was taken on each arm with a 10-minute interval between measurements. For those with diastolic and/or systolic blood pressures higher than or equal to 90 mmHg and/or 140 mmHg, respectively, a second measurement was taken on both arms with a 10-minute interval between measurements. In all cases, the lower values were retained for each participant.

The fasting capillary blood glucose test was carried out using a strip and a glucometer.

The variables defined from the questionnaire and measurements taken were as follows:

- smoking: "Yes" response in answer to the question, "Do you smoke?"
- alcohol intake: "Yes" response in answer to the question, "Do you consume alcohol?"
- weight status: 4 categories were defined according to BMI: underweight (BMI<18.5 kg/m^2), normal weight (18≤BMI<25 kg/m^2), overweight (25≤BMI<30 kg/m^2), and obese (BMI≥30 kg/m^2)
- high blood pressure (hypertension): defined as having a systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg (BP-103H Upper Arm Lifestyle Blood Pressure Monitor, Idass) or taking any medication prescribed by medical personnel to reduce hypertension
- diabetes: defined as having a fasting blood glucose ≥7 mmol/L (OneTouch Ultra 2, Lifescan Canada Ltd) or taking any medication prescribed by medical personnel to treat diabetes
- cardiovascular risk: determined by summing up the individual's risk factors, including being a smoker,

excessive alcohol consumption (defined as an AUDIT score ≥8), being overweight or obese, or having hypertension or diabetes. It was considered high if the participant had a combination of at least 3 risk factors.

Statistical Analyses

All analyses were performed using Epi Info software (version 7.2; Centers for Disease Control and Prevention). The Pearson chi-square test was used for comparing proportions. The Mann-Whitney test and analysis of variance were carried out according to their indications to compare the numeric variables. A multiple logistic regression analysis was performed to determine the population with the greatest cardiovascular risk regardless of age or gender. The significance threshold was set at $P<.05$.

Ethical Considerations

The study was authorized by the military hierarchy (ref 016082/AU/DSM/RSM3/SSM5), and the participants all agreed to the use of the information collected for the purposes of this study.

Results

We sampled 566 volunteers comprised of 295 soldiers and 271 civilians of approximately the same ages (mean 35 [SD 11] years versus 36 [SD 11] years, respectively; $P<.57$). A total of 460 of 566 (81.3%) people in the sample population were men. The BMI of the military personnel was on average higher than that of their civilian counterparts (mean 26.18 [SD 3.96] kg/m^2 versus 24.74 [SD 4.91] kg/m^2; $P<.001$). On the other hand, clinical parameters such as blood glucose and blood pressure levels were similar for the two populations. The demographic characteristics and clinical parameters are presented in Table 1.

Table 1. Demographic characteristics and clinical parameters of the sample population.

Characteristics	Total sample (n=566)	Military (n=295)	Civilians (n=271)	*P* value
Gender, n (%)				
Women	105 (18.7)	34 (11.5)	72 (26.6)	.001[a]
Men	461 (81.3)	261 (88.5)	199 (73.4)	
Age (years), median (IQR)	33 (26-44)	32 (26-43)	33 (26-45)	.65[b]
BMI (kg/m^2), median (IQR)	25.20 (22.49-27.97)	25.73 (23.72-28.04)	24.22 (21.20-27.43)	.001[b]
SBP[c] (mmHg), median (IQR)	126 (116-136)	127 (117-137)	125 (114-135)	.12[b]
DBP[d] (mmHg), median (IQR)	77 (69-86)	78 (69-87)	77 (69-85)	.19[b]
Glycemia (mmol/L), median (IQR)	5.29 (4.89-5.79)	5.19 (4.88-5.73)	5.36 (4.95-5.79)	.47[b]

[a]Calculated using chi-square test.

[b]Calculated using Mann-Whitney test.

[c]SBP: systolic blood pressure.

[d]DBP: diastolic blood pressure.

Of the 295 military participants, 31 (10.5%) were officers and 264 (89.5%) were noncommissioned officers (NCOs), with the former being older than the latter (mean age 50 [SD 8] years versus 34 [SD 10] years; $P<.001$).

With respect to the distribution of cardiovascular risk factors, the number per participant was higher among the military population than among the civilians (median [IQR]: 2 [1-2] versus 1 [0-1]; $P<.001$). There were 279 (279/566, 49.3%) people who reported consuming alcohol. Among them, the proportion of soldiers was greater than that of civilians (70.2% versus 26.6%, respectively; $P<.001$). The AUDIT scores were higher in the military population than in the civilian population (median [IQR]: 9 [0-9] versus 0 [0-3], respectively; $P<.001$). Even when the analysis incorporated nonmodifiable cardiovascular risk factors, such as age and gender, the military population still had a higher risk profile than the civilians (odds ratio [OR] 2.7, 95% CI 1.51-4.81). Tables 2–4 show the distribution of the risk factors in the sample population.

In the military population, officers had significantly more cardiovascular risk factors than NCOs (OR 6.54, 95% CI 2.98-14.35). This is shown in Table 5.

Table 2. Distribution of cardiovascular risk factors in the sample population.

Risk factors	Total sample (N=566), n (%)	Military (n=295), n (%)	Civilians (n=271), n (%)	*P* value
Smoking	53 (9.4)	41 (13.9)	12 (4.4)	.001
Excessive alcohol consumption	222 (39.2)	182 (61.7)	40 (14.8)	.001
Diabetes	19 (3.4)	8 (2.7)	11 (4.1)	.37
Obesity or overweight	292 (51.6)	177 (60.0)	115 (42.4)	.001
Blood pressure above normal	132 (23.3)	68 (23.1)	64 (23.6)	.87
High cardiovascular risk	77 (13.6)	53 (18.0)	24 (8.9)	.001

Table 3. Distribution of cardiovascular risk factors by gender.

Risk factors	Male			Female		
	Military (n=295), n (%)	Civilians (n=271), n (%)	*P* value	Military (n=295), n (%)	Civilians (n=271), n (%)	*P* value
Smoking	40 (15.3)	12 (6.0)	.002	1 (2.9)	0 (0)	.32
Excessive alcohol consumption	165 (63.2)	34 (17.1)	.001	17 (50.0)	6 (8.3)	.001
Diabetes	7 (2.7)	10 (5.0)	.19	1 (2.9)	1 (1.4)	.058
Obesity or overweight	151 (57.9)	74 (37.2)	.001	26 (76.5)	41 (56.9)	.05
Blood pressure above normal	60 (23.0)	43 (21.6)	.72	8 (23.5)	21 (29.2)	.54
High cardiovascular risk	49 (18.8)	19 (9.6)	.01	4 (11.8)	5 (6.9)	.41

Table 4. Multivariate analysis of the relationship between high cardiovascular risk, occupation, age, and gender.

Variables	Odds ratio (95% CI)	*P* value
Age	1.11 (1.08-1.13)	0.001
Gender (male/female)	1.36 (0.61-3.03)	0.45
Occupation (military/civilian)	2.70 (1.51-4.81)	0.001

Table 5. Distribution of cardiovascular risk factors in the military population.

Risk factors	Officers (n=31), n (%)	Noncommissioned officers (n=264), n (%)	*P* value[a]
Smoking	8 (25.8)	33 (12.5)	.04
Excessive alcohol consumption	24 (77.4)	158 (59.9)	.06
Diabetes	2 (6.5)	6 (2.3)	.17
Obesity or overweight	26 (83.9)	151 (57.2)	.001
Blood pressure above normal	17 (54.9)	51 (19.3)	.001
High cardiovascular risk	16 (51.6)	37 (14.0)	.001

[a]Calculated using chi-square test.

Discussion

Principal Findings

The objective of this study was to determine the level of exposure of the military population of Ngaoundéré to CVD. Our results suggested that they were effectively at risk and that the risk factors were generally more frequent among them than in the civilian population. In fact, the number of risk factors in the military population was double that in the civilian population. Similarly, behavioral cardiovascular risk factors such as smoking and excessive alcohol consumption were observed in more military participants than in civilians. Within the Cameroonian military population, we found that officers had a higher cardiovascular risk than NCOs, which was hardly surprising, given the fact that the officers were significantly older.

Considering the general distribution of these cardiovascular risk factors in our sample population, there was barely a difference compared with the prevalence observed in other studies in Cameroon. For hypertension, we found a prevalence of 23.3%, which was obviously different from the current general prevalence in Cameroon that is estimated at 32.1% [17].

However, it should be noted that at least one-half of our participants were younger than 33 years of age, and the prevalence of hypertension among those under 35 years of age in Cameroon is 24% [17], which is perfectly in line with our result of 23.3%. In addition, the proportion of patients with hypertension in our study was in agreement with the 20.43% found in a study carried out in 2016 in the general population of Ngaoundéré [15]. In our study, the proportion of smokers was 9.4%, which was very close to the prevalences of 8.4% and 8.3% observed by other authors in the cities of Yaoundé [13] and Ngaoundéré [15], respectively. Diabetes was present in 3.4% of our participants, which was not far off the prevalence of 5.8% found in a recent study in Cameroon [14].

With regard to the distribution of cardiovascular risk factors among the military population, our overall results showed some similarities with studies carried out in other countries. Thus, our finding of 23.1% of soldiers with hypertension was not far off the 28.4% found in the Senegalese army [4] or the 21.7% in the Guinea-Conakry army [8].

On the contrary, in industrialized countries such as the United States, the prevalence of hypertension is 13% [3]. This difference can be explained by the fact that many industrialized nations embarked on the fight against NCDs in their armies much earlier than African countries did [3]. While 13.9% of Cameroonian soldiers used tobacco, other armies had higher prevalences, such as 17.3% in Senegal, 47.3% in Guinea-Conakry, 20.3% in Nigeria, 34.8% in Uganda, 47.1% in Côte d'Ivoire, and 32% in Taiwan [4,18-22]. This difference can be explained by the fact that in general, the Cameroonian population, including the military population, seems to have a low propensity for smoking [13-15]. Also, the proportion of Cameroonian soldiers who were obese or overweight was 60%, which was very similar to the proportion observed in Saudi Arabia (69.9%) [8].

Study Limitations

Some limitations of our study on the Cameroonian defense forces were that these results would have been more complete if they had included other cardiovascular risk factors such as hyperlipidemia/hypercholesterolemia, food imbalance, and physical inactivity. However, the assessment of physical activity was deliberately excluded from the procedures because the practice of sports and other types of maneuvers are an integral part of the lives of Cameroonian soldiers. For example, 2 days of collective sports per week are the compulsory minimum for all military units. Therefore, our hypothesis was that, a priori, Cameroonian soldiers carry out regular physical activity.

The lipid and cholesterol levels of the participants were not evaluated due to our limited financial means. Nonetheless, some authors suggest that the BMI assessment is an alternative measure that can be substituted for the cholesterol assessment in estimating cardiovascular risk in low-income countries [23,24]. It is also important to put BMI into perspective in participants, such as military personnel, who do a lot of sports because BMI can be high in athletes. This is because muscle mass represents a significant weight that does not necessarily correspond to body fat. Therefore, BMI can certainly overestimate the weight of participants, although it remains a very practical epidemiological tool for the evaluation of weight status. It gives an overview, which can be estimated more precisely with other specific tools.

We were unable to include the evaluation of the participants' diets because during the pretesting of the questionnaire used in our study, people found it difficult to respond clearly to the questions about the amounts and types of food they consumed.

Among the limitations of the study, we should also mention the sample size. However, this was an observational study from which we could show differences—for example, in the use of tobacco. Furthermore, the population of the Ngaoundéré area is not representative of the Cameroonian population, either in soldiers or in civilians, because this city is close to an armed conflict area. As a result, the soldiers in this garrison could be selectively those who are more able to fight, while the civilians could include many internally displaced persons fleeing from the looting and killing by insurgents in their villages.

Finally, the WHO's STEPS methodology is designed to provide standardized information on key modifiable risk factors that can be measured in population-based surveys without the need for high-technology instruments. However, since the behavioral risk factors were self-reported, some of the information could have been concealed, especially those related to alcohol and tobacco use.

We chose to sum up of the cardiovascular risk factors because scoring methods are often used in studies conducted on non-African populations, and their applicability to African subjects is much discussed. An alternative would have been the use of the WHO/International Society of Hypertension risk prediction charts, but these tables are intended for subjects aged 40 years and older [25,26]. Therefore, we opted for this simpler method already used by other authors [4].

Despite these shortcomings, which can be remedied in future studies, our results remain valid and provide information on the distribution of cardiovascular risk factors in the Cameroonian Armed Forces. They can easily be taken into account when developing strategies for the reduction of these risk factors in the country of Cameroon in general, and in the Cameroonian defense forces in particular.

Conclusion

Cameroonian soldiers are particularly exposed to cardiovascular behavioral risk factors, which implies that national programs in the fight against NCDs and their risk factors should devote greater attention to the military population. These programs should focus on providing adequate sensitization on complications arising from CVDs.

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Authors' Contributions

Study conception: WBN, LEEB, and ASPEN. Data collection: WBN and ASPEN. Statistical analyses: WBN and BB. Drafting: WBN, BB, and ASPEN. Critical analyses and revision of the manuscript: LEEB, FR, LG, and SHM.

Conflicts of Interest

None declared.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
CVD: cardiovascular disease
NCD: noncommunicable disease
NCO: noncommissioned officer
WHO: World Health Organization

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Original Paper

Informing the Development of a Digital Health Platform Through Universal Points of Care: Qualitative Survey Study

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Abstract

Background: Epilepsy, multiple sclerosis (MS), and depression are chronic conditions where technology holds potential in clinical monitoring and self-management. Over 5 years, the Remote Assessment of Disease and Relapse - Central Nervous System (RADAR-CNS) consortium has explored the application of remote measurement technology (RMT) to the management and self-management of patients in these clinical areas. The consortium is large and includes clinical and nonclinical researchers as well as a patient advisory board.

Objective: This formative development study aimed to understand how consortium members viewed the potential of RMT in epilepsy, MS, and depression.

Methods: In this qualitative survey study, we developed a methodological tool, universal points of care (UPOC), to gather views on the potential use, acceptance, and value of a novel RMT platform across 3 chronic conditions (MS, epilepsy, and depression). UPOC builds upon use case scenario methodology, using expert elicitation and analysis of care pathways to develop scenarios applicable across multiple conditions. After developing scenarios, we elicited views on the potential of RMT in these different scenarios through a survey administered to 28 subject matter experts, consisting of 16 health care practitioners; 5 health care services researchers; and 7 people with lived experience of MS, epilepsy, or depression. Survey results were analyzed thematically and using an existing framework of factors describing links between design and context.

Results: The survey elicited potential beneficial applications of the RADAR-CNS RMT system as well as patient, clinical, and nonclinical requirements of RMT across the 3 conditions of interest. Potential applications included recognition of early warning signs of relapse from subclinical signals for MS, seizure precipitant signals for epilepsy, and behavior change in depression. RMT was also thought to have the potential to overcome the problem of underreporting, which is especially problematic in epilepsy, and to allow the capture of secondary symptoms that are not generally collected in MS, such as mood.

Conclusions: Respondents suggested novel and unanticipated uses of RMT, including the use of RMT to detect emerging side effects of treatment, enable behavior change for sleep regulation and activity, and offer a way to include family and other carers in a care network, which could assist with goal setting. These suggestions, together with others from this and related work, will inform the development of the system for its eventual application in research and clinical practice. The UPOC methodology was effective in directing respondents to consider the value of health care technologies in condition-specific experiences of everyday life and working practice.

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KEYWORDS

epilepsy; multiple sclerosis; depression; wearable electronic devices; remote sensing technology; health personnel; mobile phones; mHealth; eHealth

Introduction

Background

Prior work has recognized the need for health information technologies (HITs) to consider socio-technical facets used over time and the varying trajectories experienced within and between health care services [1]. Previous work in mobile health has indicated how technologies may be able to alter the relationship and dynamics of clinician-patient interactions, where previously the clinician has been seen as the main decision maker and expert provider of information and knowledge [2,3]. The introduction of monitoring, measurement, and communication technologies should, in principle, support informed patient-clinician partnerships and greater shared decision making, although there may be barriers to their use [4,5].

The importance of ensuring that the requirements of all users are considered early in the design process of products and services is well established. The benefits of user-centered design approaches underpin improved usability and adoption, and human factors and ergonomics is a key discipline in this area [6]. In particular, through a systems approach to design, the added value of novel technologies can be understood when these advances enable new ways of working, speed up or make existing practices easier, or enhance the user experience [7]. In addition, this perspective supports the inclusion of all users within a system and aims to understand the multiple socio-technical interactions of a new intervention, whether they are human-to-human interactions, human-to-technology interactions, or any permutation. Despite this knowledge and a regulatory landscape supporting the inclusion of all stakeholders during design and development, there is evidence that HITs producers are still responding to technology push, and the requirements of all users are not necessarily prioritized during system development [8].

In this study, we aim to investigate how the introduction of a remote measurement technology (RMT) platform might alter current practices in care pathways for people with epilepsy, multiple sclerosis (MS), or depression and identify where, how, and why clinicians and patients may derive value from the RMT platform once in practice.

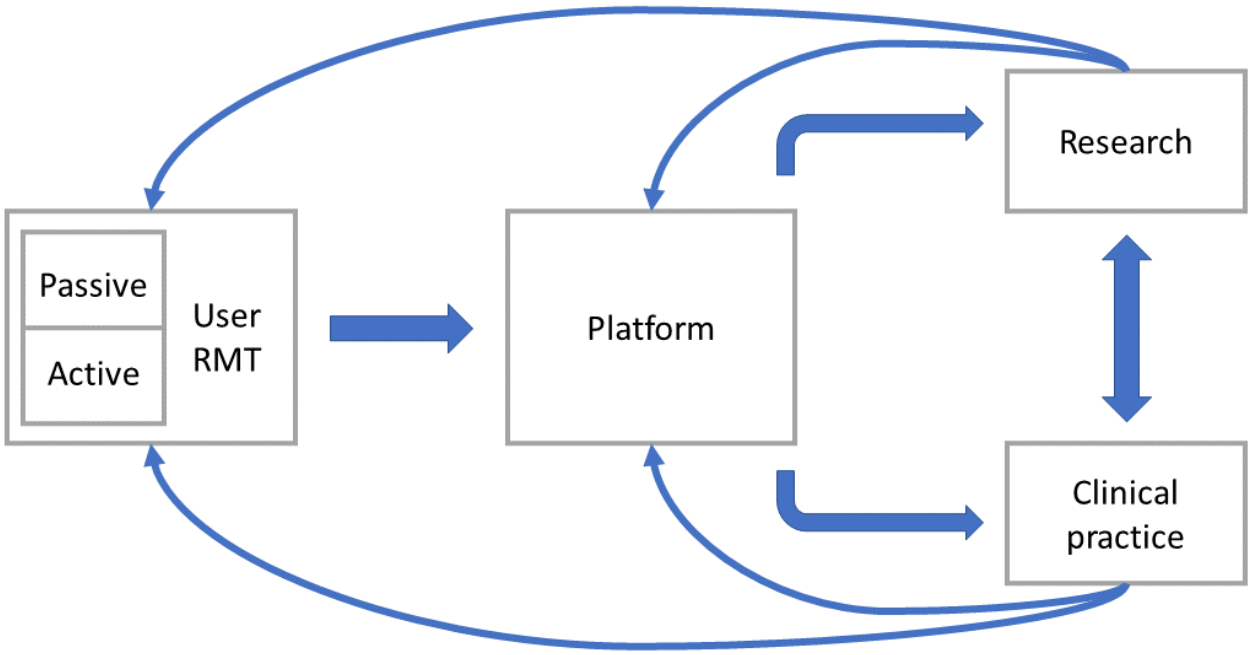
Study Technology Overview

The Remote Assessment of Disease and Relapse - Central Nervous System (RADAR-CNS) RMT platform under consideration in this study is being designed for use in the clinical management and patient self-management of 3 long-term conditions: epilepsy, MS, and depression. However, the long-term goal is for a flexible, ubiquitous platform that can be adapted to support the management of a wide range of conditions spanning physical and mental health domains as well as use in research.

The RMT system in development consists of wearables and mobile phone apps run on consumer mobile devices. A passive remote measurement technology software component processes sensor data such as activity and location. Passive data collection systems have been used in various applications in general health [9] and mental health in particular [10]. An active remote measurement technology component processes user-supplied data entries. This includes data from short questionnaires completed at regular intervals on mobile devices after notification to the user, usually termed ecological momentary assessment or experience sampling method, and other prompted input such as voice samples. Longitudinal data sets are collected from individual users with the aim of processing through predictive algorithms to understand whether early detection and warning of relapse and/or disease change (worsening or improvement) can be identified via RMT.

Furthermore, a number of translational work packages exist to probe the user acceptability and fit of RMT to health care systems and in the everyday lives of health care professionals and patients. All work is at a formative stage, and no system has been introduced into health care practice at this stage. In the initial iteration of the system, which is used in observational research studies, there is no predictive element and no feedback from the system to the patient, although these are features that have the potential to be developed and included in the longer term. Figure 1 illustrates how use in research and practice will inform further development of the platform.

Figure 1. Diagram showing how the platform under development is intended for use in clinical practice and research. The platform is supplied with data from passive and active remote measurement technology worn or carried by patient users, as instructed by the clinic or in research protocols. Use in research and practice will inform further development of the platform. RMT: remote measurement technology.



Scenario-Based Design

Use cases and design scenarios have been used in design processes since the early 1990s [11] and constitute a key tool when exploring technology users' needs and the nature and requirements of cooperative work systems [12,13]. Within the field of health care, use case scenarios have been applied in investigations into clinical decision making and associated tools and aids [14-16] and in further understanding knowledge sharing in distributed working practices [17]. Scenarios help participants to envisage how new technologies might be implemented in practice where these are not yet common. Scenarios are useful because they encourage consideration of multiple facets of a situation and foster elicitation of views that can inform the development of tools and services. However, use case scenarios tend to work best in task-specific contexts, where parameters are clearly defined and the outcome of use is predictable [18].

Conversely, digital health care systems tend to be complex in nature, with multiple users, addressing multiple medical conditions, and with unpredictability in use [19]. In this paper, we describe the use of a new methodology, based on use case scenarios, to inform the design of the RADAR-CNS RMT system, which is to be used in research and ultimately in clinical practice. The system is required to work across multiple conditions, collecting data from patients who have differing requirements from health care professionals treating them. Thus, we required a methodology to inform the design of the system to ensure applicability within and between conditions. The methodology was also required to allow participants in the research program (clinicians and patients) to contribute from their own expertise and experience, without having to adapt the research method for each condition. We call our approach universal points of care (UPOC).

Methods

Approach

A survey was developed to elicit opinions from European health care professionals and researchers within the consortium and the patient advisory board (PAB), which was made up of individuals with lived experience of the 3 conditions of interest. The aim was to focus on the potential and practicalities of RMT use in everyday practice. In particular, we sought to carry out a preliminary investigation into the current practices across the 3 central nervous system (CNS) conditions. The intention was to provide space for clinical opinion to explore prospectively how practice would (or could) be affected by the introduction of the RADAR-CNS RMT system and to uncover needs and concerns about this. The approach taken was to ask participants about a series of preidentified points of care common across the 3 conditions, and then to elicit further points of care that may be affected by the introduction of the RMT system. Generic clinical scenarios were identified through expert elicitation and exploration of clinical pathways. The developed scenarios became UPOC exemplars, providing the basis for an inquiry that would be relevant to multiple clinical conditions.

Development of UPOC Exemplars

Clinical pathways provide a framework through which changes relevant to the implementation of new technologies and devices can be considered. Clinical pathways represent care management within a clinic setting [20] and can also refer to the planned, managed delivery of care over time and by care teams in a range of clinical settings, as per the definition of clinical pathways provided by the European Pathway Association [21].

The UPOC were informed by consultation of academic and gray literature on clinical pathways in each of the following conditions: a review of treatment pathways for MS [22], an international audit of epilepsy services worldwide [23], and the European Psychiatric Association's guidance on psychotherapy in chronic depression [24], among other work. The UPOC were derived by reviewing existing clinical pathways and decision points of the 3 target clinical areas via examination of the National Institute for Health and Care Excellence care pathway maps [25]. These maps consist of interactive flowcharts presenting details of the recommendations for managing patients of different groups (eg, by age), including the recommended steps involved in diagnosis and treatment. Here, we focused on the pathways for epilepsy, MS, and depression. Knowledge was also gained from informal discussions with clinicians in the consortium, focusing on personal experiences of care provision and reflecting on the current clinical pathways for epilepsy, MS, and depression.

Once identified, the UPOC were designed into the survey, and participants were asked to consider how those UPOC might be experienced both without and with an RMT system in place, to contrast current care provision with future care provision when the RADAR-CNS RMT system is deployed. It was decided that participants would also be invited to describe any additional use scenarios that they believed would be encountered in care delivery or receipt with the use of RMT.

Participants

A convenience sampling method was used to recruit members of the consortium to take part in the survey, some at an annual meeting that took place in April 2018 and some shortly after. To encourage engagement, a panel session was held at the annual meeting, with presentations by 3 clinicians and 3 members of the PAB discussing value propositions of novel health care technologies. This also included details on the content, aims, and importance of the survey. Delegates of the meeting were asked to complete the survey immediately afterward. Members of the consortium were freely able to take part (or not). The survey was administered via a web-based interface for ease of access and to provide the opportunity for remote completion. PAB participants were given the option to complete the survey by hand, by email, or by phone—in the latter case, a researcher made hand-written notes on a printed survey form for each survey administered. Due to their involvement in the research program, all the participants had baseline knowledge of the RADAR-CNS RMT system and its potential functional capabilities, for example, remote monitoring of disease, distributed and computer-supported delivery, and receipt of care and personalized medicine. Participants were asked to respond in relation to the condition on which they had most knowledge.

Survey Sections

The survey was divided into 6 sections, A-F, as follows. All respondents were encouraged to answer all questions. The survey instrument is available in Multimedia Appendix 1. An overview of survey sections is provided in Table 1. These are shortened titles of the survey sections; more comprehensive titles were used in the survey itself, and they can be found in Multimedia Appendix 1.

Table 1. Survey sections.

Sections	Survey sections
Section A	Respondent information
Section B	Promise of RMT[a]
Section C	UPOC[b] 1-6 comparing existing and future potential care
Section D	Respondent-provided UPOC
Section E	Use of RMT data
Section F	Reflections and comments

[a]RMT: remote measurement technology.

[b]UPOC: universal points of care.

Section A of the survey collected demographic information about the respondents, including names; geographical location; role in the partnership; and where relevant, place of work, clinical or research specialty, and for the PAB respondents, their clinical condition.

Section B was designed to gather general opinion about the promise of RMT.

Section C presented the UPOC to participants for them to consider how these occurred in their experience *before RADAR-CNS* and how they may occur *after RADAR-CNS*. Questions in the survey text prompted consideration of various aspects of the UPOC: *Where does the interaction take place? Are any communications in real time or is there a delay? What are the positives about this way of interacting? What are the negatives about this way of interacting?* Six UPOC that were identified and used in the survey are presented in Textbox 1.

Textbox 1. The 6 universal points of care for which the respondents were asked to provide details about the scenarios before and after the introduction of remote measurement technology.

Patient sharing data with clinician

- A patient has been monitoring how they feel (activity, mood, sleep, etc) for 2 weeks. They have some concerns and would like to share their data with their clinician. How might this happen?

Relapse detection (symptomatic)

- A patient is not feeling well and might be on the path to relapse. How do you (patient or clinician) try to understand if a relapse is imminent or occurring?

Relapse detection communication (recently diagnosed patient)

- The patient might be headed for a relapse. The clinician and the patient have not been working together for very long, and the patient is still getting used to their diagnosis. How would this be communicated?

Relapse detection communication (patient diagnosed for a long time)

- The patient might be headed for a relapse. The clinician and the patient know each other well, and the patient has been living with the condition for a long time. How would this be communicated?

Medication selection or dosing (recently diagnosed patient)

- The patient's medication needs modification. What is the best way of informing them of this decision and providing them with information?

Medication selection/dosing (patient diagnosed for a long time)

- The patient's medication needs modification. What is the best way of informing them of this decision and providing them with information?

In section D, respondents were asked to offer up to 2 additional UPOC of their own, inviting them to consider "other situations where use of the technology might change your decisions, behaviours or experiences or the way in which you interact with other people (clinicians, patients, other healthcare professionals)." In section E, respondents were asked to consider the possibility of 2 more speculative UPOC specific to RMT implementation: (1) stratification of patient risk for relapse and (2) dealing with different patient responses to treatment. During analysis, these were then rated as either *considered useful*, *considered possible*, *would need more research*, or *have concerns*. In section F, any final additional comments were collected.

Data Analysis

Data were gathered via a web-based interface, Bristol Online Surveys [26], which collected and grouped the raw data of respondents for section A-F of the survey. The raw data consisted of single sentences or short paragraphs written by individual respondents to each question that was posed. Thematic analysis [27] was carried out on the collected data. Responses were coded by 2 coders in 2 iterations, whereby each individual response (or excerpt from a paragraph) was given a descriptive term to create a set of initial themes for each section of the survey (refer to the *Results* section for examples of these terms). The responses or excerpts coded with the initial themes were cut and pasted into tables that were reviewed and combined into a smaller set of final themes for that section. During the transfer to tables, data from the different clinical specialties were color coded to help identify condition-specific patterns. In the presentation of the final thematic coding structure, this approach enabled analysis within and between conditions. Data from the PAB were themed separately by a third coder in a single iteration after analysis of the results. The coding was based on the themes found in the web-based survey, with the intention to draw out commonalities and differences from the health care professionals.

Responses within the final themes were analyzed further to qualify the benefits participants saw to the introduction of RMT, using the following framework of descriptors adapted from Sharples et al [7]:

- Enabler: The introduction of the device/system permits a new process or function to be possible (ie, it is not currently possible).
- Enhancer: The introduction of the device/system permits an improved outcome (ie, it has an impact on effectiveness).
- Facilitator: The introduction of the device/system makes a process or function easier (ie, it has an impact on satisfaction and adherence).
- Catalyst: The introduction of the device/system speeds up a process or function (ie, it has an impact on efficiency).

Results

Overview

The surveys returned were generally well completed. No portions of the survey were consistently ignored, although in response to some questions, participants signposted to earlier responses given, indicating that the answer was applicable to multiple UPOC. Furthermore, not all respondents provided their own suggested use cases in section D.

Section A: Respondent Information

Table 2 shows number of respondents to the survey from different roles within the consortium. As the health care system was the main focus of the work package, survey responses from

translational, technical, and clinical respondents were analyzed separately from responses provided by the 7 members of the PAB, results for which are presented at the end of this section.

Table 2. Respondent roles in the consortium.

Role in research program	Participants (n=28), n (%)
Translational	
Health service researchers (clinical pathways, patient and public involvement, regulatory requirements)	3 (11)
Technical	
Health technology researchers (devices and software platform, data analysis, biosignatures)	2 (7)
Clinical	
Epilepsy	4 (14)
Multiple sclerosis	8 (29)
Depression	2 (7)
Clinical harmonization	2 (7)
Patient advisory board	
Epilepsy	2 (7)
Multiple sclerosis	3 (11)
Depression	2 (7)

Section B: Promise of RMT

Table 3 shows a summary of the 9 final themes arising from section B. Further details on the contents of each theme are available in Multimedia Appendix 2. Responses to the section on the promise of RMT (potential uses) were analyzed thematically, where 15 initial descriptive terms were attached to the qualitative data and were merged to form a shorter list of 9 final themes, which are listed in Table 2. The themes were generally aligned to the purposes of the study and revealed aspects that were clinician focused as well as reflecting on patient behaviors and experiences. The themes also revealed opportunities for use of the platform, for example, roles in clinical trial design and clinical decision making as well as raising concerns for their use.

Table 3. Themes derived from section B concerning the promise of remote measurement technology.

Final theme	Enabler	Enhancer	Facilitator	Catalyst
Relapse prediction	✓[a]	—[b]	✓	—
Clinical verification	✓	✓	—	—
Monitoring potential	✓	✓	—	✓
Patient behavior	✓	✓	✓	—
User experience	✓	—	—	—
Changes to treatment approach	✓	—	—	—
Clinical decision making	✓	—	—	—
Clinical trials design	✓	—	—	—
Device issues	—	—	—	—

[a]Present in transcript.

[b]Not present in transcript.

We assigned relevant qualifiers to responses under each theme (*enabler*, *enhancer*, *catalyst*, and *facilitator*, as described above). For example, under the theme of *clinical verification*, participants suggested that the RADAR system could *enable* the measurement of deterioration of motor system in progressive MS. Under *monitoring potential*, respondents indicated that the system could *enhance* patient management through faster and more detailed ecological assessment of emotional and physical state. In relation to research, respondents suggested that data collected using the RADAR system could be used to detail the characterization of the progression of MS and that this could *enable* new designs of clinical trials.

The results demonstrate that participants largely viewed RMT as *enabling* new processes or functions that were not currently possible. Fewer responses described ways that RMT would enhance or *facilitate* care provision, and only one provided an example of how RMT could speed up, or *catalyze*, existing processes (Table 3).

One theme, *device issues*, did not fit with the classification of these qualifiers; however, it was considered important to include this in the analysis, as this theme captured some of the practical challenges associated with use of these devices, for example, the accuracy of activity trackers. Device issues have been explored in further detail elsewhere in the consortium [28,29].

Section C: UPOC 1-6 Comparing Existing and Future Potential Care

The findings from section C, consisting of comparisons between existing care and potential care with the RADAR-CNS RMT system in different UPOC scenarios, are summarized below.

UPOC 1: Patient Sharing Data With Clinician

Respondents described that currently, information from patients is conveyed at face-to-face appointments or by phone but that RMT could permit transfer of data to a patient health information system before an appointment, permitting the automatic creation of a report. Clinician respondents suggested that this could be done over an encrypted channel to ensure data security.

Survey responses also indicated that the conventional means for aggregating data was via a manual patient diary; however, it was thought that the RADAR-CNS RMT system could summarize data automatically. The patient may have access and filter the data for relevance beforehand. In terms of clinical utility, RMT might replace or supplement conventional measures made in the clinic (eg, disability measures in MS), with the added advantage in epilepsy to overcome underreporting of seizures and thereby better inform medication adjustments.

In terms of timing, RMT permits data submission (by patients) and data analysis (by clinicians) at convenient times. However, concerning workload, respondents noted the potential for added burden to the clinician or, more generally, the health care provider organization, outside of appointment times.

UPOC 2-4: Relapse

Clinicians expected that the RADAR system would allow them to see if a relapse occurs; however, there was concern about both sensitivity and specificity, for example, that the relapse signal might be a false positive arising from another illness like influenza or that a true relapse may be missed (offering false reassurance). In terms of immediacy, respondents mentioned a delay in consultation without RMT either to a clinic appointment or a phone call from the clinician, whereas with the system, the emergency clinical service could receive an automatic alert (for depression relapse) or else prompt a clinician contact if an early sign of relapse had occurred (MS), employing a digital dashboard for the clinical team to manage this for all their patients.

It was considered that RMT could afford the opportunity to start an immediate intervention via a smartphone or else afford an earlier intervention than was possible without it. In terms of health care system benefits, there was a concern that data from RMT could overload or overburden the system; however, it could also benefit the health care system by reducing routine clinic visits for patients who are well and substitute routine visits by information provided remotely using RMT.

For a patient with a recent diagnosis having symptoms of relapse (UPOC 3), respondents described that the conventional approach was to see the patient in clinic, and this would be essentially unchanged with RMT, except for the potential for more continuous monitoring, resulting in a blended solution. As mentioned above, the main method for interaction with RMT would be via a clinician or team dashboard. For a very new depression diagnosis, RMT could be used to provide patients with access to information about their condition. For epilepsy, the system would detect closely spaced seizures or physiological markers indicating imminent relapse. For MS, it was also judged that it would take time to understand the symptoms in context from the RMT data, for example, variation due to the weather.

For a patient with a longer-term diagnosis having symptoms of a relapse (UPOC 4), the picture was similar to the above, but because a patient's relapse pattern would more likely be known, the additional RMT data might prompt a change in the treatment plan. There was an additional general concern (not specific to RMT) that communication with the patient about a new depressive episode could increase the likelihood of depressive symptoms.

In general, longer-term data should enable more remote consultation, for example, by a phone call rather than a clinic visit, and a faster response.

UPOC 5 and 6: Medication Management

This section of the survey asked respondents to consider medication management before and after the imagined implementation of the RADAR-CNS RMT system, first in a new diagnosis of a CNS condition (UPOC 5) and second when a patient had lived with a condition for a long time (UPOC 6), with a view to examining differences in practice or perception. The results showed little difference between these 2 phases of conditions; thus, the results have been presented together.

The added benefit of RMT for newly diagnosed patients was considered to be low, as medication reviews would still need to happen face to face. Without RMT, people with epilepsy would write their own notes and wait for a change to a drug prescription, whereas with RMT, this could be done more efficiently via a mobile app. For depression, behavioral or social problems were considered difficult to detect remotely, although clinical information sent by the patient via RMT was envisaged as a way to trigger scheduling of an appointment. For MS, it was considered that the system might replace clinical scoring and magnetic resonance imaging, and fluctuations in disease activity might prompt a change in therapy. For a longer-term patient (UPOC 6), the results were mostly the same as those for UPOC 5, but one clinical respondent thought a change in treatment for a longer-term MS patient might be enacted via a phone call and the platform used to monitor the effect, rather than face to face (which they would recommend for a new patient).

Sections D-F

Respondents were asked about the use of RMT data in clinical practice in general and were then asked about patient stratification and treatment response as 2 areas of interest. Areas of use of RMT data included improvement of clinical decision

making and the enabling of more personalized care. RMT would be used to identify individual baselines or norms and individual patterns of behavior. It could also help discover population-level risk factors in MS and epilepsy, although it might not be as useful in the latter due to greater variation between individuals. For depression, RMT data could help educate the patient even if it were not possible to identify relapse signatures for individuals. It was considered, by a technical team respondent, that anomaly detection algorithms used in finance and industry could be used for RMT data to detect both individual- and population-level patterns. More research is needed, including the results of observational clinical studies, to determine whether RMT could be employed in therapeutic trials and to confirm whether it has a positive impact on individual disease management and patient outcomes.

Focusing on stratifying patients by risk or clustering in general, there were differences between specialties. In epilepsy, one example was dividing patients with more hazardous, frequent convulsive seizures from those with frequent focal seizures. For MS, RMT could allow clinicians to confirm a set of risk factors in the general MS population and determine how many of those risk factors are present for an individual patient. For depression, it was considered that RMT data could be used to test different treatments (on different groups) and potentially to stratify by genetic risk. It was considered that more research would be required to see how much data are needed to discover population risk factors and to determine if the population data are informative at the patient level for individual management.

PAB

A total of 7 members of the PAB completed the survey as potential users of the system and provided a range of views on the benefits of RMT, mentioned personal areas of interest for using the technology, and raised some concerns. These 7 members included 2 members with experience living with depression, 2 members with epilepsy, and 3 members with MS.

Like clinicians, patients emphasized the importance of collaborative decision making about medication and highlighted across all 3 conditions the need to maintain face-to-face appointments even with the introduction of new technologies. However, with an RMT system in place, patients saw potential in having clinicians view their records between appointments, allowing side effects to be detected early on, and medication changes to be instigated earlier.

Patients also gave specific examples of signals that might be of interest, such as spelling mistakes and typing speed on mobile phones in MS. These points were not raised by health care professionals. There was also interest in considering potential negative effects arising from RMT use. For example, people with MS highlighted that they may not want to be informed by RMT that their condition was deteriorating, and people with depression mentioned that they prefer not to think about their condition between their 6-monthly clinical appointments.

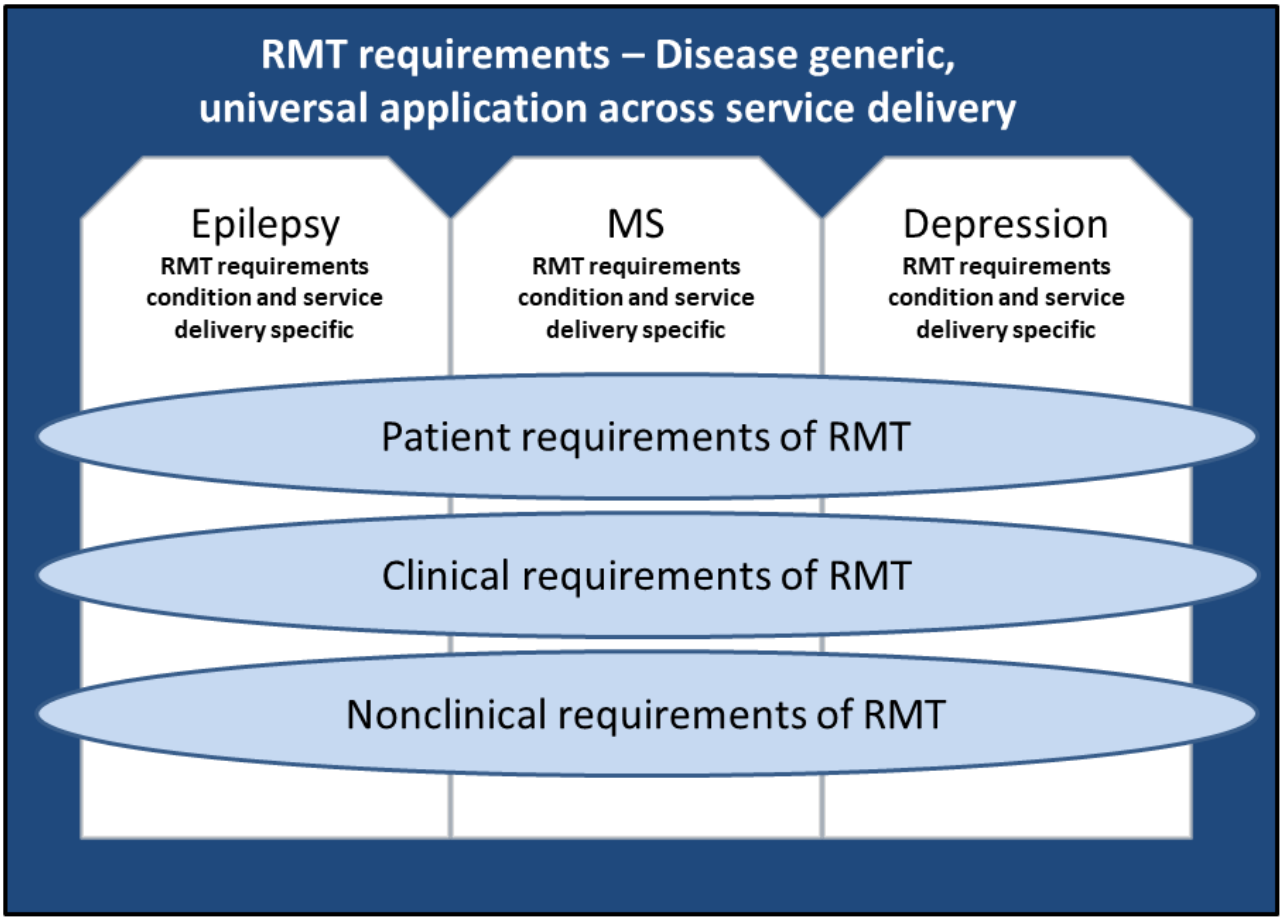
Patients explained that they currently relied to a high degree on verbal communication with clinicians and their own memories of what had occurred between appointments. They acknowledged that these memories may not always be accurate, particularly in the case of epilepsy where some seizures may go undetected, and that the use of the system could provide more accurate data to base clinical decisions on. On the other hand, they also suggested that there may be a risk of increased anxiety due to tracking.

Discussion

Formative Development of the System via UPOC Methodology

From a methodological perspective, UPOC have been effective in eliciting condition-specific descriptions of current and potential processes from clinicians and patients. Figure 2 illustrates the coverage of the UPOC methodology across conditions and stakeholder requirements. Although the survey form provided was identical in all cases, participants were able to describe aspects of care within their relevant condition with details on their particular context, providing a rich set of data to support analysis of need, opportunity, and concern within and between conditions. For example, it was suggested that RMT should enable recognition of early warning signs of relapse, including identifying subclinical signals for MS, seizure precipitant signals for epilepsy, and behavior change in people living with depression. In terms of clinical utility, it was considered that RMT might overcome the problem of underreporting, which is especially problematic in epilepsy. It was also thought that RMT may allow the capture of secondary symptoms that are not generally collected in MS, such as mood.

Figure 2. Diagram showing the coverage of the universal points of care methodology in the development of a novel remote measurement technology system. MS: multiple sclerosis; RMT: remote measurement technology.



Several novel and unanticipated uses of RMT were suggested by respondents. For depression, it was considered that RMT could help extend investigations into psychotherapies and digital mental health interventions. For epilepsy, active remote measurement technology with questionnaires could also be used to detect emerging side effects of treatment, although care would need to be taken to understand the responses correctly before acting. It was considered that RMT could enable behavior change for sleep regulation and activity and that it could be helpful in detecting minor relapses for people with cognitive impairments who may not mention them in the clinic and thus help prompt or guide escalation of care. RMT was also considered to offer a way to include family and other carers in a care network, which could assist with goal setting, although with care to avoid the risk of overreliance on information from carers, which may not be reliable. Although the current iteration of the system was not designed to feed data or analyses from the system to the patient, this is an aspect of usage that could be added to future iterations to facilitate the operations described here.

The novel adaptation of a medical device usability model [7] with its 4 embedded qualifiers (*enabler*, *enhancer*, *facilitator,* or *catalyst*) helps developers understand more precisely how patients perceive value in the system being designed. In this study, the method was used to structure the results of the end user inquiry. The method could also be used in summative evaluation to test whether the promise of improvement is realized at key stages of an iterative design process.

Comparison With Related Work

This study included patients and research clinicians to contribute a multistakeholder perspective considering where and how RMT might improve care in 3 conditions, which has been described as lacking in a review of the literature in this area [9]. In particular, this study has added to the existing work by demonstrating how clinicians and patients view the promise of RMT as a way of altering clinician-patient interactions. Previously, the clinician has been seen as the main decision maker and expert provider of information and knowledge in the clinician-patient relationship [2,3]. Both parties envisaged ways that patients could act as custodians of their own data (eg, by being able to access and manage it) but they also emphasized that enabling the remote transmission of data should not result in the removal of all face-to-face interactions, a finding that is supported by other work in this area [30].

The consortium has also explored wider patient views of RMT in the 3 conditions [5,31,32]. Although these studies focused on the barriers and facilitators of the use of RMT, this study involved members of the PAB who had significant knowledge of the project, enabling the collection of their ideas on particular features in the data collected from the RMT that could be used for monitoring the deterioration of their own condition. For example, PAB members made the observation that in MS,

spelling mistakes and typing speed on mobile phones may be of use in detecting changes in their cognitive state. There was also interest in detecting early side effects of medications, permitting the earlier change of medication where this was problematic. Thus, patients themselves were empowered in this study to speak from their own insight and suggest how RMT could be serviceable to them both in detecting changes in their condition and managing potential for harm.

In addition to this study, we have conducted further work with a wider community of health care professionals outside the RADAR-CNS consortium in the form of an interview study to gauge their views on the potential of RMT [33]. Whereas the interviews in the study by Andrews et al [33] aimed to elicit the types of data, specific time points, and job roles where RMT data would be used, the use of UPOC in this study asked participants to be more creative and imagine how particular processes could be differently managed with the use of RMT. Thus, responses in this study permitted capture of imagined scenarios of use for RMT at specific points of care, for example, how a change in treatment for MS might be enacted via a phone call and the platform used to monitor the effect. The results here are therefore more indicative of how clinical pathways might change to accommodate the use of these technologies than in the results of our previously published work, and the results of this study incorporate both clinician and patient perspectives.

Limitations and Future Work

The results of this study are limited due to the population sample, albeit by design, with its primary focus on health care professionals and patient representatives from a research consortium where one could presume most to be enthusiasts of the technology being developed. In this study, the use of UPOC has guided clinicians and patients to portray their own views of how RMT should augment care. Within these portrayals, participants were able to articulate where further inquiry was necessary to achieve such improvements. Participants were of the opinion that more research is needed to assess the sensitivity and specificity of relapse prediction and that future prospective trials should take place to assess the impact on clinical care and patient outcomes. It is too early to say whether RMT could be employed successfully in therapeutic trials or whether it can really support individual disease management and stratification of patients based on risk factors or treatment response.

Despite the benefits of our approach, responses in some areas were not detailed enough to design a system based solely on the outputs of this study. For example, it is not yet clear exactly how the alerts and follow-up appointments that are triggered by RMT will be managed in routine care, for example, would they be directed first to patients, carers, or clinical services? Would they generate automated (eg, programed behavioral advice) or human responses? The survey did not reveal the details of information that health care professionals require from the system, for example, the required sensitivity and specificity thresholds for alerts. However, it is clear that the UPOC method was able to reveal the need to consider such details.

Beyond the scope of this study, the UPOC approach provides learning for the design community, specifically those working in the health and medical domains and in the development of complex Information and Communication Technology platforms. The approach taken to identify and design a requirements capture exercise around UPOC has shown that formative data capture is possible and will provide important insights into how multifaceted platforms can meet the needs of different stakeholders from different clinical specialties, for whom there are different end goals.

Conclusions

The UPOC method employed in this study provided a targeted and structured means by which to inquire about use of RMT in real-world practice and bring clinical and patient opinion into its design process. In addition, by adapting the model by Sharples et al [7] to label solutions as enablers, enhancers, facilitators, or catalysts, we were able to offer signposting to technologists about how different aspects of the digital platform could provide value in a number of different use case scenarios.

More generally, the UPOC approach provides a means to explore the requirements of a complex technology system that not only needs to meet the broad needs of traditional user groups, such as health care professionals and patients, but also has to accommodate the diverse experiences of those groups of stakeholders from the range of clinical specialties within them. A greater understanding of these needs will inform a meaningful formative and summative evaluation of system design.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey instrument used the present study.
[PDF File (Adobe PDF File), 288 KB - formative_v4i11e22756_app1.pdf]

Multimedia Appendix 2
Themes derived from survey section B on the promise of remote measurement technology.
[DOCX File , 27 KB - formative_v4i11e22756_app2.docx]

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Abbreviations

CNS: central nervous system
EFPIA: European Federation of Pharmaceutical Industries and Associations
HITs: health information technologies
IMI: Innovative Medicines Initiative
MS: multiple sclerosis
NHS: National Health Service
NIHR: National Institute for Health Research
PAB: patient advisory board
RADAR-CNS: Remote Assessment of Disease and Relapse-Central Nervous System
RMT: remote measurement technology
UPOC: universal points of care

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Original Paper

Smartphone and App Usage in Orthopedics and Trauma Surgery: Survey Study of Physicians Regarding Acceptance, Risks, and Future Prospects in Germany

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Abstract

Background: In the course of digitization, smartphones are affecting an increasing number of areas of users' lives, giving them almost ubiquitous access to the internet and other web applications. Mobile health (mHealth) has become an integral part of some areas of patient care. In contrast to other disciplines, routine integration of mobile devices in orthopedics and trauma surgery in Germany is still in its infancy.

Objective: This study aimed to investigate physicians' current state of opinion regarding acceptance, future prospects, and risks of medical apps in the field of orthopedics and trauma surgery in Germany.

Methods: A web-based survey among orthopedics and trauma surgeons in German university hospitals on the use of medical apps in everyday clinical practice was conducted between September 2018 and February 2019. The survey consisted of 13 open- and closed-ended or multiple-choice questions. A logistic regression analysis was performed to ascertain the effects of interindividual characteristics on the likelihood of participants' app and smartphone usage behavior.

Results: A total of 206 physicians participated in the survey. All of the participants (206/206, 100%) owned a smartphone, and 79.1% (159/201) used the device, while 64.7% (130/201) used apps regularly in everyday clinical practice. Medical apps were perceived as beneficial, given their substantial future promise, by 90.1% (181/201) of the participants. However, 62.5% (120/192) of the participants were not satisfied with the current supply of medical apps in app stores. Desired specifications for future apps were "intuitive usability" (167/201, 83.1%), "no advertising" (145/201, 72.1%), and "free apps" (92/201, 45.8%). The attributes "transparent app development and app sponsoring" (75/201, 37.3%) and the existence of an "easy-to-understand privacy statement" (50/201, 24.9%) were of minor relevance. The majority of the participants (162/194, 83.5%) considered that future apps in the field of "medical research" would provide the greatest benefit. The greatest predicted risks were "data misuse" (147/189, 77.8%), "usage of untrustworthy apps" (135/189, 71.4%), and "alienation from patients" (51/189, 27.0%). Increasing age was significantly associated with a reduction in the likelihood of regular smartphone (odds ratio [OR] 0.91, 95% CI 0.86-0.97; *P*=.002) and app (OR 0.90, 95% CI 0.85-0.96; *P*=.001) usage, while the medical profession grade had no significant impact on the usage behavior.

Conclusions: The study demonstrates that young German doctors in orthopedics and trauma surgery already use smartphones and apps in everyday clinical practice. Medical apps are considered to play an important role in the future. However, a significant

discrepancy exists between the supply and demand of mHealth applications, which creates a legal and ethical vacuum with regard to data protection.

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KEYWORDS

mHealth; smartphone; communication; medicine; surveys and questionnaires; technology; orthopedics; trauma surgery

Introduction

The "digital transformation" of medicine began about 30 years ago with the replacement of analogue recordings by electronic systems in clinics and outpatient care facilities. At present, the establishment of the electronic health card to record patient data dominates health policy debates on the subject of digitization in Germany [1]. Since the beginning of the 21st century, information technology has not only served automation and optimization, but has also led to automation and individualization of processes by using "disruptive technologies." However, the digital transformation goes far beyond the literal digital conversion of analogue media [2]. It stands for a dynamic reformation based on digital technologies that include society as a whole, the health care system with its involved companies, treatment facilities, and health care professions [3].

Smartphones, which have been rapidly integrated into various areas of life, have replaced mobile phones with keypads within a very short time, and thus, they can be classified as a disruptive technology [4]. The omnipresent mobile device offers qualitatively different functions in addition to pure web-based benefits via the implementation of native application programming interfaces and operating system functions. The portability and accessibility of smartphones enable their usage anywhere and at any time [5]. Numerous studies have shown that the number of smartphone users and the time spent using smartphones per day continue to rise significantly [6-8]. Interestingly, 81% of Germany's 62 million internet users used smartphones to access the internet in 2016 [9]. The rise in smartphone usage and the introduction of app stores have facilitated individually customized software installation. This ready individualization provides people almost ubiquitous access to the vast amounts of available web-based information as well as innovative technologies accessible through mobile web-based applications [10].

The term "mobile application," colloquially known as "app," is defined as application software for mobile operating systems. Apps enable web-based, application-specific functions by operating with an intuitive user interface ("frontend"). The daily use of apps in private and professional contexts, such as online banking or communication via messenger and email, has become commonplace [11]. However, the use and integration of smartphones in medical care in Germany, especially in the fields of orthopedics and trauma surgery, is still in its infancy.

Although a total of 39,319 apps appeared under the "Medical" category on Google Play Store (Google LLC) in March 2019 [12], currently, no unified definition of "apps" exists in the medical context; they may be called "lifestyle apps," "health apps," "care apps," or "medical apps." Apps developed for patients should be differentiated from those directed at medical staff and those with a direct influence on the diagnosis of or therapy for a disease, and are therefore to be regarded as medical devices, unlike apps that focus purely on lifestyle [13].

Simple distribution, typically low development costs, and ease of use have resulted in a constantly growing and unmanageable supply of apps. Moreover, the offers provided by app stores are often unclear and heterogeneous for their users due to their complexity, dynamics, and rudimentarily regulated organization [14]. The range of available apps is so dynamic that their quantity and quality can vary even from day to day [14,15].

Irrespective of the rapid developments in the field of medical apps, young physicians especially have experienced a fundamental change in their information behavior over the past few years [16]. An increasing number of studies have focused on the benefits and consequences of smartphone use in the fields of orthopedics and trauma surgery [17-22]. Today, the majority of American orthopedic surgeons use smartphones and a wide variety of apps in their daily clinical work [23]. Apps published by representative institutions such as the AO Foundation, those focusing on education, and apps serving as a reference demonstrate the highest usage rates among orthopedic surgeons in Germany. However, the number of regularly used apps is low. The causes of this lack of acceptance have not yet been clarified conclusively [24].

Thus, the integration and use of smartphones in medical care, especially in the fields of orthopedics and trauma surgery, are in the nascent stage. In view of the rising smartphone usage in highly developed societies, this study aimed to investigate German physicians' current opinion regarding their acceptance, future prospects, and risks of use in the field of orthopedics and trauma surgery in Germany.

Methods

Study Design and Sample

A survey among 836 orthopedics and trauma surgeons in German university hospitals on the use of medical apps in everyday clinical practice was conducted between September 2018 and February 2019. The link for the digital questionnaire, which appeared on a Google Docs platform (Google LLC), was sent to the participants by email. The email addresses of the potential test persons were generated manually via the homepages of the university hospitals or established in-house email distribution lists. The participants' profession (orthopedic or trauma surgery) was confirmed before starting the survey. A positive vote from the responsible ethics committee was obtained in advance (No. 18-8142-BO). All of the investigations described in this study were carried out with the consent of the

abovementioned committee and in accordance with national law and the Declaration of Helsinki.

Survey Items

The survey consisted of 13 open- and closed-ended or multiple-choice questions encompassing the following domains: (1) The medical profession, qualification, and age of each participant; (2) their usage behavior regarding smartphones and medical apps; (3) a subjective assessment of currently available medical apps, and future potential risks and benefits; and (4) an evaluation of the readiness to purchase apps.

As no gold standard exists for mHealth surveys, our research group developed app- and smartphone-related questions. The questions were validated by a group of medical experts in the field of digitization and survey development, and their feedback was integrated into the final draft of the questionnaire. Their medical competence was determined by the level of training and years of clinical practice. According to our interpretation, a senior or chief physician has higher medical competence than a resident physician. The survey participants did not have to answer every question; they could skip parts of the questionnaire. The participants completed the survey within 90 seconds on average. Medical apps of relevance for this study were defined as apps with a clear medical purpose. Messenger services or system apps, such as WhatsApp (WhatsApp Ireland Ltd.) or a browser, were not taken into consideration.

Data Analysis

The survey results were temporarily saved on the web in a Google Drive folder (Google LLC) and then transferred into an Excel table (Microsoft Corp.). Descriptive statistics were calculated for all items. A logistic regression analysis was performed to ascertain the effects of age and medical qualification grade on the likelihood of app and smartphone usage by the participating orthopedics or trauma surgeons and their usage behavior. Equivalent to the t test in linear regression, the Wald test checks the null hypothesis that the respective regression coefficient B in the population takes the value 0. Statistical significance was determined by *P* values less than .05. All statistical analyses were conducted using SPSS (version 25, IBM Corp.).

Results

Descriptive Statistics

In total, 24.6% (206/836) of the contacted orthopedic or trauma surgeons participated in the survey. Tables 1 and 2 show the characteristics of the survey participants as opposed to those of the members of the German Society for Orthopaedics and Trauma (DGOU).

Table 1. Characteristics of the DGOU[a] members (N=10,487) and survey respondents (N=189) with regard to age.

Age groups (years)	Values
DGOU, n (%)	
<35	1413 (13.47)
36-45	3091 (29.47)
46-55	2644 (25.21)
56-65	1937 (18.47)
>65	1402 (13.37)
Survey respondents, n (%)	
<30	30 (15.87)
30-39	93 (49.21)
40-49	41 (21.69)
50-59	16 (8.47)
>60	9 (4.76)

[a]DGOU: Society for Orthopaedics and Trauma. Status as of February 2020. Source: DGOU Office.

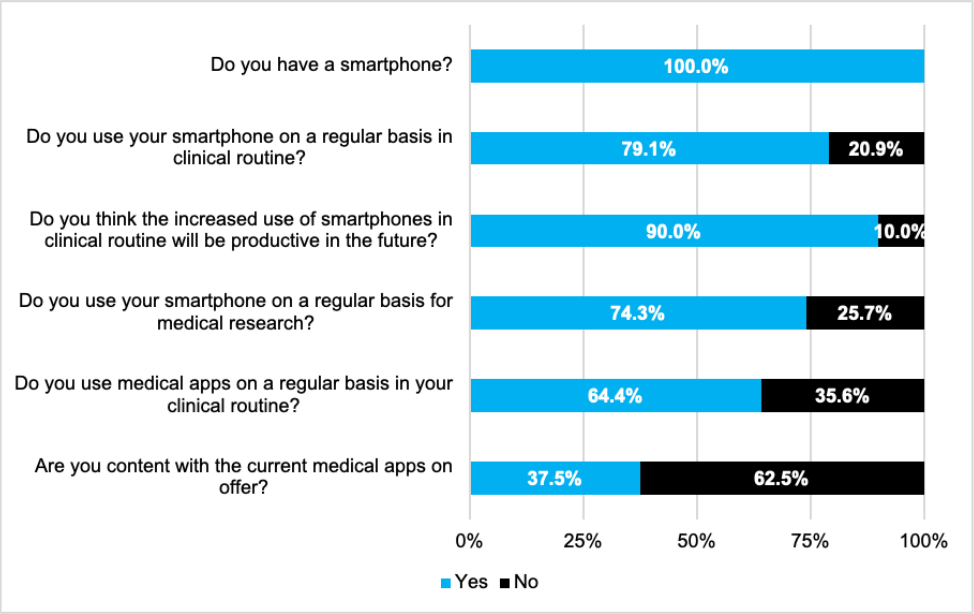
Table 2. Characteristics of the DGOU[a] members (N=10,487) and survey respondents (N=206) with regard to area of activity.

Area of activity	DGOU, n (%)	Survey respondents, n (%)
Higher education	1624 (15.49)	0 (0)
Resident physician	2686 (25.61)	93 (45.15)
Consultant	1093 (10.42)	41 (19.90)
Senior consultant	2932 (27.96)	67 (32.52)
Other medical employment	1702 (16.23)	5 (2.42)

[a]DGOU: Society for Orthopaedics and Trauma. Status as of February 2020. Source: DGOU Office.

All the participants stated that they owned a smartphone (206/206, 100%). Smartphones (159/201, 79.1%) and apps (130/201, 64.7%) were used regularly by the majority of doctors in their daily clinical routine and for medical research. Most surgeons were not satisfied with the current supply of medical apps in the app stores (120/192, 62.5%), but they felt that the use of smartphones on a regular basis offered great potential for the future of health care (181/201, 90.1%) (Figure 1).

Figure 1. Usage behavior of smartphones and medical apps in orthopedics and trauma surgery (N=206).



By analyzing the participants' responses to the multiple-choice questions focused on the future potential, fields of application, and risks of day to day use of smartphones and apps in daily clinical routine, we were able to identify the most frequently requested features (Figure 2) as well as the greatest perceived benefits (Figure 3) and risks (Figure 4) of future app usage.

Figure 2. Functions or features important to the survey participants in future medical apps (indicated via responses to multiple-choice questions; N=194).

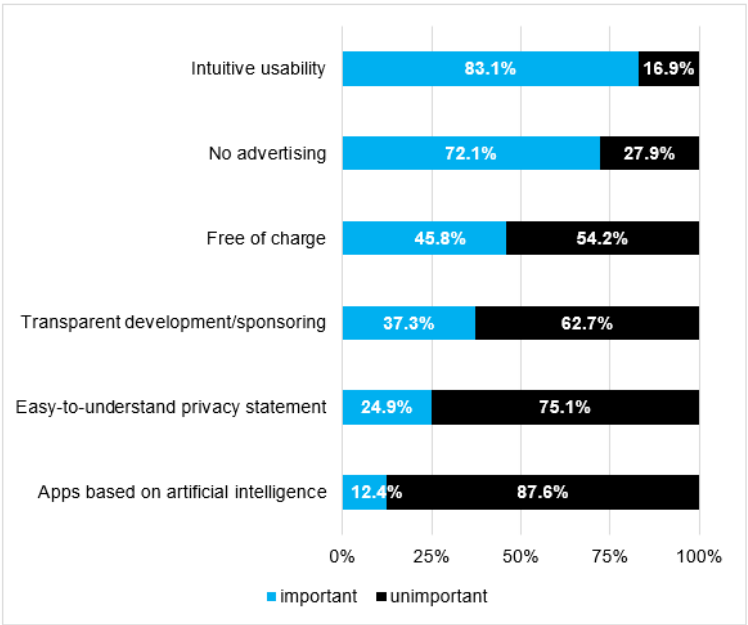


Figure 3. Participants' responses regarding the greatest benefits of using of medical apps (indicated via responses to multiple-choice questions; N=201).

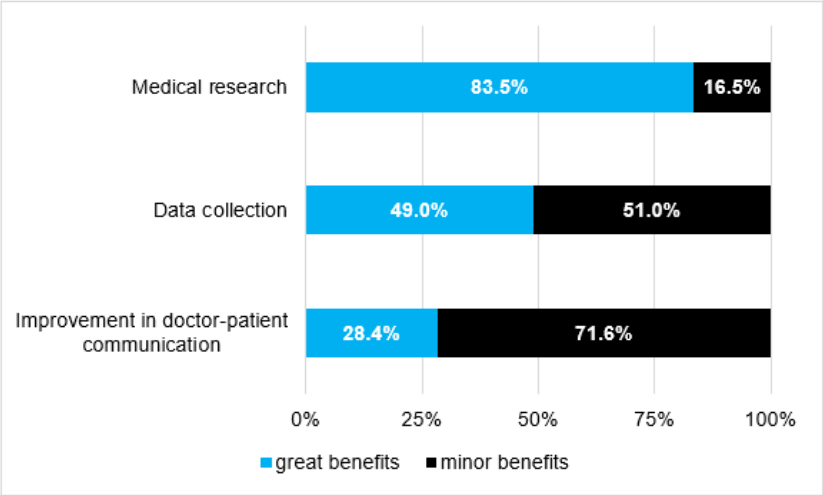
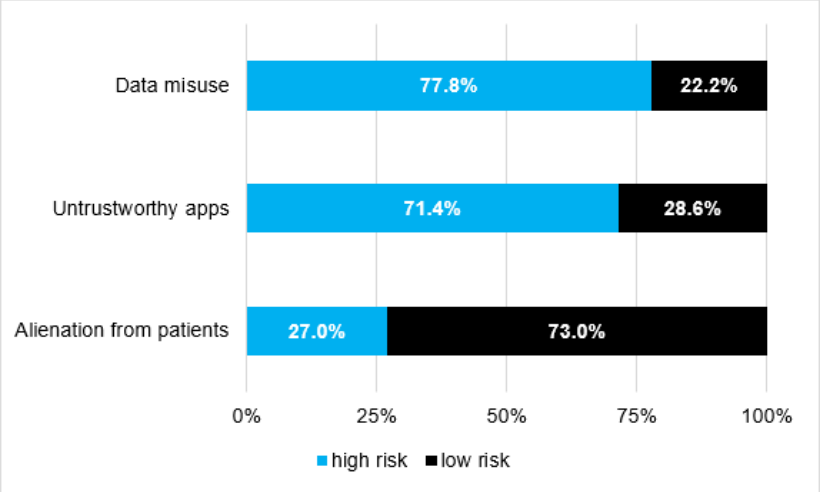


Figure 4. Participants' responses regarding the risks that can arise from the regular use of medical apps in the future (indicated via responses to multiple-choice questions; N=189).



Logistic Regression Analysis

Respondents who stated that smartphone usage has great potential for the future were 45.22 (*P*=.001) times more likely to use smartphones and 10.32 (*P*=.009) times more likely to use apps in their daily clinical routine than physicians who rejected the use of smartphones in everyday clinical practice. In addition, an increasing readiness to buy apps was associated with an increased likelihood of smartphone usage in daily clinical routine (odds ratio (OR) 1.73, 95% CI 1.32-2.26; *P*=.008). Increasing age demonstrated a significant negative correlation to regular smartphone (OR 0.91, 95% CI 0.86-0.97; *P*=.002) and app (OR 0.90, 95% CI 0.85-0.96; *P*=.001) usage. Increasing medical competence was accompanied by a decrease in the use of smartphones (*P*=.21) or apps (*P*=.58), but the result was not significant. The dissatisfaction with the current supply of apps was not associated with a significant correlation to app usage behavior (Tables 3 and 4). Conversely, none of the elicited parameters had a significant influence on satisfaction with the currently available apps on offer (data not shown).

Table 3. Statistical analysis of respondents' answers to the question "Do you use your smartphone on a regular basis in your clinical routine?"[a]

	B	SE	Wald (*df*)	P	Exp (B)
Medical qualification	–0.42	0.33	1.60 (1)	.21	0.66
Age[b]	–0.09	0.03	9.16 (1)	.002	0.91
Future potential[b]	3.81	1.12	11.67 (1)	.001	45.22
App costs[b]	0.54	0.20	7.06 (1)	.01	1.72
Constant	0.69	1.49	0.22 (1)	.64	2.00

[a]χ^2_4=73.4; *P*<.001. The model explains 52.3% (Nagelkerke R^2) of the variance and correctly classifies 88.2% of the cases.

[b]Values are significant for age, future potential, and app costs at *P*<.002, *P*<.001, and *P*<.01, respectively.

Table 4. Statistical analysis of respondents' answers to the question "Do you use medical apps on a regular basis in your clinical routine?"[a]

	B	SE	Wald (*df*)	P	Exp (B)
Medical qualification	–0.15	0.27	0.31 (1)	.58	0.86
Age[b]	–0.10	0.03	12.00 (1)	.001	0.90
Future potential[b]	2.33	0.89	6.87 (1)	.011	10.32
App costs	0.26	0.16	2.56 (1)	.11	1.30
Apps offered	0.62	0.44	1.98 (1)	.16	1.86
Constant	1.63	1.32	1.53 (1)	.22	5.12

[a]χ^2_4=51.4; *P*<.001. The model explains 36.6% (Nagelkerke R^2) of the variance and correctly classifies 76.9% of cases.

[b]Values are significant for age and future potential at *P*<.001 and *P*<.01, respectively.

The benefits of increased smartphone use in the future were not significantly influenced by age (*P*=.96), medical profession (*P*=.92), satisfaction with the currently available apps on offer (*P*=.13), and current app usage behavior (*P*=.73). However, the respondents who were already using their smartphones regularly in daily clinical practice (OR 150.3, 95% CI 5.04-4484.02; *P*=.004) and spent considerable amounts of money on apps (OR 2.03, 95% CI 1.13-3.62; *P*=.02) believed that the increased use of smartphones in clinical practice offered great potential. These parameters were significantly correlated (*P*=.004 and *P*=.02; Table 5). Older and experienced physicians demonstrated reduced usage of smartphones in the context of medical research (OR 0.93, 95% CI 0.89-0.97; *P*=.001) compared to their younger colleagues (Table 6).

Table 5. Statistical analysis of respondents' answers to the question "Do you think the increased use of smartphones in clinical routine will be productive in the future?"[a]

	B	SE	Wald (*df*)	*P*	Exp(B)
Medical qualification	–0.06	0.56	0.01 (1)	.92	0.94
Age	–0.00	0.05	0.00 (1)	.96	1.00
App costs[b]	0.71	0.30	5.67 (1)	.02	2.03
App offer	–1.30	0.87	2.24 (1)	.13	0.27
Clinical smartphone usage[b]	5.01	1.73	8.37 (1)	.004	150.30
Clinical app usage	–0.52	1.49	0.12 (1)	.73	0.59
Constant	–0.91	2.74	0.11 (1)	.74	0.40

[a]χ^2_4=60.4; *P*<.001. The model explains 67.0% (Nagelkerke R^2) of the variance and correctly classifies 95.2% of the cases.

[b]Values are significant for app costs and clinical smartphone usage at *P*<.02 and *P*<.004, respectively.

Table 6. Statistical analysis of respondents' answers to the question "Do you use your smartphone on a regular basis for medical research?"[a]

	B	SE	Wald (*df*)	*P*	Exp (B)
Medical qualification	–0.09	0.24	0.14 (1)	.71	0.91
Age[b]	–0.08	0.02	11.78 (1)	.001	0.93
Constant	4.26	0.77	31.03 (1)	.001	71.05

[a]χ^2_4=21.5; *P*<.001. The model explains 16.2% (Nagelkerke R^2) of the variance and correctly classifies 76.2% of the cases.

[b]Values are significant for age at *P*<.001.

Discussion

Principal Findings

The results of this study indicate that younger and less experienced doctors in the field of orthopedics and trauma surgery already use their smartphones and apps on a regular basis in clinical practice. Free apps and intuitive usability were considered to be the most important factors for regular app usage. In contrast, satisfaction with the currently available apps on offer was low. The greatest perceived risks regarding the use of mHealth apps were data misuse and the danger of using untrustworthy apps.

Usage Behavior

Several important findings can be drawn from this study. First, smartphones and apps were used regularly by most of the participants (159/201, 79.1%; 130/201, 64.7) in their daily clinical routine. In the future, it is expected that these devices will not be confined to a minority (eg, medical students or young physicians); rather, they will commonly be utilized by all medical professionals. In detail, the physician's age had a significant influence on the intensity of smartphone and app usage in clinical daily life. Younger physicians were more likely to integrate smartphones or apps into their daily work. Interestingly, medical qualifications did not have a significant influence in this regard. Although the use of digital media tended to decline with increasing medical qualification, even experienced doctors used smartphones in daily clinical routine. This result may be attributed to the very extensive range of apps supplied and the vast application possibilities of smartphones [25]. The different features offered cover the needs of a large target group. Overall, young doctors are more likely to use mobile devices, which can be explained by learned "media adaptation." If people were influenced by the digital media in their adolescence, the use of proven and learned informational or communication tools and the corresponding behaviors are to be expected [26]. This aspect emphasizes the fact that young age, not lower medical qualification, is associated with frequent use of smartphones to carry out medical research, a finding that coincides with those of studies from other disciplines [3].

Current established user scenarios of apps in clinical practice focus on areas of education and reference purposes (Table 5). The number of orthopedics and trauma surgeons satisfied with the currently available apps on offer was quite low (72/192, 37.5%). The discrepancy between the high digital acceptance and the dissatisfaction with existing apps could lead to the use of inadequate apps in a medical context. For instance, the messenger service WhatsApp is commonly used as communication medium in everyday clinical practice. The benefits of a messenger service-based communication of text, image, and sound are evident, as it allows optimized professional consultations in comparison to simple verbal conversations by telephone. However, the clinical use of WhatsApp in a medical treatment context is problematic from the ethical and legal points of view (ie, data protection) and may lead to a violation of medical confidentiality [27,28].

Improper app usage in everyday clinical practice could give rise to problems if the content-related algorithms and guidelines used do not comply with the applicable country-level requirements. In addition to these non-negligible content-specific discrepancies, the variations in software specifications across countries must be taken into account.

Apps that exclude any user-related liability (eg, by the statement "only for training purposes") are also questionable in the context of Germany's Act on Medical Devices [29]. Nevertheless, there is reason to believe that these apps are used in clinical practice contexts [30]. Although such apps may contain information relevant to clinical practice, thus presenting an objectifiable added value for the user, in the event of damage, accusations of culpability stemming from the use of a (potentially) unsuitable/ Conformité Européenne (CE)-/Food and Drug Administration-certified app in the treatment context must be refuted. The surgeon cannot assume that every app is free of errors. Therefore, before using the app, physicians must assure themselves that the app is suitable for the intended purpose and is also recognizably safe in order to be covered by liability law [31]. This aspect illustrates the demand for an objective and transparent evaluation process for medical apps to protect doctors and hospitals against liability consequences. Textbox 1 shows established medical apps recommended or evaluated positively by German orthopedic or trauma surgeons [24,32].

Textbox 1. Established medical apps recommended or evaluated positively by German orthopedic or trauma surgeons.

Apps for referencing

- *Surgical training*: AO Surgery Reference, AO/OTA Fracture Classification, Touch Surgery: Surgical Videos
- *Databases*: Arznei Aktuell, Arzneimittel Pocket 2018, eRef App, Orthorad, ICD-10 Diagnoseauskunft, PRO-IMPLANT Pocket Guide, Pedi Help App, MDCalc Medical Calculator, BoSTT, MRI Essentials, Ortho Guidelines
- *Education*: AMBOSS Wissen für Mediziner

Apps for rehabilitation

- Sprunggelenks-App
- DocCheck Help-Arzt

Future Prospects and Risks for Medical Apps

In addition to information on the usage behavior of the surveyed physicians, this study was able to gain some insights into expected features and risks with regard to future smartphone usage and apps. According to the surveyed physicians, intuitive usability was considered the most important factor for regular use, followed by the quality of apps. However, the development of an intuitive frontend is complex and involves high development costs and test phases [33]. Nevertheless, approximately half (92/201, 45.8%) of the orthopedists and trauma surgeons expected mobile software to be free of charge, and most of the respondents (145/201, 72.1%) favored advertisement-free apps. This raises the question of financing the development of high-quality apps in the future.

Paradoxically, the transparency of the development process was not considered important by the surveyed physicians, indicating the possibility of potential risks stemming from app development being overlooked. Thus, it appears that the risk of using smartphones in clinical/patient practice (ie, alienation from the patient) was underestimated by the study participants who, instead, focused to a greater extent on data misuse and the danger of using untrustworthy apps. In fact, recent data scandals have led to a fundamental distrust of applications that might be implemented in the context of “Big Data” [34].

Artificial intelligence (AI) was of no significance for the majority (176/201, 87.6%) of the respondents, although several already established apps in the medical (and orthopedic) field use AI algorithms. Given that technological progress has already successfully optimized the use of AI in apps and supportive AI systems are being applied in radiology, the interest in mHealth apps geared toward orthopedics and trauma surgery is still quite low [35-38].

Future app usage could offer great benefits in terms of data collection and retrieval; however, their benefits as a medium for improved doctor-patient communication in daily clinical routine are perceived to be low. The possibility of simplified data processing using smartphones is unquestionable, but it could offer a solution for the continuously increasing bureaucratic efforts and limited human resources [39,40].

Limitations

There are some limitations to this study. The 206 participants of the survey may not be representative of all orthopedics and trauma surgeons in Germany. The subjects in our cohort were younger compared to the average age of DGOU (Society for Orthopaedics and Trauma) members. However, the findings of this survey were consistent with those of a study estimating the use of smartphones in daily clinical practice [41]. The survey primarily addressed general clinicians in maximum care hospitals, leading to a potential bias toward academic centers and younger orthopedic or trauma surgeons. It can be said that smartphone-savvy orthopedics and trauma surgeons primarily participated in our survey. The vision of the “early adopters” can, however, be more informative than nationally representative data in relation to the future potential for smartphone-based benefits in clinical practice. Further studies are also necessary to obtain evidence regarding app usage in the ambulatory sector.

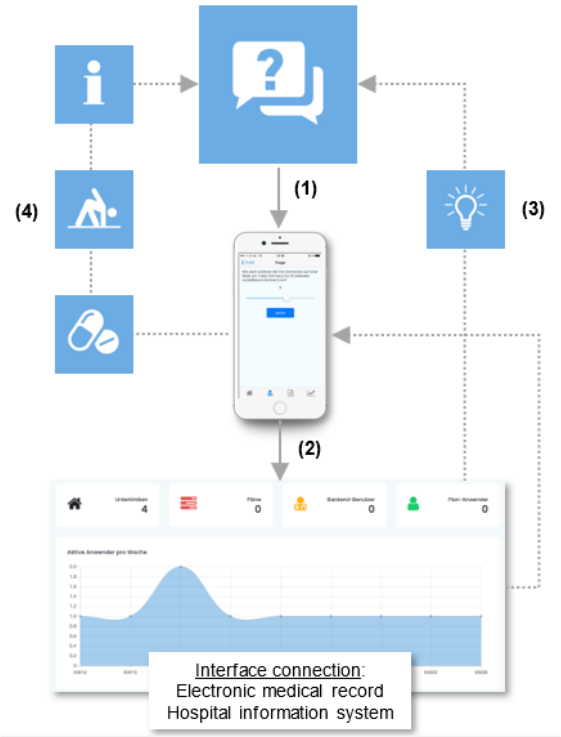
Outlook

After the initial groundbreaking steps, Germany’s legislature recently provided considerable momentum in the direction of a stringent national digitization strategy in the country. The Law for Better Care Through Digitization and Innovation (Digitale-Versorgung-Gesetz, DVG) passed by the Bundestag on November 7, 2019, paved the way for apps on prescription, the improved use of web-based video consultation services, and greater security in the communication of health data [42]. However, the majority of German orthopedics and trauma surgeons, especially the decision makers, are unfamiliar with the contents of the DVG despite their basic positive interest in digitization. Skepticism currently prevails regarding apps on prescription and potentially unpredictable risks [43]. In a recent joint letter, the German National Association of Statutory Health Insurance Physicians opposed the digitization plans of the Federal Minister of Health. Lack of interface interoperability and the development of software solutions that did not meet the target group’s requirements were identified as major shortcomings [44]. One of the most complex and unsolved problems so far is the integration of health apps into hospital information systems and the upcoming German electronic medical record in 2021. Germany is sorely in need of suitable health apps.

Adequate evaluation of smartphone and app usage requirements is essential for the development and implementation of future

innovative digital technologies. However, interface interoperability represents a prerequisite for successful implementation of medical apps (Figure 5). Collaboration between the medical and information technology sectors and the legislature via interdisciplinary expert groups and the involvement of medical societies are essential.

Figure 5. Future innovative usage scenarios of apps in daily clinical routines requiring the implementation of smartphones as the central information and communication medium. (1) Collection of patient-related data via smartphones (wearables). (2) Data storage into databases communicating with additional information systems. (3) Data processing by AI (including determination of risk factors or patterns, conducting interdisciplinary case discussions, and facilitating data backflow to the patient (individualized therapy recommendations and patient monitoring). (4) Treatment recommendations (exchange/communicate information with other physicians; eg, digitized guidelines for antibiotic treatment).



Conclusions

The study demonstrates that some orthopedics and trauma physicians in Germany already use smartphones and apps on a regular basis in everyday clinical practice. The continued development of apps was considered to provide the greatest future benefit for daily practice. However, some alarming trends are also emerging. If the demand for high-quality apps becomes apparent, the development process is likely to become more complex and cost-intensive. In the context of software development, monetary-, advertising-, or data-based refinancing represent the cornerstones of project realization. Therefore, special attention must be paid to completely plausible transparent financing, development, and data flow for future apps. Currently, discrepancies persist between the supply and demand of orthopedics and trauma surgical apps, creating a legal and ethical vacuum with regard to data protection.

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Conflicts of Interest

FD and SB are active in Mediploy GmbH and in the development process of the Sprunggelenks-App. DAB, KH, SL, FR, and SS declare no conflict of interest.

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Abbreviations

AI: artificial intelligence
CE: Conformité Européenne
DGOU: Society for Orthopaedics and Trauma
mHealth: mobile health

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Original Paper

Development of a Web-Based Acceptance and Commitment Therapy Intervention to Support Lifestyle Behavior Change and Well-Being in Health Care Staff: Participatory Design Study

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Abstract

Background: Positive emotional well-being is associated with healthier lifestyle choices and overall health function, whereas poor mental health is associated with significant economic and psychological costs. Thus, the development of effective interventions that improve emotional well-being is crucial to address the worldwide burden of disease.

Objective: This study aims to develop a web-based emotional well-being intervention for use by health care staff using participatory design to consider adherence and engagement from a user perspective.

Methods: A 3-staged iterative participatory design process was followed, including multiple stakeholders: researchers, computer scientists, mental health experts, and health care staff. Stage 1 used document analyses, direct observation, and welcome interviews; stage 2 used focus group discussions, rapid prototyping, and usability tasks; and stage 3 evaluated a high-fidelity prototype.

Results: Different health care staff (N=38) participated during a sustained period. A structured, sequential, automated, 12-week, web-based emotional well-being intervention based on acceptance and commitment therapy was developed. Freely navigated psychoeducational resources were also included.

Conclusions: The iterative and collaborative participatory design process successfully met its objectives. It generated an in-depth understanding of well-being within the workplace and identified barriers to access. The 3-staged process ensured that participants had the opportunity to explore and articulate criteria relevant to their roles over time and reflect on decisions made at each stage.

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KEYWORDS

participatory design; eMental health; engagement; acceptance and commitment therapy

Introduction

Background

The role and importance of mental health on physical health outcomes, lifestyle behavior, and overall health status has received global recognition [1]. Poor mental health is associated with increased mortality, increased prevalence of physical health conditions, and poorer lifestyle behaviors [2], whereas positive emotional well-being is associated with healthier lifestyle choices and overall better health function [3]. In the United Kingdom, the related economic burden is reported to cost employers between £34.9 (US $45.5) and £45 (US $58.7) billion per year [4,5]. Economic analysis has therefore suggested that investment in staff well-being will lessen this financial impact through reduced absenteeism and staff turnover [5]. Workplaces

offer a vital opportunity for health promotion and early intervention to improve poor health-related lifestyle behaviors and are appropriate places to provide well-being resources and support. Equally, public sector staff has higher sickness and absenteeism rates than private sector staff [6]. Thus, the development of effective interventions that improve mental health and emotional well-being is crucial in addressing the disease burden in this population.

Web-Based Approach

Web-delivered interventions, which are understood to be effective and cost-effective, may be helpful in this regard [7-12]. However, poor adherence and engagement remain a critical concern that limits treatment outcomes [13]. This is particularly the case for open access programs in which adherence has been as low as 3% [14]. Many avenues have been explored to address this issue, including interactive design features [15,16], persuasive technology [17], social interaction [18], rideshare services [19], and gamification [14].

Participatory Design

This study seeks to describe the development of a web-based emotional well-being intervention using participatory design (PD). We adopted this approach to improve adherence and engagement. PD is a collaborative process that includes anticipated end users in the development of new products, uses diverse research methods such as qualitative inquiry, and has the potential to offer critical insight and understanding of users' motivation and engagement in such interventions [20]. Informed by action research, PD has seen rapid growth in popularity and application across diverse fields, including commercial product design, industrial design, architectural design, and government space programs [21]. PD has also been incorporated in several health care contexts [22-25], including youth mental health [26,27] and dementia care, or mental health care for older adults in general [28,29].

Findings from this diverse literature have highlighted that end-user input can be incredibly useful. Specifically, the involvement of anticipated end users, not unlike the *expert patient* role in the psychological literature, can highlight, early on, key information regarding user needs, understanding, knowledge, and values that can support the development of effective resources [23]. In addition, active user involvement across health care research has been widely promoted in patient settings and continues to be of critical importance. For example, the Patient and Public Participation policy 2017 [30] set out the National Health Service (NHS) England's commitment to strengthening user involvement in service design and delivery, and the National Institute for Health and Care Excellence [31] has published similar sentiments.

Although PD has been used to investigate well-being in other contexts and has reported positive findings, [32,33], we are unaware of any study that has used PD in the development of a web-based emotional well-being intervention for staff use within a health care setting, with the underlying purpose of addressing adherence and engagement.

Objectives

We aim to develop a web-based emotional well-being intervention for use by health care staff using PD, with specific objectives of exploring the following:

1. The workplace context, access and availability of existing resources, and workflows;
2. Understanding of well-being in a workplace context;
3. Therapeutic approach;
4. Website design (style, logo, and layout);
5. Interactive and access features (structure, gamification, and audio or visual components);
6. The aforementioned concerning adherence and engagement;
7. Identification of criteria relevant to participants.

Methods

Ethics

Ethical approval was provided by the Swansea University Human and Health Research ethics committee (July 2015). Abertawe Bro Morgannwg University Health Board (ABMU HB) granted approval for service development.

Participants

Participants were staff from a Welsh health board (HB) in the United Kingdom. There are 7 HBs in Wales that serve a total population of 3.2 million people; each HB includes hospitals, outpatient clinics, and general practices. Staff was invited via intranet, email, and presentation. Digital and physical notice boards displayed the study flyer.

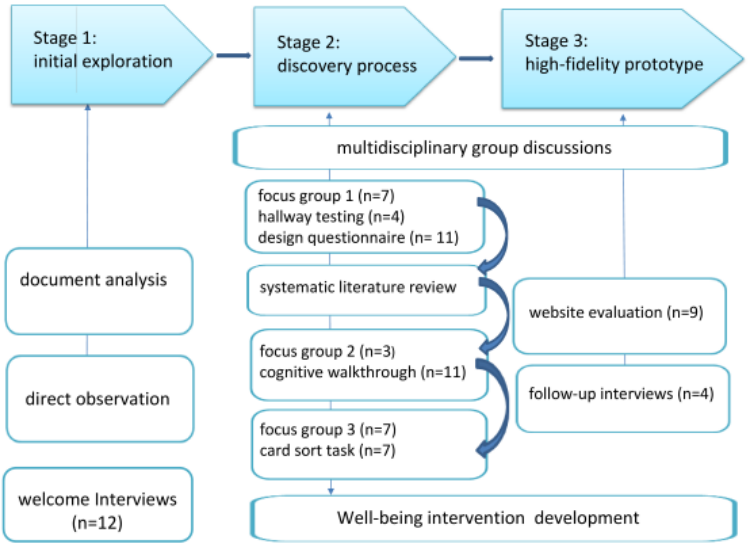
Inclusion Criteria

The inclusion criteria were being a member of staff at the selected HB and age ≥18 years.

Procedure

The PD process followed 3 distinct stages (Figure 1) specifically combined to elicit a progressive design process [34] in line with the ISO (International Organization for Standardization) 134407 (1999) [35] standards of human-computer design.

Figure 1. Study diagram.



Stage 1–Initial Exploration

We conducted the identification and exploration of organizational work environments (Table 1). Workers' routines, day-to-day functions, traditions, and practices alongside the availability of existing (workplace) health and well-being resources informed the understanding of how and when staff might access the intervention [36].

Table 1. Data sources.

Sources of evidence	Description	Data collected
Document analysis	• ABMU HB[a] public website • Published publicly available reports from ABMU HB • Publications from phases I and II of Champions for Health[b] • Public Health Wales evaluation documents of Champions for Health • Well-being through work service	• Major and local hospital sites in ABMU HB • Staff roles within the health board • Employment statistics • Champions for Health development • Evaluation of past campaign results (phase I): engagement, retention, and adherence • Profile of typical staff member who took part • Health improvement rate • Identification of current well-being resources available via the service
Direct observation	• Visit to main hospital sites	• Observations of physical space, organization, and use
12 open-ended welcome interviews	• Staff from a variety of roles within ABMU HB	• Description of the design process • Discussion of the role in the design process • Clarify understanding and requirements of participation • Explore motivation for participation • Explore previous experiences of PD[c] • Explore initial thoughts on well-being • Administer a questionnaire to explore access to internet-capable devices and the current work environment • Description of benefits and difficulties of participation • Clarify the ability to attend focus groups

[a]ABMU HB: Abertawe Bro Morgannwg University Health Board.

[b]Champions for Health was a health promotion platform developed by Public Health Wales, which consisted of 5 lifestyle behavior change modules (quit smoking, alcohol reduction, weight optimization, regular exercise, and eat healthily) for use by health care staff in Wales, United Kingdom.

[c]PD: participatory design.

Stage 2–Discovery Process

In line with accepted traditions [37], this stage focused on study objectives 2 to 7 via clarification of participants' values and tacit knowledge through continuous and cooperative interaction with multiple stakeholders [37], focus group discussion, and rapid prototyping [38,39].

Focus Groups

The initial focus group (FG1) included the principal researcher (MB) and anticipated end users. The group explored

participants' goals and values, with the purpose of generating a shared project plan, which specified well-being needs that could or should be met by the intended resource. Participants' understanding of well-being in the context of their workplace was explored in-depth. Thereafter, a discussion was held, which focused on evaluating existing websites (eg, *MOODGYM* and *Color Your Life*). This generated initial design ideas and identified likes, dislikes, key website features, intervention content [36], and therapeutic approach. Ideas from the welcome interviews were presented in the form of a word cloud to generate further discussion.

New members (anticipated end users) were included in subsequent focus groups, in line with accepted recommendations [34], as were 2 computer scientists. Their insight supported discussion on interactive features and design guidelines and ensured that a variety of perspectives were incorporated [36]. To promote and strengthen the relationship between researchers and participants, focus groups were held at a variety of hospital locations [37]. Focus group 2 (FG2) recapped the project plan, undertook a data validation exercise based on FG1 outcomes, and explored options for the therapeutic approach. Focus group three (FG3) explored content requirements, including structure, gamification elements, and audio or visual features. Gamification elements included health points and trophies as a reward for website engagement and feedback graphs to show progress. This stage was also informed by 2 systematic literature reviews [14,40].

Rapid Prototyping

Regular multidisciplinary group discussions were held to discuss and interpret the data. Low-fidelity prototypes (Multimedia Appendix 1) were produced to attend to cost and time considerations, stimulate early design discussions [37], and identify design errors early, in line with the 5 essential processes of human-centered design principles [35]. Rapid prototyping was undertaken after each focus group in an iterative cycle, and feedback informed subsequent designs.

Hallway Testing

Individuals in an office setting were randomly approached and asked to participate. The office setting was selected because of its environmental similarity to the anticipated end-user context. Context is considered a key factor in the development of web and mobile apps [41,42]. Participants were briefed and debriefed. Layout ideas were explored using paper prototypes.

Design Task

Visual aesthetic appeal is of critical importance in web design [43-46]. For example, empirical findings suggest that individuals reach a decision regarding the visual appeal within 50 milliseconds [46]. The design task was conducted in a group setting, in a large room with a large whiteboard at the front, with a clear view. Participants were briefed and administered a printed questionnaire. A researcher displayed designs on the whiteboard for 7 seconds. Participants rated each design using a 5-point Likert scale ranging from 1=very unappealing to 5=very appealing; 2 sets of logo designs were also shown, and preference was indicated (Figure 2). Once completed, the designs were discussed, and written feedback was provided.

Figure 2. Home page designs version 1 and 2 used in stage two.

Cognitive Walkthrough

The cognitive walkthrough was selected for its ability to generate data regarding typical user responses to designs and navigation. Testing the initial designs in this way ensured that development remained focused on user experience, interaction, and responses [44]. However, exploration and evaluation were

limited to the use of simple designs and were not assumed to be indicative of response times.

Participants' verbal responses and interactions with the *system* were video recorded. A video camera was set up on a tripod behind the participant to capture hand movements while navigating the prototype. Initial website designs were prepared beforehand for the task, and designs were printed out in full color. Participants were asked to "imagine themselves in their usual work environment, with some time available to explore on-line, their interest in their own health and well-being." One researcher asked a series of realistic questions, and another acted as the *system*, responding according to user behavior. For example, the home page was presented, and participants were asked to select a well-being resource they would like to explore. They showed their selection by *pretending* to click on the website buttons available. Depending on their selection, the *system* then presented the next screen (ie, if they selected *improve your well-being*, this led to the *yoga girl* page. Alternatively, if they selected *module description*, a drop-down menu appeared). A third researcher took field notes.

Card Sort Task

An audio-recorded, open card-sorting task informed the organization of content and created category labels. Participants worked collaboratively. The group approach was selected because of staff time constraints. Participants were briefed and debriefed and provided with a set of 25 cards with the following categories: acceptance and commitment therapy (ACT), mindfulness, acceptance, cognitive fusion, being present, self as context, committed action, values, relaxation exercises, benefits of relaxation, sleep hygiene, sleep and well-being, sleep diary, photo gallery, map, restorative effects of nature, symptoms of stress, symptoms of anxiety, symptoms of depression, what is stress, what is anxiety, what is depression, ACT exercises, whom to contact, and homework. Participants were asked to categorize the cards as they saw fit. No limit was placed on the number of categories available. Once all the cards were sorted into categories, participants were asked to discuss among themselves the possible labels for each of the categories identified. Options were written down on blank cards and discussed to reach consensus.

Intervention Development

The iterative development process among researchers, computer scientists, and participants was mirrored with an iterative intervention development process. The primary researcher compiled a draft informed by data from stages 1 and 2. This was discussed and reviewed by a mental health expert and an expert ACT practitioner who provided detailed feedback. This ensured that the content was developed in line with therapeutic principles, incorporated appropriate scenarios and examples, outlined key concepts clearly, and supported positive well-being.

Stage 3–High-Fidelity Prototype

A high-fidelity prototype website, informed by data from stage 2, was developed (Multimedia Appendix 2), and therapeutic content was added. Participants accessed a private WordPress website for 6 weeks. Participants provided consent by actively visiting the website and requesting access. A blog update was posted to the website once a week, which served as a reminder to access the website. Structured feedback was requested on completion of each week via anonymous embedded surveys. Alternative feedback routes were available: website blog and direct email. At the end of week 6, a debrief message was posted, and the website was closed. All users were invited to participate in an interview to discuss their experiences. Users completed 2 validated self-report measures before accessing the website, the World Health Organization Well-Being Index (WHO-5) [47] and the Acceptance and Action Questionnaire version II (AAQ-II) [48], an assessment of psychological flexibility.

Data Analysis

Interview and Focus Group Data

Interviews and focus groups were audio-recorded and transcribed verbatim. Inductive thematic analyses were performed, informed by the work of Braun and Clark [49], where a staged process of data analysis was followed: familiarization with the data, reading and rereading of transcripts, and immersion in the data set, which was achieved through an active process of memoing keywords, trends, and recurring patterns observed in the data. Initial codes were then generated using a line-by-line approach, summarizing the data to capture the essence of participants' thoughts and views. This was followed by reporting the codes in a formal coding structure document. Stage 3 involved searching for themes across the data set using the coding structure and thematic mapping of codes and emergent concepts. A full review of themes and codes was undertaken in stage 4, followed by refinement and development of theme names. Throughout the process, emergent themes were discussed with a second researcher. Participant quotes and extracts were highlighted, and theme development memoing was undertaken using a constant comparative method to ensure all data were included for analysis and interpretation.

Prototype and Usability Data

Hallway Task

A multidisciplinary group discussed feedback. Design questionnaire data frequencies were reported, and free-text comments were qualitatively analyzed.

Cognitive Walkthrough

Data were analyzed in a structured manner [44]. First, the video-recorded data were watched, and question responses transcribed verbatim to capture verbal and physical responses. Second, the data were scrutinized for error frequency and type [44]. A correct response was indicated by a score of 0 and an incorrect response by a score of 1 and a full description. This was undertaken for each task question. A response was considered correct if it met the expected user action for that question. For example, when asked, "What would you do if you were interested in finding out about emotional well-being?" the expected responses would include "click on the well-being icon" or "navigate to the drop-down menu, explore modules and click on emotional well-being option." All potential navigation routes were identified. An incorrect response would be any other answer, for example, "click on the five a day icon or option in

the drop-down menu." Finally, incorrect responses were assessed and assigned a risk score. A summary document was produced, which categorized all incorrect responses and risk assignment and highlighted critical incidents.

Card-Sorting Task

Categories and subcategories labeled by the group were reported.

High-Fidelity Prototype

Engagement was measured by weekly survey completion.

Results

Results are presented per PD stage; in stage 1, document review data are presented only on HB.

Stage 1

Document Review

At the time of the study, ABMU HB employed 16,000 staff and served a population of approximately 6000,000 with an annual budget of £1.3 billion (US $ 1.70 billion; ABMU annual report 2010-2011). The HB consisted of 4 acute hospitals, 10 community hospitals, and 77 general practices. Within the NHS Wales and ABMU HB, anxiety, stress, depression, and other unspecified psychiatric illnesses affected 7945 staff members (ABMU HB report) in 2015 and 2016 and accounted for 23% of sickness absences in 2015, second only to musculoskeletal conditions (25%). Employee well-being (occupational health) consisted of clinically led well-being through work service. Later (2016), a voluntary staff *Well-being Champions* scheme and an annual staff well-being week (2017) were introduced alongside a range of informal local initiatives (eg, running club and book club).

Welcome Interviews

A total of 12 welcome interviews were conducted between August 8, 2015, and September 23, 2015, across a variety of locations. Interview duration ranged between 30 and 60 min, and 83% (10/12) of the participants were women aged 31 to 60+ years (Table 2). Staff was from a range of occupations: consultant, physiotherapists, occupational therapists, speech therapists, administration, education, and managerial staff.

Interview data identified that all participants had access to an internet-enabled computer device during their working day, and 10 also had Wi-Fi access. However, access restrictions varied, and some were limited to 30 to 45 min of personal use during break time. Initial resource ideas were identified and presented as a word cloud to generate discussion in FG1 (Multimedia Appendix 3). A key issue that emerged was related to how individuals managed the constant changes at the organizational level, which affected health and well-being. This theme was then explored further in FG1.

Table 2. Participant data.

Stage and task	Date	Location	Duration (min)	Number of participants	Number of women, n (%)	Age range (number)
Stage 1						
Welcome interviews	August 11 to September 23, 2015	Multiple locations[a]	30-60	12	10 (83)	31-40 (4), 41-50 (4), 51-60 (3), and 60+ (1)
Stage 2						
Focus group 1	September 28, 2015	Princess of Wales Hospital	120	7	5 (71)	31-40 (1), 41-50 (3), 51-60 (2), and 60+ (1)
Focus group 2	December 8, 2015	Princess of Wales Hospital	60	4	1 (25)	21-30 (1), 31-40 (2), and 60+ (1)
Focus group 3	March 21, 2016	Neath Port Talbot Hospital	60	7	4 (57)	31-40(1), 41-50 (3), 51-60 (2), and 60+ (1)
Hallway task	October 5, 2015	Swansea University singleton park campus	—[b]	4	—	—
Design task	October 12, 2015	Singleton Hospital	—	11	—	—
Cognitive walk-through	February 26, 2016	Singleton Hospital	—	7	—	—
	December 8, 2015	Princess of Wales Hospital	—	—	—	—
Card sort	March 21, 2016	Neath Port Talbot Hospital	—	7	—	—
Stage 3						
High-fidelity website	October 1, 2018	N/A[c]	6 weeks	9	—	—
Follow-up interview	December 3, 2018-January 9, 2019	Neath Port Talbot Hospital, Princess of Wales Hospital, Morriston Hospital, and Singleton hospital	12-30	4	3 (75)	31-40 (4)

[a]A variety of locations across ABMU HB and Swansea University singleton campus.

[b]Not collected.

[c]N/A: not applicable.

Stage 2

A total of 38 different staff members participated; some took part in multiple tasks.

Focus Groups

Following the welcome interviews, 5 female participants decided not to take part in the subsequent stages of the project. One was unable to travel to attend a focus group, another changed roles, and 3 others had limited availability to participate; 9 additional participants were recruited (2 participants from FG1 also attended FG2).

A total of 3 focus groups were conducted (n=18) at 2 hospital locations between September 28, 2015, and March 21, 2016; 56% (10/18) were women, and the duration of discussion ranged from 60 to 120 mins. Participants were aged between 21 and 60+ years (Table 2) and from a variety of professions: education, speech therapy, physiotherapy, nursing, occupational therapy, and management.

A shared project plan was created based on discussions of participants' goals and values (Multimedia Appendix 4). Discussion of participants' views and understanding of well-being led to the emergence of 5 themes (FG2 and FG3 data validation process did not identify any new themes) that directly shaped the emergent intervention: meaning, causes of poor well-being, well-being as taboo, well-being needs and barriers, and resource suggestions (Multimedia Appendix 5: Themes). For example, well-being was broadly described as a sense of life balance and positive living across different life domains: work or career, family, personal and social life, and took into account aspects of enjoyment, responsibility, and choice and ability to pursue activities in a domain without feeling restricted by responsibilities in other domains. As such, the intervention resources needed to reflect this perspective. Equally, attention was paid to causes of poor well-being at the

individual level, and as such, the intervention needed to focus on encouraging a growth mindset to address perceived poor self-awareness and enable users to self-manage their own well-being through the provision of interactive ideas and information. Well-being was considered a taboo workplace topic, and it was felt that the resources needed to reach across the organization to ensure all staff was included. As a result, individual profiles (for different staff groups) were not included to give a sense of cohesion or commonality.

Participants openly discussed their experiences with different therapeutic approaches, some from the educator's role, others from a more personal perspective. There was a collective sense that something new was needed, a divergence from existing knowledge, and the need to not duplicate existing resources available within the HB. During discussions, a range of approaches was presented; participants identified that cognitive-behavioral therapy was already available and widely used and that an alternative approach would be beneficial. ACT emerged as an appropriate choice; several participants had experience of ACT and believed it was not too out of step with staff experiences despite being less well known. The key focus was on creating a resource that would promote positive well-being on a day-to-day basis and could be relied upon in times of emotional difficulty.

Stress management was a central focus and a range of resources and interactive content were identified for inclusion, for example guided mindful meditations, Tai Chi and breathing exercises, and experiential exercises (a key feature of the ACT model) supplemented with tailored scenarios to (nonspecific) health care staff needs and downloadable activities. Likewise, personal shared stories and the need for clear signposting were identified as important to help staff understand their personal experiences and identify onward sources of support. This resulted in the inclusion of 5 well-being films (Multimedia Appendix 6) and a list of outward organizations.

Equally, alongside content options, intervention features and organization were discussed. Participants were happy with a sequential format because of its ease of use and familiarity, but they wanted different progress routes to recognize the different professional groups working across the HB, for example, the stress and strains experienced by professions and the different access and time options available. Therefore, additional psychoeducational materials were included. This would also attend to the needs of those looking for a *quick fix* on the understanding that not all users would need or want a long-term approach. Audio and visual communication was preferred over long text sections. A mobile responsive website was also a key requirement. Blogs and chat rooms were discussed, and their relative merits were considered with regard to the feasibility of programming and privacy issues informed by computer scientists.

Rapid Prototyping

We undertook 4 prototyping and usability tasks (n=33) at 4 locations between October 5, 2015, and March 21, 2016. Demographic data were not collected.

Hallway Testing and Cognitive Walkthrough

The hallway testing data were combined with low- (paper designs used) and high-fidelity cognitive walkthrough data. We identified 3 key issues: first, user difficulty navigating away from the *pop-up* pages (nature, sleep, and relaxation pages); second, user uncertainty regarding the use of the resource; and third, confusion over expectations of the *nature page*. As such, an additional close button was added to each pop-up, instructions for use were incorporated into the registration page (to guide users), and the pop-up was renamed *Green space*.

Design Questionnaire

Design data informed the color scheme, module logos, well-being design (Figure 3), and home page layout (design 2 was selected).

Figure 3. Initial well-being design.

The Card Sort

We identified 8 categories, labels or headings, and subcategories. Key outcomes were category labels, the requirement for additional information on stress, depression, anxiety, and integration of resources throughout the module.

Stage 3–High-Fidelity Prototype

In this stage, 2 new participants were included. A total of 9 participants piloted the high-fidelity intervention for a period of 6 weeks (October 2018). No demographic data were collected. Four participants completed a follow-up interview, conducted between December 3, 2018, and January 9, 2019, at 4 hospital sites. Most of them were women (3/4, 75%), aged 31 to 40 years, and from the following professions: therapy, pharmacy, physiotherapy, and occupational therapy. The interview duration was between 12 and 30 mins.

A total of 7 participants completed the WHO-5 questionnaire, and 8 completed the AAQ-II before accessing the website. Engagement with the intervention content varied; 1 participant remained engaged until week 5, although the interview data indicated that the content across all 6 weeks was viewed. The survey responses indicated that overall, the content was considered useful and contained adequate information. Moreover, the responses indicated that most interactive content (ie, experiential exercises, YouTube clips, and *try now* activities) was explored and that the *lesson summary* was helpful.

3 feedback routes were utilized: blog post (n=2), email (n=2), and handwritten feedback (n=1; Table 3). Written feedback and interview data highlighted additional suggestions, including alternative ways to display content, the need to expand descriptions and embed YouTube clips, the use of audio files as an alternative to text, and inclusion of *time to complete* estimates for each experimental exercise and interactive element. Barriers to use were a lack of time (during the working day) to access the website, lack of internet access via workplace computers, no headphones for audio components, perceived lack of managerial support, and volume of text content. Interview participants discussed the length of time they felt they had spent each week and how this might be reduced or broken down into shorter, more manageable segments to encourage engagement.

Table 3. Summary of key survey results and free-text feedback.

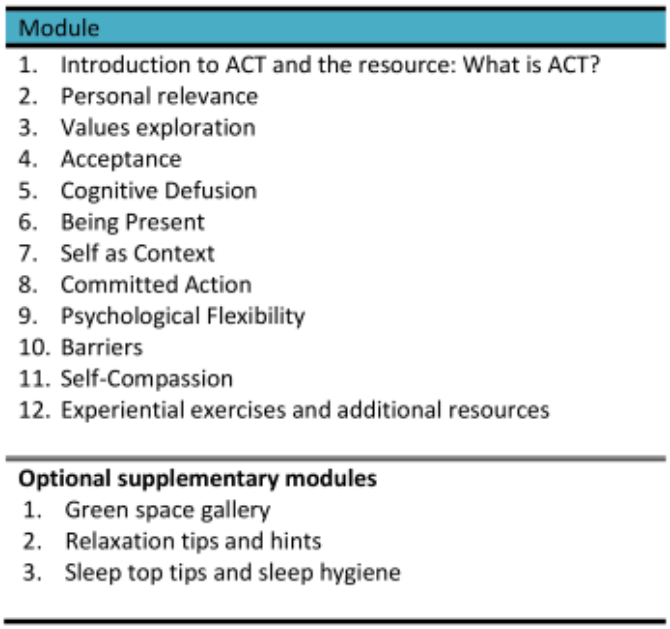
Week	Number of respondents, n (%)	Overall usefulness of week, 5-point Likert scale (number of responses)	Participants who completed interactive content, n (%)	Free-text comments (feedback route)
1	6 (67)	• Useful (3) • Somewhat useful (1) • No response (2)	4 (44)	• "ACT model may need more of an intro/explanation or something like 'the model will be revisited throughout the programme' or 'the 6 techniques will be expanded upon throughout...'" [Blog] • "The watch links need some text to contextualize why we are now moving to deep breathing etc as they feel a bit random at the mo." [Blog] • "An explanation at this point [Psychological flexibility questionnaire] on what the scores mean would also be helpful." [Email]
2	3 (33)	• Useful (3) • Somewhat useful (1)	3 (33)	• "good - week two seems a lot easier to read through and doesn't feel as intense" [Survey] • "I liked the really clear language and the great use of examples. The metaphors were well chosen. I wonder about the tiger metaphor though... I did not download PDFs but I used them at the time" [Survey]
3	3 (33)	• Very useful (1) • Useful (1) • Somewhat useful (1)	3 (33)	• "I think there were too many exercises this week" [Survey] • "In the ending you mention thoughts and feelings as barriers, but not necessarily behaviors. Wondering if it was worth putting that in as all three impact each other." [Survey]
4	3 (33)	Useful (3)	3 (33)	• "Maybe somewhere it could advise on the amount of time needed" [Survey] • "The unwanted party guest YouTube example was excellent and in my opinion the most engaging." [Survey]
5	1 (11)	Useful (1)	1 (11)	• "It was quite a short week compared to the others, but I would not have wanted anymore on the particular topic, there was more than enough detail on it." [Survey]
6	0	No responses	0	• "I like the way it's got the same layout every week it makes it easy to follow" [Interview] • "I think people could use it for their CPD time." [Interview] • "I've seen things like they tell you how many mins it might take, so this is going to be a 5 mins exercise." [Interview] • "I haven't been able to access them [YouTube clips] not because of your website but because of our, we are only allowed on certain websites." [Interview]

The Intervention

A 12-week, emotional well-being intervention based on ACT was developed in line with participant discussions and systematic review [14,40] outcomes. This was added to the new study website alongside the existing Champions for Health 5 lifestyle modules. ACT [50] is a third-wave therapy that encourages the development of psychological flexibility. Specifically, it aims to equip people with the ability to more skillfully relate to their unwanted thoughts and feelings such that they are still able to move toward personally chosen values. Contrary to other approaches, ACT asks people to be willing to experience negative private events, rather than seeking to change them, and a central theme of the approach is to support people in returning their attention to the present moment through mindful practice.

The intervention incorporated 6 core processes of ACT (Figure 4). Each resource was compiled as a *week* and designed to *stand-alone* to encourage repeated use and skill consolidation and avoid overwhelming those new to ACT. Users-identified features that reduced or encouraged engagement were added (Textbox 1).

Figure 4. Intervention sequence.



Textbox 1. Engagement.

Participant-led suggestions to enhance engagement:

- Short interactive segments
- Time to complete information (ie, estimated amount of time the exercise will need)
- Lesson summary or take-home message
- Management and organizational-level support for workplace use of resources and specified well-being time
- Completion certificate to integrate with organizational-level professional development reviews in recognition of time spent and skills acquired

Discussion

Principal Findings

This study aimed to develop a web-based emotional well-being intervention for use by health care staff in the workplace, following a staged PD process. Specific objectives were to explore workplace context, access and availability of existing workplace well-being resources, and anticipate end-user opinion on well-being workplace needs, therapeutic approach, website design, and interactive features while exploring these in reference to promoting user engagement. The process also aimed to identify and explore additional criteria relevant to participants.

A structured, sequential, automated, 12-week, web-based emotional well-being intervention based on ACT was developed as a result of an iterative, 3-staged PD process. A wide range of staff engaged in many activities at different time points during a sustained period. Workforce groups with high- and low-rate absenteeism were represented. Absence due to sickness among ambulance staff, health care assistants, and support staff was 6.3% and 6.2%, respectively, whereas absence among nurses, midwives, health visitors was lower (1.05%), as well as medical and dental staff (1.21%) [51].

The collaborative approach supplemented by recommended mental health design guidelines [41] incorporated qualitative methods of inquiry, facilitating open discussion, and generating a collective codeveloped understanding of well-being in the workplace. Open discussions between researchers and participants created a supportive group environment, evidenced by staff discussions of personal mental health experiences and well-being needs. This enabled topics to be revisited over time, and as new members joined. *Design for outcomes* [41] advocated concise goals and focus on intended outcomes, adhering to this enabled effective management of expectations at each stage and resulted in an immediate array of design suggestions, resources, and the participant-led selection of ACT.

The inclusion of multidisciplinary experts and participants from different workplace environments outlined in “design in collaboration with mental health professionals” [41] provided critical insights from a range of perspectives and allowed issues relating to access, organizational support, and stigma to be considered.

Frequent meetings with computer scientists and rapid prototyping not only stimulated discussions on website style, look, and color scheme but also generated specific design

requirements. The design questionnaire, cognitive walkthrough, and card sort enabled quick and accurate identification of frequent user error, unsuitable features, and areas that required further clarification. Participants engaged easily with these tasks, which were selected for ease of use. Similarly, the importance of identifying user needs and being sensitive to mental health state when considering delivery and reminder options to participants [22] was central to the intervention created. Equally, the iterative intervention content development process was informed directly by participants at all stages, while remaining under careful inspection of clinical experts.

Adherence and engagement remain a critical concern in web-delivered mental health interventions. PD was selected specifically to address this issue. Participation in the design and development process is thought to increase the likelihood of user ownership and alignment with the end product [52] while simultaneously affording the opportunity to explore anticipated end-user views on methods to promote sustained engagement and adherence. The continued interest of different participants over a sustained period indicated that this was successfully achieved, despite lower engagement in stage 3. Participants were also asked to suggest ways in which to address poor use in relation to their workplace. Barriers to access (to well-being resources) identified in the qualitative discussions led to a series of communications and a meeting with the executive director of public health at the HB and the establishment of a sustained working relationship with the *employee's well-being* team at the HB. Support at the organizational level, including managerial support, remains an integral component of the project.

Comparison With Previous Work

Our findings are in line with those of Wadley et al [26], who reported successful use of PD processes to develop a web-based social therapy intervention for adolescents with psychosis. Similar to our approach, they followed a PD process where initial design ideas were presented to patients to stimulate discussions surrounding web-based delivery of therapy and personalized preferences, followed by separate discussions with clinicians.

Kelders et al [16] developed an intervention to prevent depression. They used participant interviews, rapid prototyping, and requirement sessions and concluded that their methods provided valuable insight beyond comments on color and layout and extended to include contextual considerations. Similar to this study, staff considered their workplace context and well-being needs throughout the development process, and this added valuable insight into how and when the program might eventually be accessed and included in daily work schedules. Barriers to use were identified, which facilitated the development of quickfire experiential exercises that specified the expected completion time (ie, 5-min duration). This ensured that the exercise was suitable for workplace use, that is, could be used on a short lunch break or during well-being time, which was supported by management. Management support and *permission* to use the resource were highlighted as critical elements to enable engagement with workplace interventions.

Limitations

Previous work has noted that PD approaches have been difficult to sustain within complex health care contexts where anticipated end users and stakeholders are busy and cannot commit adequate time to the iterative process of designing [53,54]. Although a range of participants from diverse professional streams worked well together and participated with active and ongoing interest, some were unable to attend successive stages because of busy work schedules, organizational commitments, and varying geographical locations. Therefore, some tasks had small numbers, which limited data analysis. Focus groups were also limited to a maximum of 2 hours. Although this was adequate, longer sessions might have facilitated further insight and design developments, which should be considered thoroughly in future projects of this kind. Future work may consider web-based focus groups and workshops to mitigate this [55].

Stage 3 was limited by a small sample and poor survey response rate; however, interactive elements were used. The final focus group was altered to one-on-one interviews because of conflicting work schedules. This limited exploration of the user experience. Further incorporation and discussion of how participants might use and practice experiential exercises and interactive intervention features could have been introduced into the design process, for example, through *future workshops*, which asks participants to envisage and discuss the future use of the technology [56]. However, mental health experts, who are arguably better placed to review content, conducted a full review of the resources, and contributed to the iterative design process.

Due to time constraints, an assessment of cognitive workload was not undertaken. This is desirable because web-based delivery methods often rely on text to convey complex messages. However, the readability of the main website was assessed and considered to be a grade level 9, meaning it should be easily understood by those aged from 13 to 15 years [57].

Conclusions

This study brings together strands of public health, psychology, and medicine with computer science to develop an emotional well-being intervention via PD methods.

This study makes two key contributions. First, it offers insights for future practice by presenting empirical data reported from a range of stakeholders. The focus on features to enhance and promote engagement in a workplace well-being resource is of particular interest. Second, it contributes to the developing body of knowledge regarding the utility of the PD approach within the context of health and well-being.

We conclude that the study objectives were met. The PD process successfully facilitated exploration of the anticipated end user's workplace context, access and availability of existing resources, and existing workflows, and it generated an in-depth understanding of workplace well-being, specifically, barriers to access. Participants selected the therapeutic approach through collaborative discussion and consideration of shared knowledge, understanding, and need. Rapid prototyping led to an iterative participant-led design cycle that identified style, logo and layout requirements, interactive intervention features, and structure.

The 3-staged process also ensured that participants had the opportunity to explore and articulate criteria relevant to their roles over time and reflect on decisions made at each stage.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Low-fidelity prototype designs.
[PPTX File , 585 KB - formative_v4i11e22507_app1.pptx]

Multimedia Appendix 2
High-fidelity prototype designs.
[PPTX File , 2002 KB - formative_v4i11e22507_app2.pptx]

Multimedia Appendix 3
User generated word cloud used in stage two.
[PNG File , 178 KB - formative_v4i11e22507_app3.png]

Multimedia Appendix 4
Project plan.
[PPTX File , 194 KB - formative_v4i11e22507_app4.pptx]

Multimedia Appendix 5
Qualitative themes.
[PPTX File , 55 KB - formative_v4i11e22507_app5.pptx]

Multimedia Appendix 6
PocketMedic well-being films.
[PDF File (Adobe PDF File), 232 KB - formative_v4i11e22507_app6.pdf]

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Abbreviations

AAQ-II: Acceptance and Action Questionnaire version II
ABMU HB: Abertawe Bro Morgannwg University Health Board
ACT: acceptance and commitment therapy
FG1: initial focus group
FG2: focus group 2
FG3: focus group 3
HB: health board
NHS: National Health Service
PD: participatory design
WHO-5: World Health Organization Well-Being Index

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Original Paper

Evolution of Bystander Intention to Perform Resuscitation Since Last Training: Web-Based Survey

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Abstract

Background: Victims of out-of-hospital cardiac arrest (OHCA) have higher survival rates and more favorable neurological outcomes when basic life support (BLS) maneuvers are initiated quickly after collapse. Although more than half of OHCAs are witnessed, BLS is infrequently provided, thereby worsening the survival and neurological prognoses of OHCA victims. According to the theory of planned behavior, the probability of executing an action is strongly linked to the intention of performing it. This intention is determined by three distinct dimensions: attitude, subjective normative beliefs, and control beliefs. We hypothesized that there could be a decrease in one or more of these dimensions even shortly after the last BLS training session.

Objective: The aim of this study was to measure the variation of the three dimensions of the intention to perform resuscitation according to the time elapsed since the last first-aid course.

Methods: Between January and April 2019, the two largest companies delivering first-aid courses in the region of Geneva, Switzerland sent invitation emails on our behalf to people who had followed a first-aid course between January 2014 and December 2018. Participants were asked to answer a set of 17 psychometric questions based on a 4-point Likert scale (“I don’t agree,” “I partially agree,” “I agree,” and “I totally agree”) designed to assess the three dimensions of the intention to perform resuscitation. The primary outcome was the difference in each of these dimensions between participants who had followed a first-aid course less than 6 months before taking the questionnaire and those who took the questionnaire more than 6 months and up to 5 years after following such a course. Secondary outcomes were the change in each dimension using cutoffs at 1 year and 2 years, and the change regarding each individual question using cutoffs at 6 months, 1 year, and 2 years. Univariate and multivariable linear regression were used for analyses.

Results: A total of 204 surveys (76%) were analyzed. After adjustment, control beliefs was the only dimension that was significantly lower in participants who took the questionnaire more than 6 months after their last BLS course (P<.001). Resisting diffusion of responsibility, a key element of subjective normative beliefs, was also less likely in this group (P=.001). By contrast, members of this group were less afraid of disease transmission (P=.03). However, fear of legal action was higher in this group (P=.02).

Conclusions: Control beliefs already show a significant decrease 6 months after the last first-aid course. Short interventions should be designed to restore this dimension to its immediate postcourse state. This could enhance the provision of BLS maneuvers in cases of OHCA.

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KEYWORDS

out-of-hospital cardiac arrest; cardiopulmonary resuscitation; basic life support; confidence; first aid; bystander; behavior; cardiac arrest; heart attack; intention; resuscitation; survey; attitude; belief

Introduction

Survival after out-of-hospital cardiac arrest (OHCA) is estimated at around 10% in Europe, with recent studies showing marked differences between regions [1]. Bystander-initiated cardiopulmonary resuscitation (CPR) is one of the most important factors explaining these differences and has been shown to increase the survival rate by three times [1-3]. Immediate CPR initiation after collapse is particularly important, as there is a 10% decrease in survival rate for every minute spent without CPR [4]. In spite of its significant benefits, and although more than half of OHCAs are witnessed, CPR is only provided for less than half of victims, with rates varying widely from 19.1% to 79.0% [5]. As ambulances rarely arrive on scene before 10 minutes, the probability of survival is limited unless CPR has been initiated before the arrival of professional rescuers [4,6]. The deployment of comprehensive OHCA management programs has been shown to improve both survival and neurological outcomes [7], and relies heavily on the training of lay people who will be and feel able to initiate CPR quickly after collapse.

According to the theory of planned behavior, the probability of executing an action is strongly linked to the intention of performing it [8,9]. Intention is determined by three distinct dimensions [10]. The first, attitude, relates to the bystander's beliefs. Regarding resuscitation, a positive attitude would be to think that performing CPR could save a life. The second dimension, subjective normative beliefs, is the person's perception of the judgment close relatives might have regarding one's actions. In the context of first aid, this would be a consideration that one's friends would approve, or even be proud, if one performed resuscitation. The third and last dimension, control beliefs, is the confidence in one's own ability to perform resuscitation [8,9].

In Switzerland, the rates of successful OHCA resuscitation vary from 10% to 17% [1,11]. These rates are not as high as could be expected given the rather high proportion of people having followed a CPR training course, which is mandatory to obtain a driving license in this country. This could be explained, at least in part, by the fact that basic life support (BLS) course participants lose both skills and confidence in their ability to perform CPR within a matter of weeks after completing a CPR training course [12-14]. We hypothesized that the intention to perform CPR might also decrease over time, thereby further decreasing the rate of bystander-initiated resuscitation and consequently of successful OHCA resuscitations.

The aim of this study was to measure the variation of the three dimensions of the intention to perform CPR according to the time elapsed since the last first-aid course. Identification of any significant difference could potentially help to design specific interventions and hopefully improve the rate of bystander-initiated resuscitation.

Methods

Design

This was a closed web-based questionnaire study following the CHERRIES [15] guidelines, which was conducted between January and April 2019. The regional ethics committee issued a nonobjection statement (ID 2018-01382) as such surveys do not fall within the scope of the Swiss federal act on research involving human beings [16].

Participants

The two largest companies providing first-aid courses in Geneva (Association Genevoise des Sections de Samaritains, a Red Cross–affiliated national society, and Firstmed, a privately owned company) were asked for a list of email addresses of former CPR course participants. To protect individual data, both societies refused to send us such a list directly but agreed to dispatch emails on behalf of the investigators. They were therefore provided with a generic text containing summarized information about the study along with the link to the online survey. Both companies were asked to send this email to participants who had followed a first-aid course between January 2014 and December 2018.

Emails were sent between January and April 2019. Although the exact number of sent and "bouncing" emails had been asked for, these data could not be gathered as one of the two companies experienced technical problems with their mailing system. Reminders could not be sent as per the request of both companies.

No financial incentive was given to participate in this study.

Survey

A website based on the Joomla! 3.9 content management system (Open Source Matters) was specifically designed for this study. The Community Surveys 5 component (CoreJoomla) was used to create the online survey and record the answers in an encrypted MariaDB 5.5.5 database (MariaDB Corporation AB) located on a Swiss server. As this was a closed study, and to ensure irreversible anonymization, we decided not to use either cookies or internet protocol address restrictions. A log search was nevertheless performed to identify potential duplicate entries.

The survey itself was displayed over 4 pages. The first 2 pages were designed to gather demographic data. The 17 questions were displayed over pages 3 and 4, which contained 9 and 8 questions, respectively. The system ensured that participants had answered all of the questions on a page before allowing them to move forward. All answers could be reviewed and changed as long as the survey was not finalized.

Upon loading, the website immediately displayed a summarized consent form and a confidentiality notice as well as a link to a detailed description of the study. A statement regarding data collection and storage was also shown, and the purpose and

duration of the survey were detailed. Participants were informed that they could decide to leave the study at any time, and were given an email address they could use to contact the investigators. No personal data were collected.

A first set of general questions was created to gather demographic data, determine the time elapsed since the last CPR training course, and record information regarding the number of prior CPR courses followed. A set of 17 psychometric questions was then designed to assess each dimension of the intention to perform CPR (Multimedia Appendix 1). Ten questions were adapted from the Canadian national survey performed by Vaillancourt et al [8] in 2013. Seven more questions were created to assess specific factors that could further affect the dimensions of the intention to perform CPR and might therefore prevent bystanders from starting CPR. Among these latter factors, usually referred to as "barriers," fear of disease, fear of incorrectly performing CPR, and fear of hurting the victim were evaluated [17-19]. Answers to all psychometric questions were based on a 4-point Likert scale ("I don't agree," "I partially agree," "I agree," and "I totally agree").

The survey and the data extraction mechanism were thoroughly tested by all investigators prior to the launch of the study.

Measures

The primary outcome was the difference in each of the three dimensions of the intention to perform resuscitation between participants who had followed a first-aid course less than 6 months before taking the questionnaire and those who took the questionnaire more than 6 months and up to 5 years after following such a course. The investigators decided to use a 6-month cutoff since the alternative of asking lay people to attend an on-site refresher course so soon after the last training course would be unlikely. Nevertheless, offering a short, targeted, and portable intervention after this time span might be considered.

Secondary outcomes were the changes in each of the three dimensions using a 1-year and then a 2-year cutoff rather than the 6-month cutoff used to compute the primary outcome, and the change in each individual question using the 6-month, 1-year, and 2-year cutoffs.

Analyses

Survey data were extracted to a comma-separated value file and imported in Stata 16.0 (Stata Corp LLC). Records were searched for potential duplicate entries as per our protocol. Health care professionals, students of health care professions, and participants who had not followed a CPR course during the previous 5 years were excluded. Incomplete surveys were also excluded.

Stata was used for statistical analysis. Numerical values (–1, –0.5, 0.5, and 1) were attributed to each of the 4 answers gathered through the use of Likert scales, with positive values assigned to the answers that were in favor of the intention to perform resuscitation. All survey questions carried the same weight and were summed by dimension. Univariate linear regression was used to assess the variation of each specific dimension of the intention to perform resuscitation according to the time elapsed since the last first aid course. A multivariable linear regression model was used to identify the effect training centers or age groups might have had on these variations. A double-sided P value <.05 was considered significant.

The original dataset is available in the Mendeley Data repository [20].

Results

Overall, 383 surveys were started, 270 (70.5%) of which were completed. A total of 204 of the completed surveys (75.6%) were analyzed after application of the exclusion criteria (Figure 1). No data suggestive of duplicate entry was identified.

Characteristics of the participants, including the number of prior BLS courses, are described in Table 1.

Participants who took the questionnaire more than 6 months after their last first-aid course had significantly lower scores regarding control beliefs and subjective normative beliefs (Table 2). The difference was particularly important regarding control beliefs, with 4 out of 5 questions displaying significant differences. Regarding subjective normative beliefs, diffusion of responsibility was the only element to be significantly lower in the group of participants who had taken the questionnaire more than 6 months after the last course. After adjusting for age group and training center, there was no change in either the direction of the effect or of its magnitude regarding control beliefs (P<.001), whereas the difference regarding subjective normative beliefs did not change direction but failed to achieve significance after adjustment (P=.06). The direction and the amplitude of the diffusion of responsibility element remained unchanged after adjustment (P<.001).

Figure 1. Flowchart of the inclusion of former first-aid course participants (Geneva, Switzerland, 2019).

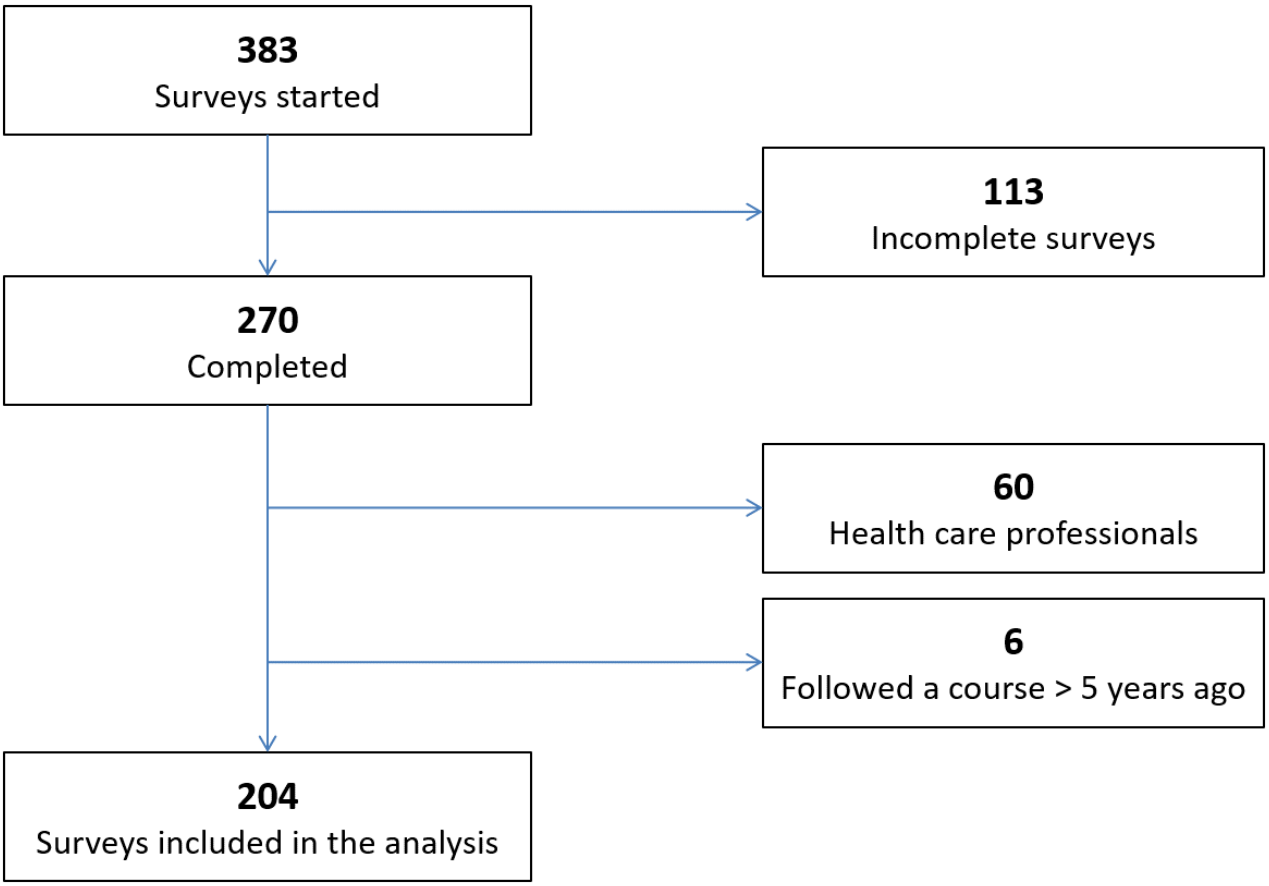

Table 1. Characteristics of the former first-aid course participants included in the analysis (N=204).[a]

Characteristic	Last course followed ≤6 months before (n=85)	Last course followed >6 months before (n=119)	*P* value[b]
Education, n (%)			.045
Mandatory education	3 (4)	3 (2.5)	
Professional diploma	18 (21)	34 (28.6)	
Secondary education	33 (39)	22 (18.5)	
High school	8 (9)	15 (12.6)	
University	21 (25)	39 (32.8)	
Other	2 (2)	6 (5.0)	
Marital status, n (%)			.74
Single	48 (56)	63 (52.9)	
In a relationship	16 (19)	29 (24.4)	
Married	21 (25)	26 (21.8)	
Widowed	0 (0)	1 (0.8)	
Age category (years), n (%)			<.001
<18	18 (21)	3 (2.5)	
18-25	32 (38)	46 (38.7)	
26-30	6 (7)	10 (8.4)	
31-35	5 (6)	11 (9.2)	
36-40	8 (9)	3 (2.5)	
41-45	1 (1)	8 (6.7)	
46-50	6 (7)	15 (12.6)	
51-55	6 (7)	17 (14.3)	
>55	3 (4)	6 (5.0)	
Sex, n (%)			.09
Female	66 (78)	79 (66.4)	
Male	19 (22)	40 (33.6)	
Number of BLS[c] courses followed, n (%)			.29
1	42 (49)	59 (49.6)	
2	15 (18)	32 (26.9)	
3	13 (15)	11 (9.2)	
≥4	15 (18)	17 (14.3)	
Training center			<.001
AGSS[d]	43 (51)	107 (89.9)	
Firstmed	35 (41)	2 (1.7)	
Other	7 (8)	10 (8.4)	

[a]Totals may not equal 100% due to rounding.

[b]*P*-values were calculated using the Fisher exact test.

[c]BLS: basic life support.

[d]AGSS: Association Genevoise des Sections de Samaritains.

Table 2. Univariate analysis of the three dimensions of the intention to perform resuscitation in first-aid course participants (N=204).

Dimension and questions[a]	Last course followed ≤6 months before, mean (95% CI)	Last course followed >6 months before, mean (95% CI)	*P* value
Attitude	6.06 (5.68-6.45)	6.06 (5.79-6.33)	.99
Thinking that performing resuscitation could save a life	0.78 (0.70-0.87)	0.80 (0.74-0.87)	.79
Knowing the importance of starting a resuscitation before EMS[b] arrival	0.91 (0.84-0.98)	0.92 (0.86-0.97)	.93
Not being afraid of disease transmission	0.47 (0.33-0.62)	0.66 (0.55-0.77)	.03
Not being afraid of hurting the victim by performing CPR[c]	0.91 (0.85-0.98)	0.84 (0.77-0.91)	.14
Not being afraid of worsening the victim's condition	0.69 (0.57-0.82)	0.75 (0.68-0.83)	.41
Not being afraid of legal action	0.78 (0.67-0.88)	0.59 (0.48-0.70)	.02
Being proud of performing resuscitation successfully	0.61 (0.48-0.74)	0.58 (0.47-0.69)	.76
Belief that knowing CPR is important for society	0.91 (0.85-0.96)	0.92 (0.89-0.96)	.59
Subjective normative beliefs	1.90 (1.61-2.19)	1.45 (1.18-1.73)	.03
Belief that relatives would be proud if the participant performed resuscitation	0.54 (0.42-0.67)	0.57 (0.46-0.68)	.72
Belief that relatives want the subject to resuscitate them if needed	0.56 (0.43-0.70)	0.45 (0.32-0.57)	.19
Knowing that relatives are the most likely victim	0.02 (–0.13-0.18)	–0.6 (–0.19-0.07)	.42
Diffusion of responsibility	0.77 (0.68-0.86)	0.50 (0.38-0.62)	.001
Control beliefs	3.62 (3.31-3.93)	2.18 (1.83-2.53)	<.001
Knowledge of the emergency number	0.91 (0.85-0.96)	0.70 (0.59-0.81)	.004
Feeling able to resuscitate	0.56 (0.45-0.67)	0.16 (0.04-0.29)	<.001
Feeling able to recognize a cardiac arrest	0.68 (0.58-0.77)	0.28 (0.17-0.39)	<.001
Not believing that only health care professionals can adequately perform resuscitation	0.77 (0.67-0.87)	0.72 (0.64-0.81)	.46
Knowing how to perform a resuscitation	0.70 (0.61-0.79)	0.31 (0.20-0.41)	<.001

[a]For individual questions, scores can range from –1.0 to +1.0; a positive score indicates an answer in favor of the intention to perform resuscitation.

[b]EMS: emergency medical services.

[c]CPR: cardiopulmonary resuscitation.

The association between the time elapsed since the last BLS course and the fear of catching a disease while providing CPR disappeared after adjustment (*P*=.23) when the cutoff was set at 6 months. However, this association was significant (after adjustment) when the cutoff was set at 1 year (*P*=.02) (Multimedia Appendix 2) and even more so when the cutoff was set at 2 years (*P*=.01) (Multimedia Appendix 3). The direction of the effect did not change: participants who had followed a first-aid course more recently were more afraid of catching a disease in all analyses.

Fear of legal action was higher in participants who took the survey more than 6 months after having followed their last BLS course. The direction and the amplitude of this association did not change after adjustment (*P*=.02).

Discussion

Principal Findings

Control beliefs, including knowledge of the emergency number to dial in case of cardiac arrest, already showed a significant decrease only 6 months after the last BLS course. Although some authors have advocated for a much shorter period than the recommended 2-year interval between BLS refresher courses given the need to freshen up CPR skills [21,22], the results of this study show that the intention to perform resuscitation also needs to be restored or at least preserved. Nevertheless, other authors have emphasized that aiming for refresher courses at more frequent intervals was likely unrealistic as even highly motivated lay rescuers would lack either time or money [23,24], and having to perform retraining sessions too frequently might lead to disinterest [25]. Other means must therefore be sought to allow for frequent yet short refresher interventions [26-28]. Such interventions should target critical elements such as diffusion of responsibility [29], which quickly rises after a BLS

course and might lead to delays before initiation of CPR, thereby increasing the no-flow time and worsening the patient's prognosis [14]. In the context of the current COVID-19 pandemic, distance interventions, whether asynchronous or synchronous, have been developed rapidly and many have met with success [30,31]. Interactivity has been shown to increase engagement, and can be achieved through the creation of eLearning modules or of serious games for asynchronous interventions [32], or by the organization of webinars when synchronous interventions are deemed preferable [33].

The participants who took the questionnaire less than 6 months after following their last BLS course were significantly younger and less likely to have been trained by the Red Cross–affiliated center. Although adjusting for these variables nullified the statistical significance initially found regarding subjective normative beliefs when the cutoff was set at 6 months, the change regarding this dimension was still significant after adjustment when the cutoff was set at 2 years. This effect was mostly related to the diffusion of responsibility element. Victims of the so-called bystander effect (ie, being less likely to help a victim when other people are present [34]) may be more prone to act if they feel confident and qualified. Thus, short interventions showcasing realistic examples of diffusion of responsibility are by themselves fighting against the phenomenon and encouraging action. Recently, a scoping review conducted as part of the update process of the international consensus on CPR and emergency cardiovascular care science with treatment recommendations concluded that specific community initiatives and bundles of educational interventions could help improve the rate of bystander-initiated CPR [35]. It has also been shown that diffusion of responsibility depends on the level of danger the victim faces [34]. There could also be a significant and lasting effect of starting CPR training at an earlier stage than currently practiced in Switzerland. Many studies have indeed provided evidence that BLS training yields excellent results in school-aged children [36,37] in whom BLS maneuvers can be taught in less time and with better results [38]. Providing junior medical students with BLS courses early in their curriculum could also prove beneficial as they are expected to take action in case of an emergency [39,40] although their CPR knowledge and skills are generally limited [41-43]. Recently, an initiative including the use of asynchronous distance learning has emerged to promote the inclusion of junior medical students in first-responder systems [44].

Although Vaillancourt et al [8] used the same theoretical model in their 2013 survey, we refrained from using the exact same question set. We considered the theory of planned behavior model to be perfectly valid; however, the way questions are phrased influences the answers given by the participants, their understanding of the problematic, and their willingness to complete the survey [45]. Moreover, some questions were added to address specific issues that were not taken into account in the original survey. For example, subjective normative beliefs were further assessed by asking whether relatives would be proud if one performed resuscitation. Questions related to control beliefs were further assessed by asking whether the participant thought that that only health care professionals would be able to correctly perform CPR. Four other questions were asked regarding attitude, including the participant's take on the impact of resuscitation on society, fear of doing more harm, and fear of catching a disease [14].

Strangely enough, although the survey was conducted before the COVID-19 pandemic, participants who had followed a BLS course in the year preceding the survey were more afraid of disease transmission. As this study was not designed to investigate this unexpected finding, its cause is not easily determined but could be a difference in course contents. A change in the guidelines could hardly play a role in this result, as the study took place in 2019 with the last major guidelines issued in 2015 [46]. Although actions could be taken to mitigate this fear, their timeliness must be assessed with regard to the current COVID-19 pandemic [47].

Of particular concern is the fact that more than half of the participants were unaware that the probability of performing CPR was higher on a relative than on a stranger. Whether this item belongs to control beliefs as suggested by Vaillancourt et al [8] or to subjective normal beliefs as suggested by the results of this study can long be debated, but the critical importance of emphasizing and spreading this message is undeniable. Indeed, lay rescuers who performed CPR for OHCA have described subsequent emotional and social difficulties [48], which may be amplified when CPR has to be performed on a close relation rather than on a stranger. Helping lay rescuers recognize this fact might help better prepare them and can ultimately avoid some of the negative psychological consequences [48,49]. Moreover, knowledge that friends and family might be efficiently helped by provision of BLS maneuvers might increase the motivation of lay rescuers in acquiring and maintaining such critical skills [50].

On a more positive note, the attitude and subjective normative beliefs dimensions were globally preserved even 2 years after the last BLS course. The fact that health care professionals are not the only people able to correctly perform CPR now seems to be well-recognized [51]. However, fear of litigation seems to increase with time, and specific reminders of local or regional legislation should be undertaken. In Switzerland, the federal law clearly states that one should help in case of emergency, but that no legal consequence can ensue should the rescuer fail [52].

Although this study has some strengths such as the relatively high number of participants despite the absence of mail reminders and the absence of outcome assessment bias thanks to electronic data recording, some limitations must be acknowledged. Lack of email reminders might have led to selection bias, as the proportion of highly motivated participants might be higher in this setting. Indeed, the high proportion of participants who had followed 2 or more BLS courses is potentially concerning, particularly given the low rate of bystander-initiated CPR in the literature and the obligation of following a BLS course to obtain a driving license in Switzerland. Nevertheless, this might, if anything, have dampened the effect of the time elapsed since the last BLS course, and led to underestimation rather than overestimation. Another limitation is that, given the aforementioned technical issues, the actual participation rate could not be calculated as

the number of sent and bouncing emails could not be obtained. Furthermore, we were unable to ascertain the actual number of first-aid course participants during the study period as both companies were either reluctant or unable to provide us with these figures. Had we been able to obtain these data, they would still have been questionable. Indeed, even though we specifically asked both training companies to send invitation emails only to participants who had completed a first-aid course in the last 5 years, 6 participants were excluded as they reported having followed their last BLS course more than 5 years before taking the questionnaire. Finally, the effect of the COVID-19 pandemic on the intention to perform resuscitation is not known as the survey was conducted prior to this crisis.

Conclusions

Control beliefs, one of the three dimensions of intention to perform resuscitation, decreased significantly within only 6 months after the last BLS course. Restoring this dimension to its immediate post-BLS course state should be the focus of future research to enhance CPR provision by lay rescuers in cases of OHCA. Far beyond technical issues, this can be achieved through short interventions aimed at building self-confidence and capacity to reinforce the need to act in the case of an emergency.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Original survey questions (in French) and English translation.
[PDF File (Adobe PDF File), 320 KB - formative_v4i11e24798_app1.pdf]

Multimedia Appendix 2
Univariate analysis of the three dimensions of the intention to perform resuscitation in first-aid course participants with a cutoff of 1 year since completion of the last course.
[PDF File (Adobe PDF File), 194 KB - formative_v4i11e24798_app2.pdf]

Multimedia Appendix 3
Univariate analysis of the three dimensions of the intention to perform resuscitation in first-aid course participants with the cutoff at 2 years since completion of the last course.
[PDF File (Adobe PDF File), 194 KB - formative_v4i11e24798_app3.pdf]

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Abbreviations

BLS: basic life support
CPR: cardiopulmonary resuscitation
OHCA: out-of-hospital cardiac arrest

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Original Paper

Multilingual Global E-Learning Pediatric Endocrinology and Diabetes Curriculum for Front Line Health Care Providers in Resource-Limited Countries: Development Study

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Abstract

Background: Electronic learning (e-learning) is a widely accessible, low-cost option for learning remotely in various settings that allows interaction between an instructor and a learner.

Objective: We describe the development of a free and globally accessible multilingual e-learning module that provides education material on topics in pediatric endocrinology and diabetes and that is intended for first-line physicians and health workers but also trainees or medical specialists in resource-limited countries.

Methods: As complements to concise chapters, interactive vignettes were constructed, exemplifying clinical issues and pitfalls, with specific attention to the 3 levels of medical health care in resource-limited countries. The module is part of a large e-learning portal, ESPE e-learning, which is based on ILIAS (Integriertes Lern-, Informations- und Arbeitskooperations-System), an open-source web-based learning management system. Following a review by global experts, the content was translated by native French, Spanish, Swahili, and Chinese–speaking colleagues into their respective languages using a commercial web-based translation tool (SDL Trados Studio).

Results: Preliminary data suggest that the module is well received, particularly in targeted parts of the world and that active promotion to inform target users is warranted.

Conclusions: The e-learning module is a free globally accessible multilingual up-to-date tool for use in resource-limited countries that has been utilized thus far with success. Widespread use will require dissemination of the tool on a global scale.

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KEYWORDS

pediatric endocrinology; diabetes mellitus; e-learning; online learning; continuing education; resource-limited country; multilingual medical education

Introduction

Background

Electronic learning (e-learning), defined as the application of telecommunications and electronic devices that enables students and learners to receive instruction from some distant location has evolved greatly due to improved and reliable access to high quality internet. In medical education, a broad spectrum of approaches that include the use of electronic media and adapted tools have been developed [1]. The objectives are to deliver educational material in various e-learning settings; to allow health care trainees and professionals to further develop their knowledge, skills, attitudes, and competencies; and to keep them actively engaged in learning in an ongoing manner. Today, it is impossible to imagine life without e-learning, consulting, and the sharing of information. The major advantages of e-learning are global availability, relatively low cost, options for unlimited expansion, and regular updates, as well as the ability to link to current textbooks in real time. Moreover, current technology allows the construction of portals in multiple languages as well as interactions between tutors and students at regional but also international levels. Importantly, an additional e-learning associated benefit is a lower carbon footprint [2].

Prephase

In an effort to combine education and formative assessment in learning as well as competency-based medical education, the European Society for Paediatric Endocrinology (ESPE) launched an initiative to develop an interactive e-learning portal for pediatric endocrinology [3,4]. The ESPE e-learning portal [5] provides a rich source of information for experts, fellows, residents, and students. The portal is freely and globally accessible through an automated login procedure and can be viewed on computers and mobile devices. Chapters on a wide variety of pediatric endocrine themes, including diabetes, concisely describe physiology and pathophysiology, along with practical approaches to management and treatment. The chapters are presented in bullet point format. In addition, real-life clinical cases accompany each chapter so that students can identify practical solutions for diagnosis and management of specific medical conditions in a step-wise and interactive manner.

In a survey initiated by Global Pediatric Endocrinology and Diabetes Society, colleagues in most continents and particularly in resource-limited countries indicated that there was a need for up to date teaching and instruction materials specifically intended for first-line physicians (nonspecialists) and health workers in resource-limited countries. The resource-limited countries module was suggested as a way of filling this gap given the advantages of e-learning. Sustainable e-learning implementation requires a systemic approach considering the objectives and the target group, availability of a curriculum and active involvement of teachers and administrators, sufficient information technology support and infrastructure, and political and institutional support [6], all of which were considered during the development of the resource-limited countries module.

In this report, we describe the development of a separate module within the portal that focuses on front-line health care providers, medical doctors, and specialists in resource-limited countries. This free e-learning module provides up-to-date globally accessible multilingual curriculum in pediatric endocrinology and diabetes.

Methods

Development of ESPE E-Learning Resource-Limited Countries Module

Target Groups

In resource-limited countries, three levels of care in pediatric endocrinology and diabetes are recognized (Table 1). In primary health care centers, the focus is to recognize and appropriately triage serious and life-threatening endocrine conditions such as diabetic ketoacidosis and adrenal insufficiency, and also, to monitor treatment of patients referred from secondary or tertiary health care centers, such as regional or central hospitals. Staff in secondary health care centers, usually regional hospitals, are expected to diagnose and investigate the most common endocrine disorders, and to treat those patients who are referred from the tertiary health care centers for ongoing care. Examples of conditions managed at secondary health care centers include congenital hypothyroidism, variations of puberty timing (early, late), and vitamin D deficiency, among others. Although diabetes should be ideally managed in tertiary health care centers to prevent complications, in reality, care will often be provided by a combination of secondary and tertiary health care centers. Examples of conditions managed at tertiary health care centers, which usually involve medical doctors or specialists working in a central hospital, include more complex endocrine disorders such as endocrine abnormalities associated with chromosomal disorders, disorders of sex development, precocious or delayed puberty, hypo- and hyperthyroidism, adrenal gland abnormalities, and chronic endocrine disorders with complications including diabetic ketoacidosis. It should be noted that tertiary health care centers, as well as equipment, medications, and other laboratory and diagnostic facilities that are described here may not be available in all resource-limited countries.

Table 1. Levels of care of health care centers in resource-limited countries.

Level of care	Staffed by	Laboratory and imaging facilities
Primary (basic or rural)	Clinical officer or assistant medical officer (paramedic)	Very limited
Secondary (district and regional hospitals)	Medical officer or pediatrician and/or pediatrician with interest in endocrine disorders including diabetes	Limited
Tertiary (zonal referral hospitals and the main/national referral hospital)	Pediatrician or pediatric endocrinologist/diabetes team	Most available but not all

In contrast to the content and cases in the main e-learning section of the portal that are targeted to students, trainees, and health care professionals in countries with access to tertiary care, content and cases for resource-limited countries were designed to assist health care professionals at all three health care levels, in a way that is practical. Therefore, for example, a primary care provider in a resource-limited country is guided by the case on the type of care that can be provided in a primary health care center in resource-limited countries and care that can only be provided in a secondary or tertiary health care center. This approach is unique to the e-learning module for resource-limited countries and is intended to assist in real-time decision making by health care professionals in resource-limited countries.

Technical Design

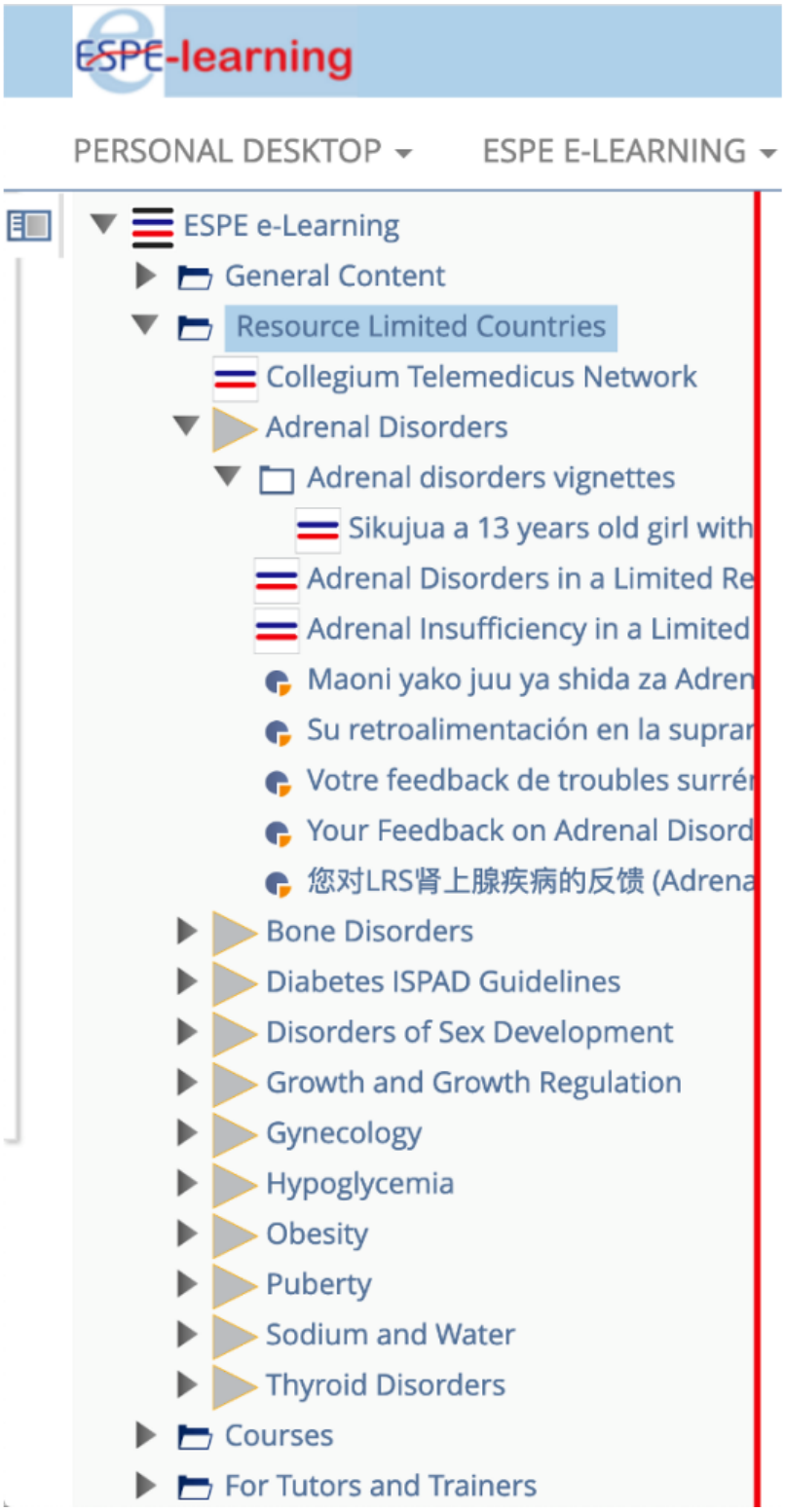
The resource-limited countries–learning module has been developed as an additional section within the ESPE website. It is based on ILIAS (*Integriertes Lern-, Informations- und Arbeitskooperations-System*), an open-source web-based learning management system [3,7].

Content Creation

For the endocrinology chapters, the content of a recent textbook [8] was taken as a starting point. The diabetes chapters are based on the content of the Changing Diabetes in Children Manual [9]. Considerations regarding social and cultural aspects as well as access to care in resource-limited countries were incorporated in the content.

Authors and colleagues from all over the world (n=63) agreed to contribute content consisting of brief chapters and complementary short cases (vignettes) with multiple choice questions and feedback that explain the rationale behind recommended and not recommended steps. In applying this approach, the three levels of care in resource-limited countries were strictly adhered to. After a review process by members of an international editorial board, with representation from all 10 participating pediatric endocrine societies, a total of 16 chapters and 23 vignettes amounting to >850 PowerPoint (Microsoft Inc) pages were published online over a 3-year period (Figure 1).

Figure 1. Screenshot of content of the resource-limited countries module in the e-learning portal.



Multilingualism (Translation)

Initially, all content was created in English after which a translation process into French, Spanish, Swahili, and Chinese was facilitated by a commercial web-based translation tool (SDL Trados Studio). A translation memory and a terminology database in French, Spanish, Swahili, and Chinese was created, with the contribution of 31 native speaking junior or senior colleagues from various continents who had agreed to assist in the translation process.

While e-learning is one of the better known cases of coordinated web-based translation, the project team implemented a solution that required, and achieved, a remarkable level of global cooperation.

The approach was based on establishing a central project management team, which was in control of the entire workflow.

To maximize the efficiency of the translation phase, the team combined state-of-the-art machine translation with expert human translation. Medical professionals from multiple continents were involved in finalizing the content in all target languages. The automated reuse of all suitable translated content was built into the workflow from the start. This approach also helped maintain high levels of consistency—always a critical factor in medical translation. To maximize the correct and consistent use of terminology, the team built and maintained a professional terminology database throughout the project life cycle.

Technologically, the project was based on a multilayered information technology infrastructure. Project management used a combination of desktop software and online components. Reviewers from all corners of the world worked online, fully remotely. Machine translation was channeled in from a cloud-based pool of translation engines. Once the translation was completed, the selected technology automatically applied the original layout of the newly created e-learning material. Subsequently, the translated text and the original English version, both in the same version of PowerPoint, were sent to the translator for final review.

Applicability

The resource-limited countries module of ESPE portal can be viewed on a computer, laptop, or any mobile device and is particularly designed for primary, secondary, and tertiary health care workers including nurses (pediatric endocrine nurses or nurse practitioners) in resource-limited countries to be used for self-study or classroom case discussion monitored by a tutor or instructor. The multiple tasks of the tutor, instructor, or e-moderator should not be underestimated (see Textbox 1). In addition, the module is useful for tertiary health care workers in regional or academic training centers as tutors of medical students or other health care workers and offers the option to be used with a virtual classroom where participants, including the instructor or tutor can join remotely. Finally, there may be an important role complementary to remote consultation.

The module is designed to address the needs of participants, and the information is intended to add to their existing knowledge. Since clinical cases are important learning experiences, relevant real cases that require problem-solving on behalf of the participant have been identified and discussed. Personal experiences and previous conclusions are the building blocks for learning on the job. Feedback is given on any multiple-choice question; the case-specific feedback will facilitate instructive hands-on learning without patient risk. Additionally, the e-learning portal is learner-oriented: the learner can make choices regarding cases, level, theory, and way of learning and support. There is easy access and navigation using mobile devices. Additionally, learners may contact expert-authors.

Textbox 1. Tasks for small private online courses tutor, instructor, or e-moderator [10,11].

- Ensuring a safe learning environment
- Helping participants to familiarize themselves with the digital environment and its possibilities
- Naming (compulsory and voluntary) activities
- Suggesting eligible criteria for the course certificate
- Answering or referring questions from participants
- Identifying and highlighting relevant comments from participants who tend to get underexposed
- Summarizing the contributions of participants
- Reflecting on what has been learned
- Clarifying the thread
- Archiving information
- Posting messages to motivate or clarify the learning process
- Encouraging active contributions from participants
- Transfer of learning needs and answers to questions from participants (sources, experts)
- Optimizing the course design based on experience of and with participants

Results

The number of visits to the resource-limited countries module during the construction phase between May 2018 and November 2019 is shown in Table 2. Case discussions using the resource-limited countries module have been held in Kenya (English, Pediatric Endocrine Training Centers for Africa), in the Dominican Republic (Spanish), in Guyana (French), in Tanzania (Swahili), and in China (Chinese).

Table 2. Number of visits to the online resource-limited countries module between May 2018 and November 2019 per region.

Region	Users, n (%)
Western Europe	46 (12)
Eastern Europe/Caucasus	68 (17)
USA/Canada	24 (6)
Central/South America	25 (7)
Asia/Australia	120 (31)
Africa	106 (27)

Discussion

General

In this report, we described the development of a free and globally accessible e-learning module containing educational material related to pediatric endocrinology and diabetes specifically intended for first-line physicians and health workers in resource-limited countries. This module offers the opportunity for feedback on every multiple choice question that is case-specific to facilitate instructive hands-on learning without patient risk. Additionally, the content and cases are available in 5 different languages, for use around the world.

In many resource-limited countries, disease burden far outweighs health care resources, and health systems are poorly adapted to the emerging burden of chronic non-communicable diseases, including endocrine disorders and diabetes. Major shortages in the health care professional workforce prevail, in particular, in subspecialties such as pediatric endocrinology [12,13].

While interaction between students and experts in the field still remains essential for an optimal learning experience through exchange, review, and reflection on one another's ideas, contact time with experts is relatively expensive and should be used as efficiently as possible, especially in low-resource settings where teachers are limited [14]. In fact, the World Health Organization and the United Nations consider the use of highly innovative, flexible, interactive, adaptive technologies in learning as one of the possible solutions to the shortage of well-trained health care teachers and workers [15]. Carefully considering which activities can take place online, and using an inverted or flipped classroom model, can lead to better utilization of contact time, reduced costs, and improved quality of the course [16].

Recent prospective controlled randomized studies [17] evaluating the effects of e-learning versus traditional learning suggest that both online and offline e-learning are equivalent, and possibly even superior, to exclusively utilizing traditional learning; however, these studies have largely focused on preclinical medical students in Western societies.

The resource-limited countries module offers actual problem-solving cases complementary to the various chapters, recognizing the value of illustrating teaching points. The goal of *case-based learning* is to prepare students for clinical practice through the use of authentic clinical cases. It links theory to practice through the application of knowledge to the cases, using inquiry-based learning methods [18]. The advantages of the case-based learning method are promotion of self-directed learning, clinical reasoning, clinical problem solving, and decision making by providing repeated experiences in class and by enabling students to focus on the complexity of clinical care [18]. As mentioned above, learning is more effective if the information is linked to a specific experience, with a relative context and different environments to which this knowledge can be applied. The use of real cases in the resource-limited countries module emphasizes to the learner the limitations that patients and health care workers could face in a resource-limited countries and how to address these limitations. For example, in many resource-limited countries, there is limited access to medication, equipment, and diagnostic facilities, requiring diagnostic tests or therapies to be performed in private hospitals or outside the country. Moreover, case-based learning promotes deeper learning, aiming toward understanding, critical thinking, and integrating what a student is learning with what the student already knows. It favors an approach with the intention to understand and to construct meaning and make assumptions, relating new ideas to previous knowledge and relating concepts to everyday experience [10].

The resource-limited countries module is well suited for classroom teaching [19,20] or small private online courses where continuous interaction and discussion between the teacher and the students are present. In fact, health professional educators may require more information and communication technology training and support to facilitate better information and communication technology integration in health professional education settings [6,10,11].

In designing an e-learning module for resource-limited countries with simulation of clinical scenarios it is important to realize that there are many relevant issues with respect to the local setting, for example, common diagnostic tests may not be available, and conditions may be diagnosed or treated according to regional rather than international standards [21]. But, specifically, cultural aspects should also be considered. The importance of culture, defined as the shared ideas, meanings, and values that are acquired by individuals as members of a society, lies in the influence it has on how individuals relate to the health information they are presented with, and in the fundamental relationship they have with the concepts of health and illness [22]. Tutors must take into consideration the cultural and demographic background of their learners to fully enhance content delivery and maximize subsequent knowledge potential. In addition, issues to be considered include understanding and

respecting cultural differences while maintaining legal or ethical standards and safe translation between languages.

In order to reach out to health care workers in remote areas and to promote accessibility in large parts of the world in the development of the resource-limited countries module, great effort has been put into making the complete content available in 5 languages: English, French, Spanish, Swahili, and Chinese.

Given the often complex layout of the original e-learning material, the decision was made early on to separate layout from content and use this unformatted content as the basis for the translation efforts. This technique made it possible to involve medical professionals from multiple continents, who were able to review the translation and provide their insight using a simple browser application and an internet connection, without problems arising from poor connectivity in their part of the world or a lack of professional design skills. Having now been proven in the field, this approach could be recommended as a potential template for similar future applications involving contributors in resource-limited countries.

Conclusions and Future Directions

Very preliminary data suggest that the module is well received, particularly in targeted parts of the world, but active promotion to inform target users such as health care workers in primary and secondary health care centers as well as training in information and communications technology of teachers or tutors in tertiary training centers is in order [23]. The next step is to assess the learned knowledge demonstrating improving clinical performance, practice behavior, and ultimately, patient outcomes.

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Authors' Contributions

All authors contributed to conception, design, and execution of the study. Material preparation, data collection, and data analysis were performed by SLSD, CvW-dV, and ES. The first draft of the manuscript was written by SLSD and EK. All authors commented on previous versions of the manuscript, as well as read and approved the final manuscript.

Conflicts of Interest

ES is employed by SDL Trados Studio. All other authors declare no potential conflict of interest with respect to the creation of content, authorship, and or publication of this article.

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Abbreviations

e-learning: electronic learning
ESPE: European Society for Paediatric Endocrinology
ILIAS: Integriertes Lern-, Informations- und Arbeitskooperations-System

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Original Paper

Arabic Translation of the Weight Self-Stigma Questionnaire: Instrument Validation Study of Factor Structure and Reliability

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Abstract

Background: While it is most often associated with its effects on physical health, obesity is also associated with serious self-stigmatization. The lack of a suitable, validated tool to measure weight-related self-stigma in Arabic countries may be partly responsible for the scarcity of literature about this problem.

Objective: This study investigated the reliability and validity of an Arabic version of the Weight Self-Stigma Questionnaire (WSSQ).

Methods: Data on the Arabic-translated version of the 12-item WSSQ were collected using two cross-sectional electronic questionnaires distributed among Saudi nationals through the Sharik Association for Health Research's database in June 2020. Internal consistency, test-retest reliability, and exploratory factor analysis of the Arabic WSSQ were assessed and compared with the original English version and other translations.

Results: For reliability analysis, 43 participants completed the Arabic WSSQ during two time periods. Internal consistency was α=.898 for the overall survey, α=.819 for the fear of enacted stigma subscale (factor 1), and α=.847 for the self-devaluation subscale (factor 2). The test-retest reliability of the intraclass correlation coefficient was α=.982. In the factor structure analysis, 295 participants completed the questionnaire. The Arabic WSSQ loading of the items was consistent with the original WSSQ, except for the loading of item 9, which was stronger in factor 2 than in factor 1. The two factors accounted for the observed variances of 47.7% and 10.6%.

Conclusions: The Arabic version of the WSSQ has good internal consistency and reliability, and the factorial structure is similar to that of the original WSSQ. The Arabic WSSQ is adaptable for clinicians seeking to assess weight-related self-stigma in Arabic-speaking people.

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KEYWORDS

overweight; stigma; weight self-stigma; Weight Self-Stigma Questionnaire; obesity; Saudi Arabia; questionnaire; validation; reliability; validity

Introduction

Obesity is a global health problem with serious complications, including cardiovascular disease, diabetes, and hypertension. It is significantly correlated with cancer, stroke, asthma, and reduced fertility [1]. From 1992 to 2005, the prevalence of obesity in Saudi men aged 25 to 34 years increased from 10.1% to 27.1%, while the prevalence in Saudi women within the same

age range increased from 16.1% to 39.5% [2]. Approximately 25% of the Saudi Arabian population suffers from obesity, and around 35% of the total Saudi population is clinically overweight. Along with its impact on physical health, obesity is also associated with psychosocial complications, including stigmatization in health care, employment, education, and other settings.

Stigma enables various forms of discrimination that ultimately deny the individual or group full social acceptance, reduce the individual's opportunities [3], and fuel social inequalities [4], and it influences population health outcomes by worsening, undermining, or impeding a number of processes, including social relationships, stress, and psychological and behavioral responses [5,6]. Stigma and its effects are classified into two main types: public stigma and self-stigma. Public stigma has been described in terms of stereotypes, prejudice, and discrimination; self-stigma is the awareness of and agreement with public stigma stereotypes and attitudes and the application of those stereotypes to oneself, which undermine self-esteem and self-efficacy [7]. Thus, the availability of recent, high-quality data on health-related stigma or self-stigma is critical for improving interventions and programs to address them, yet such routine data are often lacking, sometimes due to a lack of validated tools for assessment [8].

To date, Arabic-speaking countries have no validated measure of weight self-stigma, constraining researchers' attempts to determine the prevalence of weight self-stigma and its contribution to adverse health and psychological effects. A reliable, validated Arabic tool would allow researchers to measure the impact of weight-stigma interventions on other health outcomes [9]. Although the Weight Self-Stigma Questionnaire (WSSQ) has wide global application, the translated version must be validated to make sure that it measures what it is intended to and produces results comparable to those of the original version. Translated versions of questionnaires are needed for researchers who intend to collect data among respondents who speak other languages, mainly to compare responses across populations of different languages and/or cultures [10]. In addition, researchers need to make sure that the translated questionnaires are assessing the equivalent construct with an equivalent metric [10].

Widespread clinical uptake of such a questionnaire can inform psychotherapeutic treatment options for overweight and obese patients experiencing psychological stressors from weight self-stigma, which impacts overall patient well-being. Obese patients who receive appropriate psychological treatment tend to lose weight and exhibit a reduction in obesity-related comorbidities [11]. Clinically, the WSSQ is used to diagnose and treat psychological issues associated with self-devaluation and fear of enacted stigma in obese and overweight patients, and such treatment can result in a range of positive outcomes, including decreased emotional overeating and increased health-promoting behaviors [12].

The WSSQ is a self-reported measure of weight-related self-stigma in overweight and obese persons. It has been translated and validated in German, French, Chinese, and Turkish, among other languages [13-16]. To date, a validated Arabic psychometric scale to evaluate weight-related self-stigma has not been adopted by clinicians. This paper reports the development and validation of an Arabic-translated version of the WSSQ. We also compared the internal consistency and test-retest reliability of the Arabic WSSQ with the original English WSSQ and other translations.

Methods

Analyses of test-retest reliability and exploratory factors were performed for the Arabic-translated version of the WSSQ using data collected via two cross-sectional electronic questionnaires distributed to Saudi nationals through the Sharik Association for Health Research's database in June 2020.

WSSQ

The WSSQ is a 12-item Likert-type measure of weight-related self-stigmatization (Table 1). It has two subscales that individually measure (1) weight-related self-devaluation and (2) fear of enacted stigma. The original version of the questionnaire had good psychometrics and a valid preliminary construct. Cronbach α coefficients were acceptable for the full scale (α=.878) and the two subscales (α=.869 and α=.812) [9]. Analyses of principal components revealed a two-factor structure [9]. WSSQ items are rated on a scale of 1 (completely disagree) to 5 (completely agree). Sum scores are calculated for the full scale and each subscale. Items 1 to 6 constitute the self-devaluation subscale (factor 2), and items 7 to 12 constitute the fear of enacted stigma subscale (factor 1). There are no reverse-scored items.

Table 1. Weight Self-Stigma Questionnaire items.

Item number	Item
1	I'll always go back to being overweight.
2	I caused my weight problems.
3	I feel guilty because of my weight problems.
4	I became overweight because I'm a weak person.
5	I would never have any problems with weight if I were stronger.
6	I don't have enough self-control to maintain a healthy weight.
7	I feel insecure about others' opinions of me.
8	People discriminate against me because I've had weight problems.
9	It's difficult for people who haven't had weight problems to relate to me.
10	Others will think I lack self-control because of my weight problems.
11	People think that I am to blame for my weight problems.
12	Others are ashamed to be around me because of my weight.

Arabic Translation of the WSSQ

Standard backward and forward translation was performed. One nutritionist and 2 research professionals independently conducted the forward translation, and 2 professional translators independently conducted the backward translation. A focus group composed of 8 participants was asked to answer and discuss the questionnaire, and their comments and understanding of each item's meaning were discussed in the first focus group. Another round of focus group discussions was conducted with a total of 2 focus groups, each with 8 participants. Based on these discussions, the language of the questionnaire items was edited and clarified further, and the final version produced received universal approval among the group members. The final translated items can be found in Multimedia Appendix 1.

Study Stages

Test-Retest Reliability

In June 2020, a group of randomly selected Arabic-speaking adults from the general Saudi population was invited to complete the questionnaire on an electronic form via the Sharik Association for Health Research's database. The population of this database project is composed of persons who are interested in participating in research projects. An increasing number of participants are registered, now more than 63,000 distributed across the 13 regions of Saudi Arabia [17]. Eligibility was determined automatically via the data collection system. The eligibility criteria were being age 18 years or older and using Arabic as the primary language. Individuals from the participant database who met the eligibility criteria were notified via SMS text message to complete the survey via unique survey links. Three reminders were sent to each potential participant within 1 week. If the participant did not respond, another participant with similar demographics was invited until the required sample size had been reached. The same participants completed the questionnaire again after 1 week. Participants were asked to complete all answers before submitting the questionnaire.

Exploratory Factor Analysis

In this stage, a group of randomly selected Arabic-speaking Saudi adults was invited to complete the questionnaire on an electronic form from the Sharik Association for Health Research's database [17]. Participants completed all answers before submitting the questionnaire. This phase used similar eligibility criteria and a similar recruitment process as was used in the test-retest stage.

Sample Size

Based on published literature, the recommended sample size for test-retest reliability is 20 to 40 participants [18,19]. The original study that established test-retest reliability of the WSSQ used 44 participants [9]. The recommended sample size for exploratory factor analysis is between 100 and 250 participants, while some studies recommend more than 300 participants to ensure rigorous psychometric validation [20]. The suggested sample size includes a minimum of 2 and a maximum of 20 participants per item. For this study, the recommended minimum sample size was 240 participants based on 20 participants per each of the 12 items on the WSSQ. Thus, the targeted sample size range was 240 to 300 participants.

Statistical Analysis

Similar to the original WSSQ validation process, internal consistency was assessed using the Cronbach α coefficient, and the test-retest reliability was assessed with the intraclass correlation coefficient. To assess the suitability for conducting an exploratory factor analysis, analyses of the correlation between the scale items were conducted using the Kaiser-Meyer-Olkin sample adequacy measure (nonsignificant results mean the data are suitable for factor analysis) and Bartlett test (significant results mean the data are suitable for factor analysis) [21-24]. To examine the factorial structure of the scales, an exploratory factor analysis using principal factor extraction was performed. The oblique rotation method was used to obtain clear factorial structures and enable comparison with the original study results; an item loading cutoff of greater than 0.15 was adopted, as in the original study, and factors with

eigenvalues greater than 1.0 were retained [9]. There were no missing data, as all questions needed to be completed before submitting the questionnaire electronically. All statistical tests were performed using the IBM SPSS statistical package (version 20).

Ethical Considerations

The ethics committee of the Sharik Association for Health Research, Riyadh, Saudi Arabia, approved this research project according to national research ethics regulations. Participants gave consent electronically, which was recorded by the data collection system.

Results

Participants' Characteristics

Of the 43 participants in study stage 1 (for test-retest reliability), 48.8% (21/43) were male and the mean age was 34.4 years (range 18-66). Of the 295 participants in study stage 2 (for exploratory factor analysis), 48.5% (143/295) were male and the mean age was 33.6 years (range 18-70).

Reliability

Internal consistency measures for both the subscales and the overall scale were good. The internal consistency of the full Arabic WSSQ was α =.898, and for the subscales—factor 1 and factor 2—internal consistency was α=.819 and α=.847, respectively. These values are similar to those observed in the original English version (α=.878 overall, and α=.869 and α=.812 for the enacted stigma and self-devaluation subscales, respectively) [9]. In the analysis of test-retest reliability, the intraclass correlation coefficient was α=.982.

Factor Structure

Correlation coefficients among the 12 items were all 0.3 or higher, except those for item 12, which were below 0.3 for some other items. The Kaiser-Meyer-Oklin value was 0.891, and values for Bartlett's test of sphericity reached statistical significance (P<0.001).

An analysis of principal components revealed two components that explained 47.7% and 10.6% of the variance. The scree plot (Figure 1) revealed a break after the second component. Oblique rotation (Table 2) was performed to compare the results with the original scale, and identical variance explanations of 47.7% and 10.6% were found.

Test-retest reliability/stability with the intracorrelation coefficient was high. Exploratory factor analysis revealed that loading of the items for the Arabic WSSQ was consistent with that of the original English WSSQ, except for the loading of item 9 (Table 2), which loaded positively in both factors but more strongly in factor 2 than in factor 1 [9].

Figure 1. Scree plot for principal component analysis: Comparison of the 12 components of the Arabic WSSQ to evaluate statistical significance of components using a scree test to determine eigenvalues.

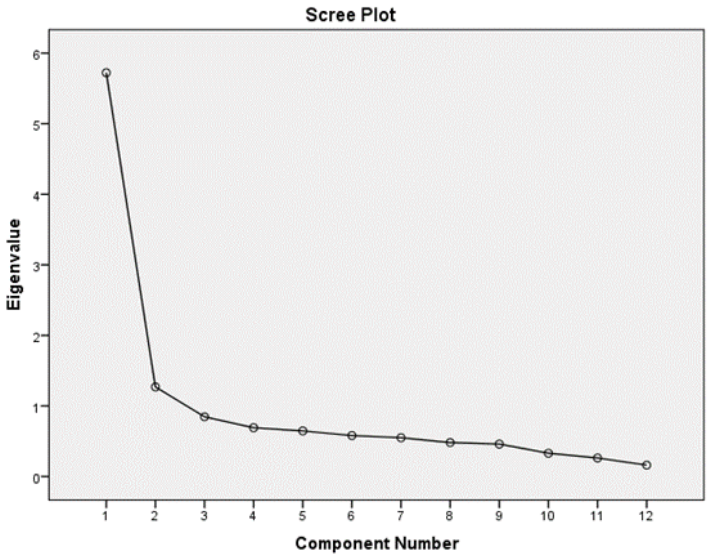

Table 2. Weight Self-Stigma Questionnaire items: item-scale correlations and factor loadings from principal components analysis with oblique rotation.

	Arabic version			English (original) version		
Item	Item-scale correlation	Factor 1	Factor 2	Item-scale correlation	Factor 1	Factor 2
1	0.65	0.26	0.69	0.55	Not reported	0.55
2	0.73	0.54	0.73	0.47	Not reported	0.66
3	0.75	0.54	0.72	0.71	Not reported	0.69
4	0.81	0.50	0.82	0.71	Not reported	0.81
5	0.53	0.16	0.65	0.63	Not reported	0.69
6	0.68	0.33	0.77	0.68	Not reported	0.79
7	0.71	0.68	0.52	0.68	0.67	Not reported
8	0.66	0.79	0.36	0.66	0.86	Not reported
9	0.62	0.32	0.69	0.67	0.72	Not reported
10	0.62	0.77	0.61	0.78	0.79	Not reported
11	0.77	0.79	0.61	0.66	0.72	Not reported
12	0.40	0.70	0.15	0.67	0.82	Not reported

Discussion

Principal Findings

This study involved translating the WSSQ into Arabic and testing the reliability and validity of the Arabic-translated version. The Arabic WSSQ demonstrated good psychometric properties, which were congruent with the original English version of the WSSQ. The internal consistency of the Arabic WSSQ and its subscales (ie, fear of enacted stigma and self-devaluation) was good: α=.898, α=.819, and α=.847, respectively. These values were consistent with the original English version of the WSSQ and its subscales: α=.878, α=.869, and α=.812, respectively [9]. Test-retest reliability of the Arabic WSSQ was high at 0.982. Exploratory factor analysis showed that the loading of the majority of the questionnaire items (except item 9) was consistent with the original English version of the WSSQ.

We searched PubMed for any published research articles from Saudi Arabia about weight stigma in general and found no related articles. The lack of research conducted on weight-related stigma in Saudi Arabia may be the result of a lack of validated tools for assessing this topic. The validation of such a tool, as presented in this study, provides an initial means to fill that gap. More tools to measure weight-related stigma for different age groups and dimensions (eg, public weight stigma) are needed to expand this research field and generate more understanding about the impact of weight self-stigma on quality of life and psychological stress. Increased use of the Arabic WSSQ has the potential to close the gap between the well-known high prevalence of obesity and the scarcity of knowledge on the frequency and severity of weight self-stigma among Saudi adults. To enable the expansion of WSSQ utilization to Arabic-speaking countries, we have provided the first Arabic translation of the WSSQ.

Study Limitations and Strengths

This study was not without notable limitations and strengths. The utility of the Arabic-WSSQ is not generalizable to children, as the study included only adults. A larger sample size is needed to assess the cross-cultural validity of this scale using confirmatory factorial analysis. Also, convergent validity was not assessed, and future studies are needed to assess correlations between the Arabic WSSQ and other scales that measure weight self-stigma.

However, the study had a high response rate among participants. The study's sample size was in line with published sample size recommendations for psychometric validation and was consistent with the sample size of the initial study that established the psychometric properties of the original English version of the WSSQ [9]. To our knowledge, this is the first Arabic translation of the WSSQ and the first demonstration of its psychometric properties among Arabic-speaking Saudi adults. The Arabic WSSQ not only allows researchers and clinicians to assess weight self-stigma among Arabic-speaking adults, but it provides researchers and clinicians with an empirical measure to assess the effectiveness of interventions to reduce weight self-stigma.

Conclusion

The Arabic WSSQ has good internal consistency and reliability. The factorial structure is similar to the original English WSSQ, which endorses its value for use in cross-cultural studies. The Arabic WSSQ appears to be a reliable measure for assessing weight-related self-stigma in Arabic-speaking people.

Authors' Contributions

All authors participated in the development and design of this study and in writing and reviewing the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Arabic translation and validation of the Weight Self-Stigma Questionnaire.
[DOCX File , 16 KB - formative_v4i11e24169_app1.docx]

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Abbreviations

WSSQ: Weight Self-Stigma Questionnaire

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Original Paper

Consumers' Intentions to Adopt Blockchain-Based Personal Health Records and Data Sharing: Focus Group Study

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Abstract

Background: Although researchers are giving increased attention to blockchain-based personal health records (PHRs) and data sharing, the majority of research focuses on technical design. Very little is known about health care consumers' intentions to adopt the applications.

Objective: This study aims to explore the intentions and concerns of health care consumers regarding the adoption of blockchain-based personal health records and data sharing.

Methods: Three focus groups were conducted, in which 26 participants were shown a prototype of a user interface for a self-sovereign blockchain-based PHR system (ie, a system in which the individual owns, has custody of, and controls access to their personal health information) to be used for privacy and secure health data sharing. A microinterlocutor analysis of focus group transcriptions was performed to show a descriptive overview of participant responses. NVivo 12.0 was used to code the categories of the responses.

Results: Participants did not exhibit a substantial increase in their willingness to become owners of health data and share the data with third parties after the blockchain solution was introduced. Participants were concerned about the risks of losing private keys, the resulting difficulty in accessing care, and the irrevocability of data access on blockchain. They did, however, favor a blockchain-based PHR that incorporates a private key recovery system and offers a health wallet hosted by government or other positively perceived organizations. They were more inclined to share data via blockchain if the third party used the data for collective good and offered participants nonmonetary forms of compensation and if the access could be revoked from the third party.

Conclusions: Health care consumers were not strongly inclined to adopt blockchain-based PHRs and health data sharing. However, their intentions may increase when the concerns and recommendations demonstrated in this study are considered in application design.

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KEYWORDS

blockchain; personal health record; health data sharing; consumers' intentions to adopt; focus group study; microinterlocutor analysis

Introduction

Recently, researchers have suggested that blockchain technology may precipitate a paradigm shift in personal health records (PHRs) [1-4]. A PHR is "an electronic application through which individuals can access, manage, and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment" [5], and blockchain refers to "a distributed ledger—write once and never erase" [2]. Current PHR systems commonly use the traditional centralized in-memory or cloud-based database technologies and are designed in such a way that health care providers and

organizations continue to be the key controllers of health records despite the intention to engage consumers in managing health care information [6-8]. In other words, it is physicians and health administrators rather than consumers or patients that determine the usage and distribution of health data. Such systems expose consumers to the "single point of failure" of traditional database technologies, in which the information of numerous patients could be lost or altered if the central database is attacked. These systems are also limited in their capability of transferring the ownership of health data to individuals, since the design and maintenance of such systems heavily rely on the resources of organizations, and individuals are not provided with any incentives to be active owners of their data [6,7,9]. As a result, the systems become the barriers to the long called-for patient-centered care [10-12]. By contrast, blockchain is a decentralized ledger where data storage, validation, and synchronization can only be completed when all the contributing system participants (ie, nodes) contribute their computational capacity. As such, a blockchain-based PHR system has the potential to enable health care consumers to take control of their health information, paving the way to materializing patient-centered care [1-4,13]. In addition, as blockchain combines cryptography, peer-to-peer networking, and the Merkle tree structure, blockchain-based PHRs can significantly decrease the risk of data breach, falsification, and tampering, protecting data security and privacy to the level that existing PHR systems are unable to reach [1,2,14]. In addition, blockchain has the technical capability of automatically synchronizing data with all the participating nodes on the network; hence, blockchain-based PHRs can surpass the existing PHR systems in addressing the problem of data siloing and fragmentation [2,15].

Equipping PHRs with blockchain also provides individuals the opportunity to share health data at their discretion with interested third parties, while privacy and security risks are minimized [16,17]. Following prior studies [18,19], this paper uses the terms "individual," "patient," and "consumer" interchangeably, since "PHR system consumers are not necessarily dealing with immediate medical concerns and can be ill or healthy" [18]. We refer to third parties as any stakeholders that are outside the patient-physician dyadic relationship while holding interest in individuals' health information, such as medical researchers, pharmaceutical companies, insurance companies, and employers. These third parties, as important components of the health care ecosystem, have long been using patient data in key organizational activities but have been reported to be collecting and exploiting the data without patient consent or sharing the data in a way that jeopardizes patient privacy [20-23]. Although studies have shown that individuals are generally not opposed to data sharing with these third parties [20,21], the concerns about privacy and security are growing, and individuals demand greater transparency as to who can access their data after they are shared and for what purpose the data are used [22,23]. Since blockchain can combine cryptography with smart contracts, smart contracts being small bits of code that embed procedural logic that is automatically executable, blockchain-based PHRs can ensure that it is consumers who initiate data sharing. This capability allows consumers to determine which data to share with which third party and under what conditions [2,16], preserving their privacy and their right to be informed to an unparallel degree. In addition, smart contracts can be combined with data tokenization, the transformation through cryptography of data into discrete objects that can be transferred over a blockchain network. Besides combining smart contracts with data tokenization, a blockchain-based PHR system can offer consumers the possibility of being rewarded for sharing health data; as such, they can be more incentivized to actively share data with third parties, such as researchers and insurance companies, which can greatly benefit medical research, drug discovery, and care management [24,25]. Specifically, with blockchain, individuals hold a health wallet, in which particular types of health data are stored, and they are the only ones that know the private key needed to access the wallet. When needed, they can share the data with third parties under the conditions specified by the smart contract, such as sharing particular pieces of the data (eg, a biomarker measure) and fees for usage. The data can be tokenized and the third parties may pay for the data use with cryptocurrency or other value tokens.

Recognizing the advantages of blockchain-based PHRs and health data sharing, researchers have begun to give focused attention to blockchain architecture and platform selection [1,4,17]. Moreover, distributed health networks and key health care organizations, such as the University Health Network and Mayo Clinic, have launched pilot applications [26,27]. However, both academics and practitioners have mainly focused on the technical components of blockchain-based PHRs and health data sharing and have conducted these studies from the vantage point of care providers. Very little is known about individuals' intentions to adopt the blockchain-based system, specifically whether they perceive themselves as motivated to and capable of taking greater control of their health information by using blockchain-based PHRs, whether they are willing to share data when blockchain is incorporated into the system, what concerns they may have about blockchain-based PHRs and health data sharing, and how these concerns can be addressed to enhance their intention. Understanding these questions can not only contribute to the understanding of consumers' receptiveness to blockchain-based health systems broadly but also inform researchers and practitioners about the issues that they are likely to encounter when designing a blockchain-based PHR system, allowing them to improve the user centeredness of the design [28]. For these reasons, we conducted a focus group study to uncover consumers' intentions to adopt blockchain-based PHRs and health data sharing.

Methods

Overview

We conducted 3 focus groups to understand consumers' intentions to adopt blockchain-based PHRs and health data sharing, observing a semistructured list of questions (Multimedia Appendix 1). Focus groups are suitable for exploring the attitudes toward new phenomena such as blockchain, since the relatively open-ended discussions can sensitize researchers to unrealized issues and hence increase the comprehensiveness of quantitative studies conducted afterward [29].

We recruited the participants for the focus group after the researchers' university approved the research ethics proposal. We posted recruitment advertisements around the campus, a call for participants on the graduate student community online forum, and posts on social media platforms and online interest groups to recruit participants with diverse backgrounds. Since we aimed to maximize the diversity of participants, anyone with an interest in participating could participate regardless of their prior knowledge about blockchain. All participants signed a consent form approved by the research ethics office before the focus group discussions began.

A PhD student trained in archival science and human-centered design led the focus group discussions with the assistance of a master's student of archival science. They began the focus groups by asking participants if they had negative experiences with the way health information is currently managed (questions 1.1 and 1.2 in Multimedia Appendix 1) and then explained to the participants the concept of blockchain and blockchain-based PHRs and solicitated participants' intentions to adopt blockchain-based PHRs and their potential concerns (questions 2.1 to 2.6 in Multimedia Appendix 1). Notably, when explaining blockchain and blockchain-based PHRs, the researchers presented the participants a prototype of a user interface for a blockchain-based PHR, giving the participants a more concrete sense of blockchain and blockchain-based PHRs. Next, they asked the participants about their willingness to share health data with third parties and their concerns and attitudes toward health data sharing via blockchain, giving focused attention to topics frequently discussed in blockchain-based health data sharing, such as privacy, compensation, and wallet services (questions 3.1 to 5.1 in Multimedia Appendix 1).

Sample Characteristics

In total, 26 individuals (13 men and 13 women) participated in our study: 8 in the first focus group, 8 in the second group, and 10 in the third group. A total of 22 participants were aged 25 to 35 years, 1 was aged 35 to 45 years, and 2 were aged 45 to 65 years. Among the participants, 3 participants had recently finished their advanced degrees (master's or PhD) and the rest were enrolled in a master's or PhD program. Five participants had an education background in information management or archival science, and 8 participants were enrolled in graduate programs in the medical field. All the participants had been patients at some point in their lives.

Data Analysis

We performed the microinterlocutor analysis suggested by Onwuegbuzie et al [30]. The microinterlocutor analysis has been increasingly used to analyze focus group data in health-related research [31-33]. It not only reveals each participant's attitude, stance, and arguments but also provides researchers with a quantitative overview of participant grouping [30]. Following Onwuegbuzie et al [30], we first read all the transcriptions of the focus group discussions, gaining an overall understanding of the transcriptions. Next, we coded participants' responses to each discussion question separately for each focus group. As some participants diverged from the discussion, we paid attention to their words throughout the group discussion and coded their responses by interpreting all the words they contributed. By taking this step, we produced descriptive statistics for all the questions, as summarized in Multimedia Appendix 2. Multimedia Appendix 2 not only depicts how each participant responded to each question but also provides an overview of the responses of the group as a whole, based on which we generated the insights explained in the "Discussion" section. Finally, we imported the responses to each question into NVivo 12.0 (QSR International) and coded the thematic categories of explanations that participants provided for their responses, which helped us understand more deeply why the participants responded in certain ways. We used the thematic categories to structure our reporting on the open-ended questions, as seen in the "Results" section.

Results

Multimedia Appendix 2 displays how each participant in the 3 focus groups responded to each question, including the indication of agreement, indication of dissent, ambivalent response, no response, and response given with an elaboration. In this section, we explain our results for each question, providing a descriptive statistical overview of the types of responses (including nonresponses) and qualitative categorizations of participants' elaborations.

Question 1.1: Health Data Distribution Without Consent

This question asked, "Can you recall hearing about any cases where someone's personal health data were distributed without a patient's consent?" In response, 9 participants indicated that they had heard of cases where patients' health data were shared without consent, while 17 did not respond. Participants provided examples in which health data were involuntarily shared by others who sought profit, institutions attempting to control citizens, or health care professionals who were not vigilant in protecting the data. One participant described a story in which health care professionals secretly sold the health data of celebrities.

Question 1.2: Interest in Controlling One's Own Health Data

Participants were asked, "Are you interested in becoming the only controller of your own personal health data? Why or why not?" In total, 7 participants indicated that they were interested in becoming the only controller of their health data, 5 were not interested, 3 were ambivalent, and 11 did not respond. Those who were interested expressed that it is more convenient and morally legitimate for patients, especially those with chronic conditions, to control and profit from their data. As one participant said:

> *I have a chronic illness, and to get diagnosed I had to go see specialists, I had to have ultrasounds. I had to get blood tests, and to get the results of those I had to badger my receptionist at my doctor's office to get her to give me the records, which are legally mine, and it was so frustrating because she made me feel like we shouldn't even be asking. And so, I would really like to own my own records, because it feels*

very demoralizing when you can't even have access to your own records.

Those who were not interested did not want to bear the risk of becoming the sole data owner, as they were worried about their inability to manage the data and the possibility of blocking data access when they were critically ill. Those who were ambivalent agreed with both sides.

Question 2.1: Knowledge About Blockchain Technology

Participants were asked, "Do you have any questions about how blockchain technology works?" Prior to asking this question, the facilitator introduced the concept of distributed databases and their use in personal health data and compared blockchain to the centralized database technology currently used in health information management. Nine participants had questions about how blockchain works and 17 did not respond. Participants had questions about the management of private keys on blockchain, although researchers had explained that private keys are automatically generated by algorithms in tandem with public keys as pairs and that they are fundamentally different from passwords. Participants also had questions about where the private keys are stored and shared and how they might be managed, though the researchers had explained that the private key is not shared. That the participants asked those questions after the researchers had given detailed explanations suggests that participants had difficulty understanding the concept and features of private keys. Participants also asked questions related to the privacy and security of blockchain, including how they could revoke others' access to their data on blockchain, how blockchain ensures the anonymity of transactions, and the proper use of health data. Notably, the issue of revoking access appeared throughout the focus group discussions.

Question 2.2: Desire to Use Decentralized Databases

Participants were asked, "Would you consider using decentralized databases (blockchain) to control access to your health data? Would you consider using them to share your health data?" In total, 4 participants stated that they would use blockchain to control and share health data, 8 said they would not, 4 were ambivalent, and 10 did not respond. The reasons given by those who wanted to use blockchain included an affinity with the ideology of decentralized systems, perceived convenience for patients with chronic disease, and the security and privacy advantages of blockchain.

The reasons given by participants who did not want to use blockchain focused on the risk of losing private keys and hence losing access to all their data, which seemed to overshadow the perceived benefits. As one participant elaborated:

Because if I lose that private key my doctors cannot access my data. Even that company [third party] uses that data for promoting their devices. At the end, that's to the benefit of patients.

Other reasons included distrust toward new technologies and worries about cyber attacks.

The ambivalent participants were mostly concerned about whether they could revoke access if they shared health data via blockchain and if the private key could be recovered by other security measures, for example, one's biometrics.

Question 2.3: Concerns About Privacy

We asked participants, "What concerns do you have about the privacy of your personal health data when using this technology, if any?" Eight participants expressed their concerns and others did not respond. Participants were concerned that blockchain may not truly protect privacy because bad actors can still print or take a screenshot of the shared data and disseminate them for profit. Participants were also concerned that they could not revoke access if they shared their health data with the wrong person, which breaches privacy.

Question 2.4: Benefits of Blockchain in Ensuring Privacy

When asked, "Do you think there would be any benefits to using blockchain to ensure the privacy of your data?" 5 participants described the perceived benefits, while others did not respond. Participants perceived that the privacy ensured by blockchain could give rise to transparency, since one can see all the updates on one's record. In addition, one could share the data with insurance companies to receive allowances.

Question 2.5: Log-In Information

When asked, "Would you be willing to use a system that will secure your data, knowing that if you lost your log-in information you would not be able to recover it?" 7 participants stated they would not use it, since they could not recover the log-in information if lost; the rest did not respond. The participants were concerned that forgetting is part of human nature and that the private key is long. As one participant described:

I don't have a good memory! [Laughter]

Question 2.6: Password Recovery System

After the previous question, participants were asked, "If not, would you be willing to give up some of your individual control and security over your data in exchange for a password (private key) recovery system?" In total, 8 participants stated yes, 2 suggested no, and the rest did not respond. Those who stated yes suggested that the augmented control and security of a blockchain solution may actually hinder access to care, for example, if they need emergency care but forget their private key. They suggested that physicians could keep a copy of the private key or that third parties such as government or health authorities could use fingerprint or face recognition to recover the private key. One participant with a background in computer science who was unwilling to give up the security emphasized:

If you are giving up your security then you are weakening the system. So then it is no use to having that system.

Another participant who had also stated "no" stressed that the privacy of health data should never be compromised because some people may have a stigmatizing disease that they wish very few others to know about.

Question 3.1: Sharing Information With Third Parties

Participants were asked, "Would you be willing to share your data with third parties (eg, universities, pharmaceutical companies, and private organizations) if they're pseudonymous? Why or why not?" Three participants stated yes, 5 stated no, 4 were ambivalent, and 14 did not respond. One participant explained that he would share because sharing pseudonymous health data allows governments and researchers to gain new insights into diseases or public health while posing minimal risks to individual privacy. However, another participant explained that he would not share because the third party may be able to predict his identity even if the data were pseudonymous. Those who were ambivalent commonly suggested that if the purpose of the third party was virtuous (eg, informing public health decisions), they would be willing to share.

Question 3.2: Trusted Third Party Types

When asked, "Which kinds of third parties would you be willing to share your data with?" 13 participants responded. Of these, 12 listed the third parties they would share the data with, and 1 expressed that he would not share the data with any third party. The third parties included universities, research institutions, government agencies, national health agencies, police and immigration officers, and pharmaceutical companies, which could be taxed for using the data. Among the third parties, universities and research institutions received the most support. As one participant suggested:

> *Universities are open. If not, it will come to a [drawback] to research. And in some cases you'll probably have difficulties to discover new breakthroughs in sciences…so I wouldn't mind sharing mine for research. We're saving lives right? It's all about saving lives.*

Overall, participants indicated that they would share if the third party used the data for collective good rather than monetary gains. Participants commonly expressed unwillingness to share data with pharmaceutical companies, which were perceived to profit from people's illnesses.

The participant who would not share data with any third party via blockchain argued that the third party may be able to identify him if they regularly receive his information.

Question 3.3: Deciding Factors in Sharing Information With a Third Party

When asked, "What factors do you consider important when deciding to share your information with a third party?" 10 participants responded. The factors they listed included the end purpose of the third party (ie, whether the third party would use the data to make money or produce knowledge and therapeutics), whether the shared data had an expiry date, whether individuals could decide which data were shared, whether the third party could be audited when using the data, and whether the identity of the third party was the same as it claimed. The end purpose of the third party received the most emphasis.

Question 3.4: Sharing Data Using Blockchain

Participants were asked, "Will you feel comfortable letting third parties (organizations, universities) see your data using blockchain? Do you think your data will be secure?" Only 2 participants responded to this question, and both indicated that they would share data via blockchain with a third party. One participant explained that he would only share the data when the third party was ethical and not corrupt.

Question 4.1: Compensation for Sharing Personal Health Data

Participants were asked, "Would you seek compensation in exchange for securely sharing your personal health data?" Six participants indicated yes, 6 indicated no, and others did not respond. Those who would seek compensation believed that they should be compensated if the third party, especially pharmaceutical companies, were making money from their data. The reasons given by those who would not seek compensation included:

> *I only want to act from my heart.*
>
> *As long as the third-party is producing knowledge, the knowledge is my compensation.*
>
> *It is weird to commodify one's body.*

Question 4.2. Important Factors in Fair Compensation

When asked, "If you were offered compensation in exchange for the use of your personal health data, what factors do you consider important when evaluating what makes for fair compensation for sharing your health data?" 9 participants responded. They suggested 3 factors that may influence the perceived fairness of the compensation: the amount of shared data relative to the amount of compensation, whether patients could receive free treatment, and the significance of the data relative to the amount of compensation. Participants indicated that if they shared DNA sequence or cell lines, they would ask for much more compensation.

Question 4.3: Preferred Types of Compensation

We asked participants, "What type of compensation would you be looking for in exchange for your personal data?" A total of 12 participants responded to this question. They suggested the following types of compensation: free treatment, money, food, cryptocurrencies, discounts on health insurance, shared research findings, and donations to a good cause. Free treatment received the most mention, followed by cryptocurrencies and money.

Question 5.1: Health Wallet Providers

Participants were asked, "Will your acceptance for the health data wallet service differ if it was provided by a company like Google? What about Apple? 23 and me? Facebook? A pharmaceutical company? Or an IT company like IBM?" Thirteen participants responded to this question. Among all the potential blockchain platform holders, IBM and government agencies received the most support, followed by Apple. Pharmaceutical companies, Google, and genetics companies received the most disapproval, as participants believed that Google already has too much information and pharmaceutical and genetics companies are ethically questionable.

Discussion

Key Findings

In this study, we investigated how health care consumers responded to the idea of blockchain-based PHRs and health data sharing through a focus group study with 26 individuals. Our primary findings are (1) consumers did not express stronger intentions to use blockchain-based PHRs and health data sharing when blockchain was introduced into the focus group discussion; (2) consumers were concerned about the risk of losing private keys, the revocability and expiration of data access, and the end purpose of the third party that could access their data via blockchain; and (3) consumers' intentions may be improved if private key recovery is provided, governments or particular companies such as IBM or Apple provide the health wallet, the data shared via blockchain could expire and be revoked, and diverse types of compensation are provided for data sharing.

We started the focus group discussion by examining participants' baseline attitudes toward self-ownership of health data (question 1.2) and found that 7 participants were interested and 7 were not interested, as shown in the first row of Multimedia Appendix 2. However, after blockchain was introduced as the enabling technology for PHRs (questions 2.1 and 2.2), the number of those who were interested decreased to 4 and the number of those who were not interested increased to 8, as shown in the fourth row of Multimedia Appendix 2. Our thematic coding suggests that although participants recognized the benefits of blockchain for augmented security and privacy, they were wary of PHRs enabled by blockchain, primarily due to the concern of forgetting or losing one's private key. Interestingly, participants suggested that they were willing to give up the augmented security and privacy for the sake of emergency access to care (see the responses to question 2.6). Taken together, these findings suggest that consumers may not be substantially more interested (and might be less interested) in PHRs when presented with a blockchain-based application due to the concerns about losing one's private key and the resulting inability to access care. These concerns complement the barriers to blockchain in health care, such as heightened transparency and low speed of transactions, that the literature is mainly focused on [1,13].

Even though consumers may not be inclined to take control of health records using blockchain, the responses to questions 2.6 and 5.1 suggest that certain design features may boost willingness. Specifically, the responses to question 2.6 suggest that patients may favor blockchain-based PHRs if key recovery is provided, although it may compromise the very advantage of blockchain. The response to question 5.1 suggests that patients would be more interested if the government, IBM, or Apple provided the health data wallet rather than Google, pharmaceutical companies, or genetic companies because the latter are perceived as ethically questionable or too powerful. Compared with the existing literature, in which design options have aimed to improve the technical features of blockchain, including consensus algorithms, oracle services, and data storage [1-4,13], the options provided here (ie, key recovery service and type of wallet provider) closely adhere to patients' attitudes and behavioral patterns, indicating the importance of placing patients at the center of blockchain design.

We also investigated how consumers would respond to blockchain-based health data sharing. We started by asking their baseline willingness and found that it could be characterized as low (question 3.1). This result is different from prior literature, in which patients expressed high willingness to share health data with certain third parties [20,21]. However, since only 3 participants expressed a clear opinion in our study, the low willingness may not warrant an interpretation. After blockchain was introduced as the enabling technology (question 3.4), participants expressed roughly the same level of willingness (2 participants). This finding indicates that participants did not become more interested in health data sharing when presented with blockchain, which provides more privacy and security.

The responses to questions 3.2 and 3.3 can explain this response. Similar to prior studies [20,21], participants' willingness to share data was mostly affected by factors such as the end purpose of the third party (ie, making money or developing knowledge) and whether the third party would be audited. These factors pertain to the characteristics of the third party, over which the existing blockchain technology still has little control. Admittedly, blockchain technology has upgraded significantly in the past decade [34]; however, blockchain-based solutions to enforce patient-stipulated data use policies have yet to emerge. Other factors, such as the chance to revoke access or impose an expiration date on consent for use, also contributed to users' reluctance to rely on blockchain, as these were perceived as being currently unavailable capabilities of blockchain, though blockchain system designers have recently developed solutions to revoke access [35]. This implies that for consumers to be more willing to share health data via blockchain, not only must blockchain system designers reconfigure blockchain so that patients can revoke access or designate an expiration time for data access but, more importantly, consumers need to be educated about the technical updates and novel capabilities of this still emerging technology.

Other measures to improve consumers' willingness may include diversifying the types of compensation for sharing data and providing nonmonetary compensation, such as free treatment, shared research results, and donations to a good cause (see the responses to questions 4.1 to 4.3). Although value tokens or cryptocurrencies are popular types of compensation on blockchain-based applications to incentivize data sharing, the participants in our study placed greater value on nonmonetary forms of compensation. This finding expands the notion of health information altruists [36] by suggesting that altruists are not only willing to share data for altruistic reasons, such as helping medical research, but are also drawn to altruistic compensation forms. Overall, these design options highlight the benefits of the principle of patient-centered design [37,38], inviting a shift from improving technical properties of blockchain to understanding consumers' attitudes and needs.

Limitations

This study has a few limitations. First, the sample size is relatively small and not demographically diverse. Most of the participants were younger and held or were pursuing an

advanced degree. This composition of the sample means our findings are conservative because young people with advanced degrees tend to be more technology savvy than older, less educated adults; if their intentions for adoption are low, the intentions of the broader population would be even lower. As such, we suggest that a more diverse sample would not weaken, and could even strengthen, our results. Nevertheless, future studies may recruit participants with more diverse backgrounds to approximate the average intention of the broader population. A related limitation is that many participants did not respond to our questions during the group discussion. Although nonresponses are not uncommon in focus groups [29,30], the nonresponses reduced our capacity to use the sample. Future research may recruit more participants or conduct more focus groups to collect more responses. Second, although the study participants had patient experience and could be considered patients in a broad sense, the study was not conducted in a clinical setting where the participants are ill and faced with the immediate task of managing their health records or sharing their health data with clinicians. This limitation may not be significant for the time being, since researchers have only begun to understand individuals' intentions to adopt blockchain-based health care applications and there is still little evidence that real-time disease experiences would affect consumers' intentions to use this technology. Future research may explore whether and in what way real-time disease experiences affect intentions to adopt blockchain-based PHRs; these studies should be conducted with patients in a clinical setting to explore how their intentions would differ from those reported in this paper. Third, since blockchain technology evolves quickly, the participants were not aware of the most recent capabilities of the technology. Future studies may conduct field experiments, allowing a large group of participants to make decisions on whether to own and share health data using an actual blockchain application that is equipped with the most recent technical developments of blockchain, and compare the findings with this study's findings. Fourth, although the findings from this study have implications for designing user-centered blockchain PHR and data-sharing applications, it is focused on exploring individuals' intentions and concerns rather than providing a comprehensive list of design recommendations. Based on the findings of this study, future research may put a stronger focus on user-centered design and describe detailed design features. Finally, only 1 participant in our sample indicated that he had prior knowledge about blockchain. Thus, we do not have enough evidence to discern whether prior knowledge about blockchain would affect individuals' intentions to adopt blockchain-based PHRs and health data sharing. We can only suggest that the effect may be ambiguous, since individuals can have weaker intentions to adopt blockchain-based PHRs if their prior knowledge about blockchain is that blockchain is associated with scammer cryptocurrency or stronger intentions if they understand and their knowledge is thorough and updated. As such, future research may systematically investigate the effect of prior knowledge of blockchain on the intention to adopt blockchain-based health care applications.

In conclusion, our study did not show strong intentions among health care consumers to adopt blockchain-based PHRs and heath data sharing, and the exploration of consumers' concerns and preferences revealed several design options that may increase the adoption intention. As understanding consumer attitudes can contribute to the dynamic coevolution of technical capabilities and user behaviors and hence enhance the development and adoption of blockchain in health care, our study lays the stepping stone for patients and blockchain system designers to become cocreators of blockchain-based health information systems so that health and patient privacy can be simultaneously optimized. This may prove critical to tackling pandemics such as COVID-19, during which public health depends on patient health data privacy and sharing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group question list.
[DOCX File , 14 KB - formative_v4i11e21995_app1.docx]

Multimedia Appendix 2
Microinterlocutor analysis.
[DOCX File , 18 KB - formative_v4i11e21995_app2.docx]

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Abbreviations

PHR: personal health record

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Original Paper

Adaptation and Evaluation of a Symptom-Monitoring Digital Health Intervention for Patients With Relapsed and Refractory Multiple Myeloma: Pilot Mixed-Methods Implementation Study

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Abstract

Background: Relapsed and refractory multiple myeloma (RRMM) is a bone marrow cancer that requires systemic treatment, which often results in severe symptom burden. Recent studies have found that electronic patient-reported outcome (ePRO) interventions implemented in the clinic setting have had positive outcomes for other oncology populations. Evidence of the efficacy of a similar approach is lacking for patients with RRMM.

Objective: Recent recommendations for digital health interventions call for the publication of descriptions of iterative development processes in order to improve reproducibility and comparability. This study is an implementation pilot aiming to evaluate the acceptability and appropriateness of an ePRO intervention for patients with RRMM and to explore its impact on clinic workflow.

Methods: A total of 11 patients with RRMM were recruited from the John Theurer Cancer Center in Hackensack, New Jersey. Patients used a mobile app to report on 17 symptoms at 4 sessions, each a week apart. Patients could also report symptoms ad hoc. When reports met predefined thresholds, the clinic was alerted and patients received automated guidance. Study end points were assessed using qualitative and quantitative methods.

Results: A total of 9 patients (mean age 69.7 years) completed the study. Overall, 83% (30/36) of weekly sessions were completed. Patients found the frequency and time required to complete reporting acceptable. All patients agreed that the app was easy to use and understand. Providers felt the alerts they received required refinement. Patients and providers agreed it would be beneficial for patients to report for longer than 4 weeks. Patients felt that the training they received was adequate but contained too much information for a single session. All patients found the symptoms tracked to be appropriate; providers suggested shortening the list. All patients understood how to use the app for weekly reporting but had confusion about using it ad hoc. Providers felt the ad hoc feature could be removed. Neither patients nor providers viewed the in-app data reports but agreed on their potential value. Patients reported benefitting from symptom reporting through increased awareness of their symptoms. Clinic staff reported that app alerts were too numerous and redundant. They had difficulty responding to alerts within their existing workflow, partially because the data were not integrated into the electronic medical record system.

Conclusions: Overall, the intervention was found to be acceptable and appropriate for patients with RRMM. Points of friction integrating the intervention into the clinic workflow were identified. Clinic staff provided recommendations for addressing these

issues. Once such modifications are implemented, ePRO data from patients with RRMM could be used to inform and improve clinical research and care. This study underlines the importance of an iterative approach to implementation that includes all stakeholders in order to ensure successful adoption.

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KEYWORDS

mHealth; digital health; electronic patient-reported outcome; ePRO; patient-reported outcome; PRO; mobile; app; implementation science; multiple myeloma; relapsed refractory multiple myeloma

Introduction

Multiple myeloma (MM) is an incurable hematological neoplastic disorder characterized by uncontrolled proliferation of clonal plasma cells (ie, myeloma cells) in the bone marrow [1,2]. Nearly all patients who have MM eventually relapse or become refractory to treatment, which is known as relapsed and refractory multiple myeloma (RRMM) [3]. Patients remain on systemic chemotherapy for the entirety of their disease course and the rest of their life following diagnosis. Many of these cancer therapies carry substantial toxicity burdens [4]. For this reason, the primary goals of treatment are to extend survival while maintaining or improving the patient's quality of life, provide lasting relief from disease- and treatment-related symptoms, obtain maximum benefit from treatment, and manage remission [3,5].

Recently, there has been a focused effort to assess the patient experience in health care via patient-reported outcomes (PROs) [6,7]. A PRO is any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or any other third party [8]. PRO measures are often self-completed questionnaires that can be used to capture data on various domains, including functional status, health-related quality of life, symptom burden, treatment experience, emotional well-being, and health-related behaviors [6,9-12].

Studies in oncology have explored how to effectively implement PRO interventions in the cancer care setting [13-17] and assessed their impact on patient-centered outcomes, health outcomes, and overall survival [18-20]. Electronic PROs (ePROs), which are collected using electronic formats, are preferable, as they allow for systematically timed reporting between clinic visits, automated reminders to complete reporting, automated alerts to investigators, and real-time monitoring of compliance [7]. Approaches to systematic collection of data using ePRO systems have been shown to prompt clinical action for symptom management [21] and make care more patient centered [22]. One study, conducted at Memorial Sloan Kettering Cancer Center among patients initiating chemotherapy for certain metastatic solid tumors, found that patients using an ePRO system had greater improvement in health-related quality of life, were less frequently admitted to the emergency department or hospital, remained on chemotherapy longer, and had increased survival compared with patients receiving usual care (ie, discussion and documentation of symptoms during clinic visits, with patient encouragement to call about concerning symptoms between visits) [18,19]. To our knowledge, evidence for the efficacy of a similar approach is lacking for patients with RRMM.

Recent recommendations for digital health interventions call for the publication of detailed and transparent descriptions of iterative development processes in order to improve the reproducibility and comparability of digital health interventions in research (eg, randomized controlled trials) and in clinical practice settings [23-25]. This is the basis of implementation science, which is focused on "understanding and accelerating the integration of research findings and research-based innovations into everyday practice settings to improve health" [26]. Multiple frameworks to inform these iterative processes have been published to guide researchers [24,27], including the mobile health (mHealth) Development and Evaluation framework [25], which guided this study. The mHealth Development and Evaluation framework outlines several phases, including focus groups, pretesting, and pilot testing with a small sample from the target audience, in order to ensure the intervention is engaging and useful to the target users before use in randomized controlled trials [25].

This study was a content pretest and implementation pilot intended to assess the adaptation of a research-based ePRO intervention for use among patients with RRMM in their oncology care setting. The study was designed to collect feedback from patients and their providers regarding the acceptability and appropriateness of the intervention and the content included within it. The results are intended to inform and provide guidance for future iterations of ePRO initiatives delivered in a clinic setting for this or a similar patient population.

Methods

Study Sample

Starting January 2019, a purposive sampling strategy was used to recruit patients with RRMM receiving care at the John Theurer Cancer Center at Hackensack University Medical Center in Hackensack, New Jersey. Based on the study design, objectives, and existing research, information power was assessed to be relatively high and, as such, the desired sample size was determined to be approximately 10 patients [28]. Potential study participants were identified through review of the clinic's electronic medical record (EMR) system. Identified patients were approached by their treating oncologist at their next clinic visit to assess interest and confirm eligibility. All participants provided written informed consent prior to participation. Clinicians who were involved in the treatment of the recruited patients also participated in the study. The clinical

team included a lead hematology oncologist, a nurse practitioner, a nurse clinician, and a research assistant. The institutional review board at the Hackensack University Medical Center approved this study.

The following patient inclusion criteria were used: (1) age of 18 years or older at the time of enrollment; (2) diagnosis of RRMM; (3) initiation of or active treatment with second, third, or fourth line of therapy; (4) treatment that was expected to continue for at least four weeks from the time of enrollment; and (5) treatment that took place at John Theurer Cancer Center. Patients were excluded if they met any of the following criteria: (1) current participation in an investigational treatment, (2) Eastern Cooperative Oncology Group Scale of Performance Status score greater than 2, (3) the inability to read or comprehend English, (4) lack of internet access at their place of residence, (5) inability to receive email or text messages, or (6) refusal to provide informed consent.

Intervention Overview

Before patient recruitment, a cocreation process including the clinic staff, technology provider, and research team was conducted to adapt and refine the intervention [18] for use with patients with RRMM and determine how to integrate it into the John Theurer Cancer Center clinic setting. The result of the working sessions was the intervention protocol and an iteration of the Medocity Home Health app to be used for ePRO collection (Figure 1). App use was governed by Medocity's privacy policy [29].

Patients were trained by the research assistant on the intervention protocol and use of the app immediately after study enrollment and collection of informed consent. Patients could access the app from the web or by downloading the native iOS or Android app from the app store on their personal mobile device. The app guided patients on what and when to report, visualized the reported data, and facilitated delivery of alerts and data reports to clinic staff.

Patients were asked to report 17 common RRMM PROs selected from the Patient-Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE) bank [30] (Table 1). The National Cancer Institute's PRO-CTCAE was developed as a standard, patient-centered approach for accurately and reliably collecting symptomatic adverse events in oncology research [4]. PRO selection was based on expert clinical review and was led by the principal investigator. The goal of PRO selection was to create a parsimonious list that maximized clinical relevance and minimized burden and duplication for clinical practice [7].

Figure 1. Screenshots of the Medocity Home Health app.

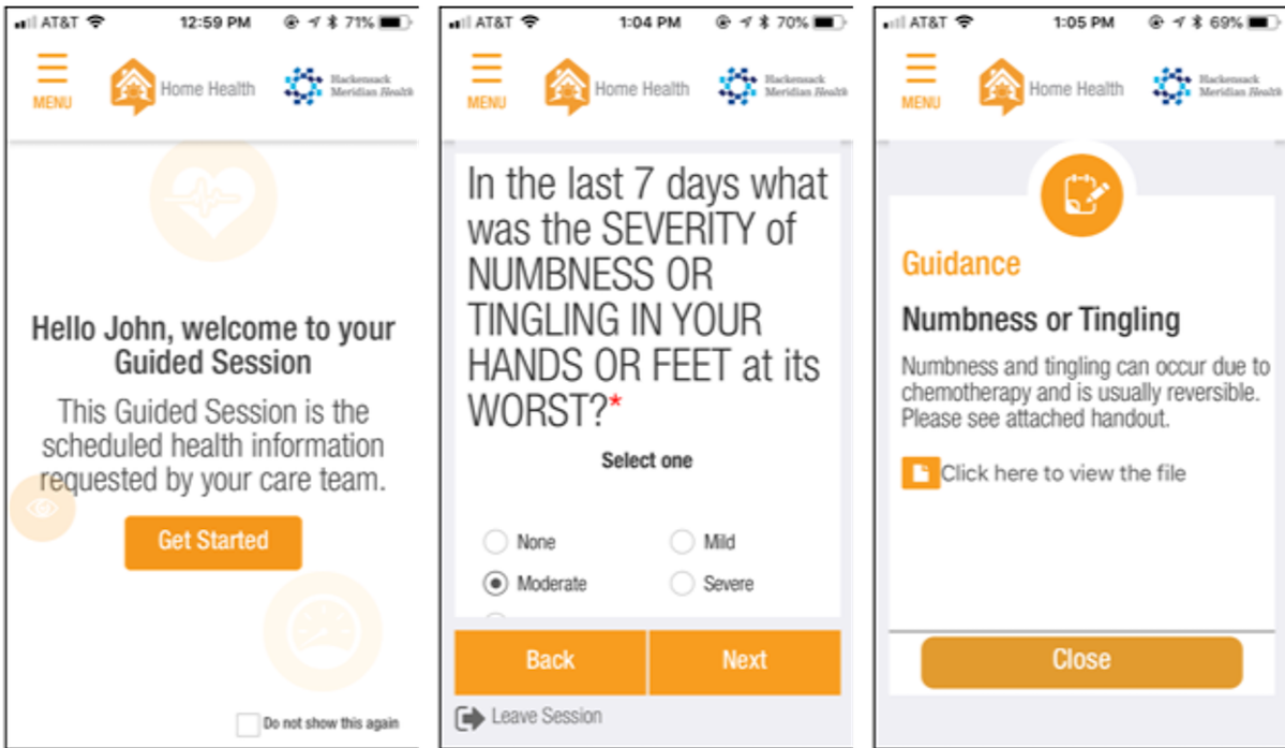


Table 1. Selected Patient-Reported Outcomes Common Terminology Criteria for Adverse Events symptom list and alert logic.

Symptom	Original grade trigger	Revised grade trigger
Anxiety	3 & 4	Removed
Appetite loss	3 & 4	4
Constipation	3 & 4	4
Cough	3 & 4	4
Diarrhea	3 & 4	4
Fatigue	3 & 4	4
Fever	3	4
Headache	3 & 4	4
Insomnia	3 & 4	4
Nausea	3 & 4	4
Numbness or tingling	3 & 4	4
Pain	3 & 4	4
Rash	3	4
Sad feelings	3 & 4	Removed
Shortness of breath	2, 3, & 4	4
Swelling	3 & 4	4
Vomiting	3 & 4	4
Ad hoc[a]	2 & 3	Removed
Inactivity	1	1

[a]After an ad hoc symptom reporting session, patients are asked, "Would you like your healthcare team to be aware of an ongoing concern?" If the patient chose "no," a grade 2 alert was created. If the patient chose "yes," a grade 3 alert was created. There is no way to generate a grade 1 or grade 4 alert from ad hoc reporting.

Patients rated the severity, frequency, and interference (or a combination of 2 of the 3) for each PRO using a 5-point Likert scale. Severity grades ranged from "none" to "very severe," frequency grades ranged from "never" to "almost constantly," and interference grades ranged from "not at all" to "very much." For rash and fever, patients were only asked about the symptom's presence.

Ratings were used to derive a composite grade ranging from 1 to 4 (Table 2). If a rating met a specified grade, then an alert was generated (Table 1) for the provider and real-time self-management guidance was sent to the patient through the app. The self-management guidance contained information on practices patients could perform to address the relevant symptom. Patients were also encouraged to call the clinic or go to the emergency room if needed. Alerts were also generated based on patient inactivity, defined as not completing the weekly guided session within the first 24 hours after it became available. These alerts were classified as grade 1 and were not communicated to the clinicians.

Reporting was done during scheduled sessions, each occurring 1 week apart; these were known as weekly guided sessions. The first session was completed during study enrollment with the research assistant. Patients completed the remaining sessions on their own or with the assistance of a caregiver. Patients were sent a reminder at the same time each week through their choice of email, text message, or push notification when the next session was available. A session was only available for 48 hours starting from the time of the notification. Patients were not required to respond to all questions at once and could complete the session at any time within the 48-hour window. In addition to the scheduled sessions, patients could use the app to report any of the 17 symptoms ad hoc. Patients were instructed to use ad hoc reporting when they experienced symptoms between the reporting sessions so that the clinicians could actively monitor their symptoms. Patients we asked to complete 4 total weekly guided sessions.

Table 2. Composite symptom grade definitions.

Symptom grade	Severity	Frequency	Interference
Grade 1	Mild	Rarely	N/A[a]
Grade 2	Moderate	Occasionally	Somewhat
Grade 3	Severe	Frequently	Quite a bit
Grade 4	Very severe	Almost constantly	Very much

[a]N/A: not applicable.

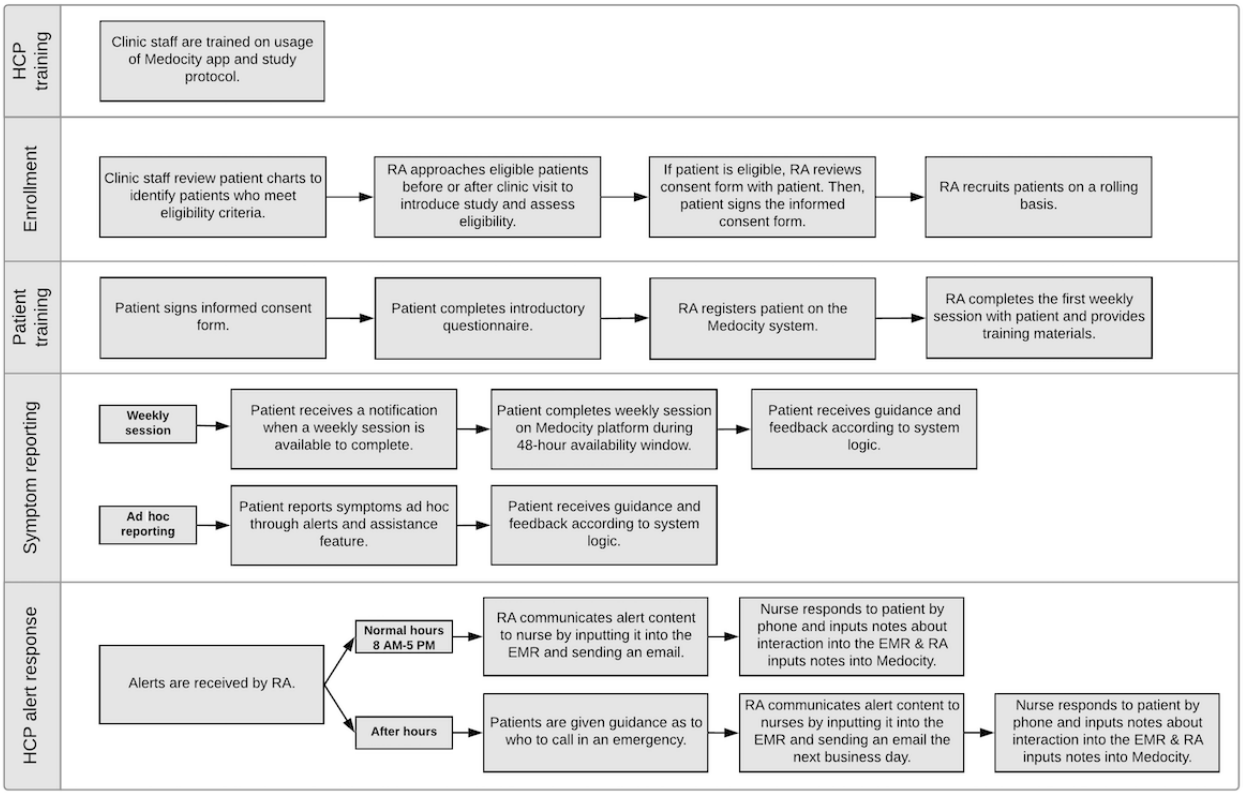
Clinic Workflow

At baseline, the clinic had 4 existing channels for patient communication: phone, email, the MyChart Patient Portal, and an online forum for patients to ask nonurgent questions. Clinic protocol required that all incoming patient communication be responded to by the end of the business day. Communications marked as urgent had to be responded to within one hour.

The staff members had access to a clinician version of the ePRO app (also available as a web portal and native mobile app), in which they could view and respond to reported symptoms and manage alerts. During the initial working sessions, stakeholders decided not to integrate app data into the clinic's EMR system until concept pretesting and refinement was complete. In order to reduce the time it took clinicians to become aware of app alerts, the research assistant manually transferred alert data from the clinician app into the clinic's EMR system and communicated to the appropriate clinician that there were new data to review. The ePRO app was considered a fifth channel of communication by the clinic and, as such, alerts were responded to by the end of the business day.

Participating staff members were trained on the intervention protocol and use of the app prior to study onset. Clinicians could incorporate the PRO data into routine care; however, no protocol was defined for how clinicians should use the data. The workflow as it was planned to be executed during the study is visualized in Figure 2.

Figure 2. Planned study workflow. EMR: electronic medical record; HCP: health care professional; RA: research assistant.



Operationalization of Implementation Outcomes

Acceptability is defined as the perception among stakeholders that an intervention or innovation is agreeable [31]. It is a critical factor to assess when planning an intervention, as unacceptable tools will likely have low usage in the target population [32]. For the purpose of this study, acceptability was operationalized through the following end points derived from interviews and app usage data: completion of the weekly guided sessions and ad hoc reports, frequency of reporting, clarity of the app content, perceived ease of use, amount of time required to complete reporting, reporting duration, and clinic response to reported symptoms.

Appropriateness is defined as the "perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem" [32]. This construct can help elucidate whether an intervention will be effective in the intended environment and is suitable for the target population. Appropriateness was operationalized through the following end points derived from qualitative interviews: adequacy of the training, relevance of the 17 preselected PRO symptoms to patients with RRMM, patient comprehension of the use of the app for structured and ad hoc reporting, sensitivity of the logic that triggers alert notifications, frequency and volume of the app alerts, utility of the graphs and reports, effect on the patient's perceptions of their oncology care, and fit within existing clinic workflow.

Data Collection Methods

It is recommended for implementation research that a mix of qualitative and quantitative methods be used to explore and obtain an in-depth understanding not possible with one approach and data source alone [33]. The methods used to assess the implementation study outcomes were informed by the mHealth framework put forth by Peters et al [31] and Proctor et al [32].

The quantitative methods used included a paper-based patient enrollment questionnaire that assessed patients' demographic information, technology use characteristics, and feelings towards their RRMM treatment and care (Multimedia Appendix 1); clinical data extracted from the EMR; app usage data; and 2 questions regarding perceived ease of app use and understandability of app content (adapted from Basch et al's patient impressions exit questionnaire [13]), which were embedded into the qualitative interviews. The 2 questions were rated on a Likert scale ranging from 1 (strongly agree) to 4 (strongly disagree). Staff members were also given a paper-based questionnaire, administered approximately halfway through the study. They were asked about the perceived clarity of the alert content, the ease of responding to app alerts within their existing clinic workflow, and the utility of receiving alerts from patients between clinic visits (Multimedia Appendix 2).

The qualitative methods used included focus groups and individual interviews. Each patient participated in 2 semistructured individual interviews during the study: one 30-minute interview was conducted within two weeks of study initiation and one 1-hour interview was conducted within two weeks of study completion. The first interview used open-ended questions to assess patients' initial thoughts, feelings, and expectations of the app. Patients were asked about their initial impressions of the app training, their experience with the weekly guided sessions, and their use of the ad hoc capability. One objective of this interview was early identification of any issues that may have hindered patients from participating.

The second interview explored patients' thoughts about the app in more detail. Specifically, patients were asked open-ended questions to assess their opinions on the timing, frequency, and duration of PRO reporting via the weekly guided sessions; clarity of the app content; relevance of the reported symptoms; utility of the data reports; perceptions of the feedback received in response to reported symptoms; and perceptions of their cancer care before and after the intervention.

In order to support ad hoc PRO reporting, the standard 7-day PRO-CTCAE question recall period was modified to reference symptoms that occurred within the past 24 hours. A cognitive debriefing technique was used to assess comprehension of this adjusted scale during the second interview. Specifically, patients were shown an example ad hoc symptom question and asked to restate in their own words what the item meant in order to confirm their understanding [34].

Semistructured group and individual interviews were also conducted with the clinic staff at the end of the study period. Interview topics included the staff's opinions of the frequency and duration of patient reporting, relevance of the selected symptoms, adequacy of the training on the intervention protocol, sensitivity of the logic that triggered app alerts, usefulness of the ad hoc reporting, utility of the graphs and reports, and fit of the intervention protocol within the clinic workflow. Impact on clinic workflow was further assessed through a workflow mapping of actual versus planned implementation.

Data Analysis

An inductive analytic approach was used to analyze all qualitative data. This approach allows research findings to emerge from the frequent, dominant, or significant themes inherent in raw data without the restraints imposed by more structured methodologies [35]. All interviews were professionally transcribed, then reviewed by 3 independent reviewers with experience in qualitative methods. Themes from the interviews were extracted and categorized. After individual review, the transcripts were discussed as a group to ensure convergence of themes.

Analysis of the quantitative measures was limited to descriptive statistics. App usage data, patient demographics and clinical characteristics, and the staff experience questionnaire responses were analyzed as means, medians, and standard deviations for continuous variables and as frequencies and percentages for categorical variables where appropriate.

Results

Demographics and Clinical Characteristics

A total of 11 patients were approached for study inclusion and agreed to participate; 2 patients discontinued after the training session. One patient discontinued because they felt they were too busy to commit to the study and the other did not feel well enough to participate. Of the 9 patients who completed the study, the mean age was 69.7 (SD 6.5) years and 44% (4/9) were women (Table 3). Patients had been living with an MM diagnosis for a mean of 10.9 (SD 7.2) years and attending John Theurer Cancer Center for treatment for an average of 9.9 (SD 7.5) years. All patients included in the study had relapsed disease and required chronic therapy with frequent clinic visits: 33% (3/9) of patients were in their first relapse (second line of therapy) and 67% (6/9) were in their second relapse (third line of therapy).

Table 3. Patient demographic information and clinical characteristics.

Characteristic	Values
Age, mean (SD), range	69.67 (6.54), 56-76
Time since multiple myeloma diagnosis (years), mean (SD), range	10.89 (7.29), 2-23
Duration of treatment at HUMC[a] (years), mean (SD), range	9.89 (7.46), 2-23
Gender, n (%)	
Male	5 (56)
Female	4 (44)
Line of therapy, n (%)	
Second	3 (33)
Third	6 (67)
ECOG[b] score at start of current therapy[c], n	
0	1
1	6
2	1
Highest education, n (%)	
Some high school, no diploma	1 (11)
High school graduate/GED[d]	4 (44)
Some college	1 (11)
College graduate	1 (11)
Some postgraduate	1 (11)
Master's degree	1 (11)
Household income[c] (US $), n (%)	
25,000-34,999	1 (11)
50,000-74,999	2 (22)
75,000-99,999	2 (22)
100,000-149,999	2 (22)
150,000 or more	1 (11)
Marital status, n (%)	
Single	3 (33)
Married	5 (56)
Widowed	1 (11)

[a]Hackensack University Medical Center.

[b]ECOG: Eastern Cooperative Oncology Group.

[c]1 patient declined to answer or data were unavailable.

[d]GED: General Educational Development.

Acceptability

App Usage

There was an overall weekly guided session completion rate of 83% (30/36). The first weekly guided session, completed in the clinic during the training session, had a completion rate of 100% (9/9). Session 2 had a completion rate of 67% (6/9), session 3 had a completion rate of 89% (8/9), and session 4 had a completion rate of 78% (7/9). In total, 67% (6/9) of patients completed all 4 weekly guided sessions. There were 5 unique ad hoc reporting sessions completed by 5 separate patients, resulting in 23 total symptoms reported ad hoc.

Frequency and Timing of Reporting

The weekly guided sessions took an average of 4.5 minutes to complete. However, patients perceived them to take an average time of 19 minutes. All patients felt the time required to complete the weekly guided session was acceptable. All weekly guided sessions were completed on the same day that the

reminder was received, except for 1, which was completed the day after.

During the interviews, patients agreed that reporting symptoms on a weekly basis was acceptable and not burdensome. All staff members felt that a weekly reporting schedule would be acceptable for patients who came to the clinic 1 to 2 times per month. However, they felt this would be too frequent for patients who came into the clinic more frequently. They felt that they were aware of the symptoms that frequently seen patients experienced and thus found the alerts from the app duplicative. They stated that there would be greater benefit from weekly reporting for patients who required less frequent visits because those patients had fewer points of contact with the clinic.

Clarity of Intervention Content and Perceived Ease of Use

All patients reported understanding the definition of each symptom and the scales used to report symptom severity and interference, including for ad hoc reporting. Patients responded favorably to the 2-item ease of use and app comprehension statements; all (9/9) patients strongly agreed with the statement "I found the Medocity Home Health app easy to use" at their exit interview. In addition, 78% (7/9) of patients strongly agreed and 22% (2/9) of patients agreed with the statement "Questions in the Medocity Home Health app were easy to understand."

Staff members responded to the question "Please rate the clarity of the alert content that you received from patients enrolled in this study on a scale of 1 to 5 (1=not at all clear, 5=very clear)." One of 4 staff members responded with "3," another responded "2," and the remaining 2 staff members responded "1."

Reporting Duration

Both patients and clinic staff agreed that it would be beneficial to report symptoms for longer than 4 weeks because it would allow them to see changes over time. The clinicians felt that longitudinal symptom data would help to improve clinical care by creating visualizations that put symptoms into perspective (eg, which symptoms were better, worse, new, or chronic). They also stated that consistently reported, longitudinal symptom data would help them make better decisions about how to manage long-term disease- and treatment-related symptom burden and help combat treatment fatigue, a psychological symptom associated with prolonged treatment engagement, which could increase duration on therapy and patient adherence to the clinical regimen [36].

Clinic Response to Reported Symptoms

A total of 33 symptom-related app alerts were generated over the study period. Clinicians reached out to patients in response to 76% (25/33) of the alerts of which they were notified. Of these, 15 alerts led to symptom counseling, 8 alerts resulted in clinicians advising patients to continue with a previously discussed management approach, 1 alert led to instructions to go to urgent care, and 1 alert led to instructions to go to urgent care and medication management. For the remaining 8 alerts, clinicians did not contact the patient because the reported symptom was chronic and already being treated.

Patients had mixed feelings about the clinic reaching out to them in response to the symptoms they reported in the app. Two patients mentioned that they appreciated having the clinic call them in response to their reporting because it reinforced that their data were being received. However, one patient reported that their symptoms did not warrant a phone call from the clinic due to its chronicity and low severity, and another patient expressed frustration at having to verbally repeat their symptoms after entering them in the app.

Appropriateness

Adequacy of Training

Initial training on the app and intervention protocol took between 20 and 60 minutes per patient. No patient proposed modifications to the duration or timing of training completion. Patients felt equipped to use the app and record their symptoms following training.

Some patients reported feeling overwhelmed with the amount of information presented during the session and reported not remembering all topics that were discussed. While patients were given a handout that reinforced key information about the app and contained contact information for the research assistant, no patient recalled using the handout for reference or proactively reaching out to the research assistant with questions. However, some patients asked questions about the app and study when contacted by the research assistant for interview scheduling. All staff members agreed that training was comprehensive, but the patient session contained too much information to digest in one session.

Relevance of the Preselected Symptoms

Both patients and clinic staff felt that the 17 symptoms were relevant and appropriate for patients with RRMM. At the end of the study period, clinic staff suggested removing anxiety and sad feelings from the list of symptoms to maximize the clinical utility of the reports and reduce reporting burden on patients.

Comprehension of App Use

All patients reported understanding how and when to complete their structured PRO reporting; however, they did not report a clear understanding of how the reported data would be used in their care. Several patients thought the purpose of the intervention was to help other patients with RRMM through the use of aggregate data and did not realize their data could be used to help them directly. Patients did cite benefitting from participation through an increased awareness of their symptoms. This was achieved by taking moments of thoughtful reflection during the weekly guided sessions.

While all patients reported finding the ad hoc PRO reporting questions clear and easy to understand, some reported confusion regarding why and when it was appropriate to use the ad hoc reporting feature. Patients were unsure if they should report chronic symptoms or acute symptoms, if they should report symptoms related to their disease and treatment or general symptoms (eg, those related to the flu), and whether symptoms reported using the ad hoc feature should also be reported during the weekly guided session.

Two clinicians felt that ad hoc reporting was not appropriate for reporting emergency symptoms and mentioned that it may interfere with the clinic-established protocol for patients to call the clinic directly or go to the emergency room when they experience severe symptoms or that it may delay the process of a patient getting immediate help. However, another clinician felt that ad hoc reporting had the potential to catch emergency symptoms that the clinic might otherwise miss or that the patient might identify as a nonemergency and stated that earlier awareness of these emergency symptoms could prevent the need for a more aggressive intervention.

Utility of Symptom Graphs

Most patients were not aware that symptom graphs were available in the app or did not view them after initially seeing them during the app training session. When patients were shown example PRO reports in the interviews, they felt the graphs could be helpful if they showed data over a longer period of time or showed significant fluctuations in symptoms over time.

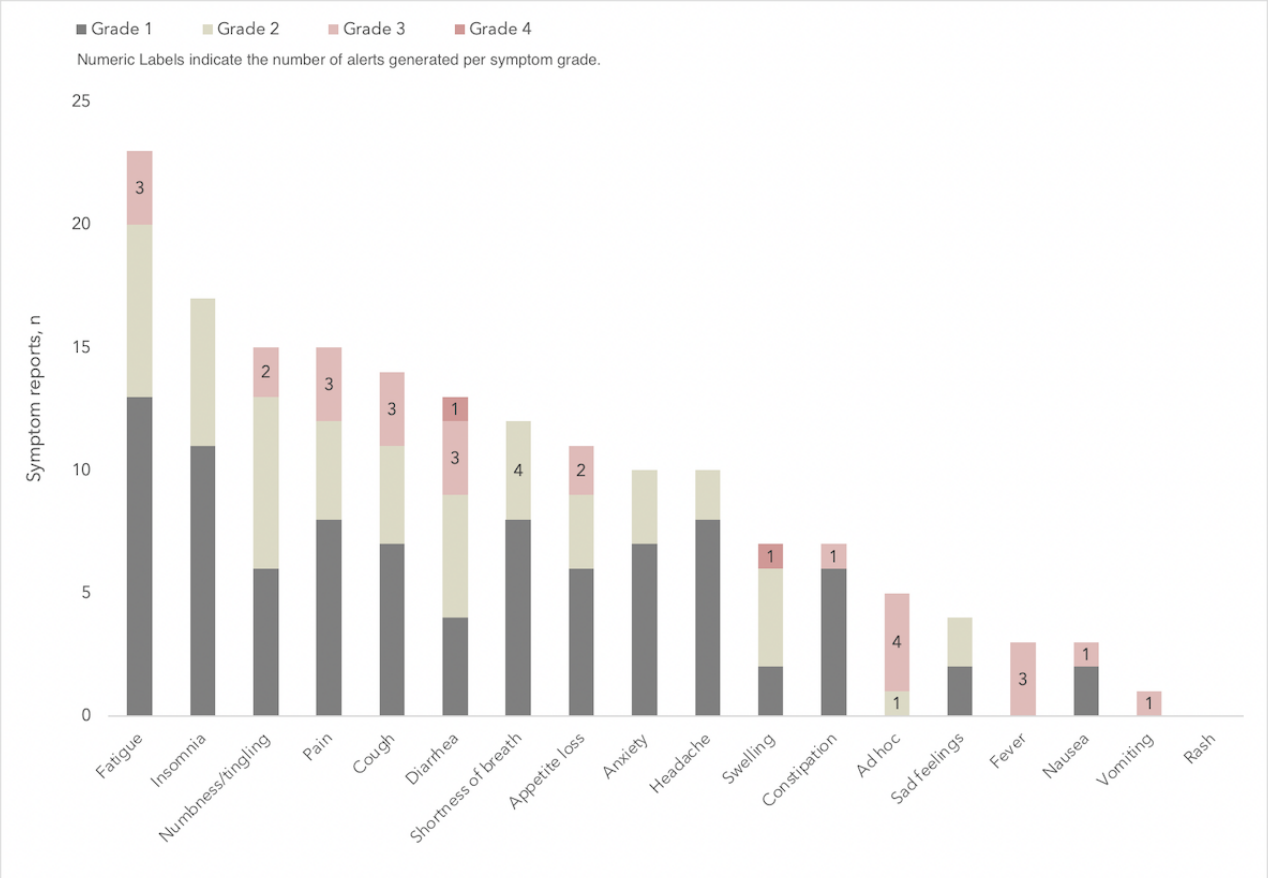
The clinicians reported not using symptom graphs and reports during the study due to the high volume of information that typically needs to be reviewed before and during a clinic visit and the lack of integration of the data into the EMR system and routine visit workflow. They did see the potential value in a summary of longitudinal PRO data because it could allow them to address patient concerns proactively and increase the efficiency and quality of a clinic visit through improved data transparency and shared knowledge.

Appropriateness of Alerts

A total of 62 alerts were generated over the course of the study. Of these 62 alerts, 29 (47%) were rated as grade 1 (inactivity) alerts and the remaining 33 (53%) were symptom related. Of the 33 symptom-related alerts, 15% (5/33) were grade 2 alerts, 79% (26/33) were grade 3 alerts, and 6% (2/33) were grade 4 alerts. Ad hoc reports (n=5) triggered the most alerts, followed by diarrhea (n=4) and shortness of breath (n=4) (Figure 3).

Clinicians, particularly the 2 nurses, reported that the volume of alerts generated was too high, alerts did not always map to clinically relevant criteria, and alerts tended to be redundant, with symptoms that had already been addressed through the clinic's established communication channels. When responding to the question "How helpful do you think it is to receive symptom alerts from patients between clinic visits? (Scale: 1=not at all helpful, 5=very helpful)," 3 of 4 staff members responded "1," and 1 staff member responded "2." Staff members explained that it would be most useful to be alerted of newly emerging, severe, or worsening symptoms; however, the alert logic also frequently captured chronic and expected symptoms. In order to maximize clinical utility, they suggested the alert criteria be made more specific so that more actionable app alerts were generated (Table 1).

Figure 3. Frequency of reported symptoms and alerts.



Effect on Clinic Workflow

Overall, the clinic staff did not feel the current implementation of the intervention was easy to incorporate into their existing workflow. When asked, "How easy is it to respond to the intervention alerts as part of your regular clinic workflow? (Scale: 1=Not at all easy to 5=Very easy)," 3 of 4 staff members responded "1," and 1 responded "2." When probed, staff members explained that integrating the intervention alerts into their existing communication channels would greatly increase the usability.

Influence on Oncology Care

Patients reported a high level of satisfaction with their RRMM care during both qualitative interviews. During the second interview, patients were shown abstract emotional imagery and asked to select an image that best represented their relationship with their providers. All patients selected images that evoked positive qualities and described themes of partnership, equality, and teamwork when asked to describe how the image made them feel (Multimedia Appendix 3).

Patients did not feel that participating in the intervention impacted their relationship with their providers. This was likely due to very high baseline relationship quality, the short study duration, the lack of data integration into clinic visits, and the benefits of the intervention being entangled with the benefits of routine care.

During the clinic staff group interview, staff theorized that an ePRO intervention could have the following benefits for patients: (1) encouragement to remain on therapy as a result of more effective symptom management; (2) more control over their symptoms through increased symptom awareness, recognition of symptom patterns, and easily accessible self-management guidance; (3) an improved relationship with the clinical team due to consistent communication through a trustworthy platform; and (4) empowerment in clinic visits through the use of PRO reports as communication tools.

Discussion

Principal Results

This study attempted to redefine the protocol for an ePRO intervention, adapted from the protocol used by Basch et al [18], for use with patients with RRMM receiving care at the John Theurer Cancer Center. Overall, the intervention was found to be acceptable and appropriate for patients with RRMM. There was a high completion rate of the weekly reporting sessions. Patients understood how and when to use the app and did not find the reporting frequency burdensome, although staff members suggested weekly reporting may be more beneficial for patients who have less frequent clinic visits. Both patients and clinic staff agreed that it would be beneficial to report symptoms for longer than 4 weeks due to the nature and progression of RRMM. All felt that the 17 selected symptoms were relevant to patients with RRMM, but staff members suggested removing questions related to mental health symptoms to maximize clinical utility and reduce reporting burden. No impact was found on the patient-provider relationship, but this was likely due to the short intervention duration, lack of integration into routine practice, and the high-quality relationship at baseline. Clinicians confirmed that such an intervention could be effectively implemented into their clinic workflow; however, modifications are required, primarily with app alerts. Challenges were observed due to app alerts adding to clinician burden, alerts being unable to differentiate between chronic and acute symptoms, patient misunderstanding of when to use ad hoc reporting, and lack of integration of the intervention data into routine care.

Each medical practice has unique qualities, strengths, and limitations. The design and development of an ePRO intervention for use in the clinic setting should take these factors into consideration and include the input of the end users along the way in order to create a program that can be successfully adopted and executed [37]. Integrating new protocols into an existing clinical workflow requires an iterative process, and the first step is to ensure the protocol is well defined in order to be usable in practice [27].

The "Recommendations for Future Implementation" section describes 5 recommendations for improving this intervention for use at the John Theurer Cancer Center and other clinics with similar characteristics. Not all recommendations will be relevant to every clinic setting, but many findings may be transferrable, and the detailed and iterative approach adopted herein can be used as an example of implementation science in mHealth research.

Recommendations for Future Implementation

First, patient training should be reduced in scope or broken into multiple sessions. Additional materials could be distributed electronically or at clinic visits to reinforce core concepts. Training should include content related to the purpose of PRO reporting and its intended use in the patient's care regimen. Setting expectations for the patient and ensuring their understanding will help them be active participants in the intervention.

Second, the symptom list and alert logic should be designed to limit the overall volume of alerts and maximize their clinical relevance. This will reduce the burden on clinic workflow, limit the burden of patient reporting, and create a data set of the most relevant symptom information for use in clinical care. It is essential to differentiate acute versus chronic versus acute-on-chronic symptoms. One approach to increasing the relevance of app alerts is to triage them by including follow-up questions within the app. Follow-up questions could clarify whether the symptom has already been discussed or whether it is new or worsening, allowing the clinical team to triage the symptom's urgency and plan patient outreach (Multimedia Appendix 4). Other authors have suggested assessing patients' baseline symptom burden and interpreting their PRO reports accordingly [38].

Third, clinic staff suggested removing the ad hoc reporting feature in favor of relying on the clinic's existing communication channels to capture urgent symptoms. This was proposed to reduce patient confusion, limit the total volume of alerts, minimize redundancy of reported symptoms, and reinforce the purpose of weekly reporting. This feature or a similar version

could be retained for clinics with less robust patient communication channels.

Fourth, the ePRO reporting mechanism should be integrated into the clinic's workflow. For example, intervention data could be integrated into the clinic's EMR system or other existing patient content (eg, paper-based calendars). Communication flows should be clearly established, and points of friction should be identified and eliminated at the beginning of the intervention implementation to facilitate successful adoption.

Fifth, protocols should ensure that PRO data are integrated into clinic visits. For example, staff members said it would have been helpful to include a printed graph of active symptoms in front of the patient chart prior to each visit. Another strategy is having clinicians set patient expectations for how the PRO information will be used in their care and encouraging patients to review their data between clinic visits.

Limitations

Some study limitations should be considered. First, this was a pilot study that included a small sample of patients with RRMM and clinic staff located at one study site, which may limit the generalizability of the findings. The 4 staff members came from different specialties, further limiting the generalizability of the staff member feedback. However, the feedback provided was valuable in creating preliminary insights from a range of providers involved in the symptom-reporting clinic workflow. Additional clinicians from each field should be included in subsequent implementations in order to gather a more representative perspective. Second, because the study was a pretest, it had a short duration of only 4 weeks. Future studies should be longer in order to investigate the impact that longitudinal symptom data can have on patient-clinician interactions and symptom management. Third, the study participants had been living with RRMM for many years and their disease was well controlled. As such, these findings cannot be applied to patients who are newly diagnosed with MM or patients with more acute symptom profiles. Fourth, this population had strong relationships with the clinical team prior to the study. This limited the ability to assess how participating in the intervention could improve the patient-provider relationship. Finally, interrater reliability was not calculated for the qualitative analysis due to the methodology employed. The themes identified in patient and clinician interviews should be validated in future work.

Conclusions

The recent push to integrate patients' voices into oncology care highlights the importance of identifying and addressing barriers to implementing PROs in clinical practice [26,39]. In addition, some have argued that iterative user-centered design strategies can be complementary to implementation science strategies in bridging "the research to practice gap" [40] by supporting the iterative refinement of interventions when translating to new populations or settings in order to systematically maximize "intervention-setting fit" [41]. We found this approach particularly important when adapting this intervention to address the unique aspects of a different population and clinic setting.

This implementation pilot study demonstrates how a successful ePRO intervention for patients with solid tumors could be adapted from research into the clinical setting for another patient population. This study underlines the importance of a systematic and iterative approach to implementation that includes all stakeholders in order to ensure successful adoption. Future research should consider these findings when attempting effective implementation of ePRO interventions in various oncology care practice settings.

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Conflicts of Interest

NB has received honoraria and research funding from Amgen Inc. RAK and SP own stock in Amgen Inc, which was the sponsor of the study. EY held stock in Amgen Inc at the time of writing. GEM and OGD are employees of Rip Road Inc, who was contracted by Amgen Inc to provide research support. AMS is a consultant to Rip Road Inc. AS is an employee of the company that provided the ePRO application, Medocity Inc. The remaining author declare no conflicts of interest.

Multimedia Appendix 1
Patient enrollment questionnaire.
[PDF File (Adobe PDF File), 62 KB - formative_v4i11e18982_app1.pdf]

Multimedia Appendix 2
Provider questionnaire.
[PDF File (Adobe PDF File), 35 KB - formative_v4i11e18982_app2.pdf]

Multimedia Appendix 3
Emotional imagery.
[PDF File (Adobe PDF File), 715 KB - formative_v4i11e18982_app3.pdf]

Multimedia Appendix 4
Proposed follow-up questions.
[PDF File (Adobe PDF File), 124 KB - formative_v4i11e18982_app4.pdf]

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Abbreviations

EMR: electronic medical record
ePRO: electronic patient-reported outcome
mHealth: mobile health
MM: multiple myeloma
PRO: patient-reported outcome
PRO-CTCAE: Patient-Reported Outcomes Common Terminology Criteria for Adverse Events
RRMM: relapsed and refractory multiple myeloma

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