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Original Paper

Developing Digital Facilitation of Assessments in the Absence of an Interpreter: Participatory Design and Feasibility Evaluation With Allied Health Groups

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Abstract

Background: To ensure appropriate and timely care, interpreters are often required to aid communication between clinicians and patients from non-English speaking backgrounds. In a hospital environment, where care is delivered 24 hours a day, interpreters are not always available. Subsequently, culturally and linguistically diverse (CALD) patients are sometimes unable to access timely assessment because of clinicians' inability to communicate directly with them.

Objective: The aim of this study was to design and evaluate CALD Assist, a tablet app to assist communication between patients and allied health clinicians in the absence of an interpreter. CALD Assist uses key phrases translated into common languages and uses pictorial, written, and voice-over prompts to facilitate communication during basic patient assessment.

Methods: CALD Assist's design, functionality, and content were determined through focus groups with clinicians and informed by interpreting and cultural services. An evaluation was conducted in a live trial phase on eight wards across 2 campuses of a hospital in Victoria, Australia.

Results: A commercial grade CALD Assist mobile app for five disciplines within allied health was developed and evaluated. The app includes a total of 95 phrases in ten different languages to assist clinicians during their initial assessment. Evaluation results show that clinicians' confidence in their assessment increased with use of the CALD Assist app: clinicians' reports of "complete confidence" increased from 10% (3/30) to 42% (5/12), and assessment reports of "no confidence" decreased from 57% (17/30) to 17% (2/12). Average time required to complete an assessment with patients from non-English speaking backgrounds reduced from 42.0 to 15.6 min.

Conclusions: Through the use of CALD Assist, clinician confidence in communicating with patients from non-English speaking backgrounds in the absence of an interpreter increased, providing patients from non-English speaking backgrounds with timely initial assessments and subsequent care in line with their English speaking peers. Additionally, the inclusion of images and video demonstrations in CALD Assist increased the ability to communicate with patients and overcome literacy-related barriers. Although a number of hurdles were faced, user uptake and satisfaction were positive, and the app is now available in the Apple App Store.

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KEYWORDS

mobile apps; cultural diversity; culturally appropriate technology; cross-cultural care; language barriers; health care delivery; ehealth allied health

Introduction

Background

Good communication in clinical settings is the key to avoiding medical mishaps [1,2]. Clinicians must obtain and communicate accurate information to patients to complete assessments and provide care. It is critical that information being communicated by a patient to a clinician is accurate and complete. Similarly, it is crucial that clinicians can communicate effectively and accurately with patients to inform them of risks and to provide education.

In acute hospital settings, assessment delays for culturally and linguistically diverse (CALD) patients are common, as clinicians require interpreter services and for a variety of reasons services may not be immediately available [3]. The requirement for accurate interpreting is never more crucial than in the medical domain. Delays in assessments can place patients at risk of dehydration, choking, falls, wound infection, and poor quality of life. For example, dysphagia is common after stroke, and early identification is important because of potential aspiration risk and to determine patients' suitability for oral feeding [4].

The traditional approach to ensuring patient safety and appropriate communication in clinical settings has been to use professional interpreters. This model has worked with much success, but as human migration increases and health service budgets are placed under increasing pressure, interpreters are not always available to assist in a timely manner. Interpreter demand is unsurprising given that communities served by Australian hospitals vary in cultural diversity, with some hospitals serving areas where more than 150 languages are spoken. Non-English speaking patients are sometimes unable to access timely assessment, causing inequity in service delivery and often frustration and anxiety for patients, their carers, and clinical staff.

The Use of Mobile Interpreter Technology in the Clinical Setting

Mobile technology has been recognized as a potential solution to interpreter availability, with Web-based tools and apps available for use. A flexible Web-based tool for translation is Google Translate [5]. Google Translate allows clinicians to type in any phrase and receive a text and audio translation in 91 languages. Google Translate has two major drawbacks for use in the medical domain: (1) clinicians are time-poor, and (2) the requirement to type phrase after phrase to receive a translation is impractical. More worryingly, Google Translate has varying levels of accuracy depending on language [6], with low accuracies reported for even simple medical terminology. A recent study in which ten phrases were translated into 26 languages showed that only 57.7% of phrases were accurately translated [7]. Errors included a mistranslation of "your child is fitting" to "your child is dead." Low translation accuracy in

serious health situations will at minimum cause distress and potentially harm.

A number of other health information translation apps, which contain libraries of phrases and translations, are now available. These include MediBabble [8], Canopy Medical Translator [9], and xprompt [10]. MediBabble is currently available in five languages, Canopy Medical Translator is available in 15 languages, and xprompt is available in 22 spoken languages and two sign languages. MediBabble and Canopy Medical Translator contain text and audio translations of extensive lists of questions and phrases covering topics such as medication, allergies, medical history, and current complaints. Xprompt, additionally contains video sequences for the two sign languages. To our knowledge, the only app that has been evaluated in a clinical setting is xprompt, with participants generally supporting the introduction of mobile apps to support communicating with foreign language patients but not very enthusiastic about the app's practical functionalities [10].

All four cited apps use text and audio to communicate the output of their translations, but evidence from cultural advocacy groups shows that CALD information should be available in a variety of formats including audio-visual and pictorial resources [11]. The requirements for multimodal formats are multifactorial. First, CALD groups have been shown to have low literacy levels, even in their first languages [11]. Second, CALD patients tend to be older and have age-associated vision and hearing decline [12], limiting the effectiveness of small text and low-grade audio.

Additionally, whereas MediBabble, Canopy and xprompt include questions and phrases for clinicians to communicate with patients, there is no functionality for the patient to respond effectively to the questions or instructions if they do not have proficient verbal skills in English. The omission of responses for questions with simple yes or no answers can be overlooked, but when clinicians require responses to open questions such as "What type of walking aid do you use?" or "How long have you been experiencing pain?" existing apps do not assist patients in responding. This scenario is likely to frustrate the patient and the clinician.

Introducing CALD Assist as a Novel Communication App

This paper reports the design, development, and feasibility evaluation of CALD Assist, a novel user-centric communication app designed to support assessments with CALD patients when an interpreter is not present. To inform the app's design and content, we conducted a user needs analysis with clinicians from five allied health groups. To assess feasibility of the resulting app under hospital conditions, the app was trialed for 6 months in a controlled introduction at Western Health, a hospital in Victoria, Australia.

Evaluation results demonstrate that a mobile app can effectively be used to assist allied health clinicians during their initial

assessments with patients from non-English speaking backgrounds. By using the CALD Assist app, clinician confidence during initial assessments of patients from non-English speaking backgrounds increased, whereas the time required to complete an assessment in the absence of an interpreter reduced.

Methods

Design

A user needs analysis was undertaken to inform the content, design, and structure of the CALD Assist app. Two components were undertaken as part of the user needs analysis: (1) a review into the languages required to be part of app and (2) focus groups conducted to elicit information from allied health end users on their current practices and modes of assessment [10].

After the final development of the app, a feasibility evaluation based on a comparative (before and after) study was conducted to quantify the value provided by CALD Assist in assisting allied health clinicians to complete assessments with patients from non-English speaking backgrounds when an interpreter was not available. Specifically, we aimed to determine (1) staff and patient acceptance and satisfaction levels and (2) efficacy of the iPad app. The evaluation was divided in two stages: a baseline data collection stage and a live trial.

All stages of the project included in the user needs analysis and feasibility evaluation were conducted with ethics approval from Western Health Low Risk Human Research Ethics Committee (LNR/14/WH/143).

Participants

Inclusion criteria for clinician participation for both components of the study required participants to be employees of Western Health, working as allied health clinicians within physiotherapy, occupational therapy (OT), speech pathology, dietetics, or podiatry.

Recruitment of user needs focus group participants was achieved through the managers of allied health discipline. Each identified staff member was invited by email. A total of 19 staff members participated.

The feasibility evaluation included clinician and patient participant groups. All focus group participants were invited and agreed to participate in the baseline data collection stage of the evaluation. Additionally, all allied health staff working on wards where the CALD Assist app was introduced were invited to participate in the live trial. Candidate clinical participants were contacted via an invitation email that included a copy of the information sheet and consent form. Clinician training was conducted by the principal investigator (PI) at designated allied health discipline staff meetings. A total of 58 clinician participants were recruited to the trial, including the 19 participants who also consented for the focus groups and baseline data collection. As opportunity to participate was dependent on a need for the app on trial wards during the trial period; not all clinicians were able to take part.

During the live trial, non-English speaking patients attending a follow-up assessment were invited to provide feedback with

an interpreter present. Consent was obtained through the interpreter. One patient participant was recruited.

Procedure

User needs focus groups lasted up to 90 min, and each group was attended by clinicians from a single allied health discipline. Each focus group was audiorecorded. Aspects under discussion included the type of patient typically assessed, the timing of the assessments in relation to the patient journey (on admission, discharge, etc), the duration, outcomes and implications of the assessments, the phrases or instructions used during an assessment, the assessment setting, and the broad challenges seen to impact on the successful integration of the app into standard care in the inpatient setting.

As a follow-up exercise, participants were asked to identify phrases suitable for their app-enabled assessments. These were provided to the researchers in the week following the focus groups. The phrase lists supplied during and after the focus groups were aggregated, refined, and classified in relevant subgroups by the project team before being circulated to participants and colleagues for discussion and approval.

The feasibility evaluation was based on a comparative (before and after) study conducted on eight wards across 2 campuses of Western Health, in Victoria, Australia. Wards comprised acute aged care, acute orthopedics and neurosurgery, general medicine, oncology and gastroenterology, surgical, respiratory, and neurology. Baseline data were collected by clinicians conducting assessments on CALD patients in the absence of the app over a period of 3 months. These data pertain to information about the patient and the nature and duration of the assessment. Following the baseline data collection, a live trial was conducted over a 23-week period. The trial commenced in February 2015, with the CALD Assist app being introduced on four wards and expanded in June 2015 to include four additional wards.

Software embedded in the CALD Assist app captured interaction logs showing all app usage during the live trial. Additionally, qualitative data were sought from primary and secondary app users, clinicians, and patients, respectively, and was captured through 3 separate questionnaires:

1. *The post assessment questionnaire*, which clinicians had the option to complete after they conducted an assessment using the CALD Assist app. This data describe the nature and duration of the assessment, as well as basic information about the patient to determine whether the app was successful in facilitating assessments and improving communication between clinicians and patients.
2. *The participant feedback questionnaire (staff)*, completed on the Web by clinical staff at the end point of the trial. A link to this questionnaire was emailed to all clinician participants upon completion of the study. The survey captured details of clinician experiences with the app.
3. *The participant feedback questionnaire (patient)*, completed by the PI through an interpreter. The survey captured feedback from patients who experienced an assessment with the app. Responses to the questions were recorded by the PI present.

Data Analysis

Qualitative and quantitative analysis was used. All audio recordings were transcribed and analyzed by themes using NVivo (QSR International). Data logs were analyzed using Java (Oracle Corporation), and quantitative data resulting from questionnaires were analyzed using descriptive statistics.

Results

This section presents the results of the user needs analysis (language identification, focus groups, and app design) and the feasibility evaluation (app log analysis, baseline data, and live trial).

Languages Identified for Inclusion

A review of the 2011 Australian Census and Australian Bureau of Statistics data showed that 19% of Australians did not speak English at home. The most common languages spoken at home, excluding English, were Mandarin (1.7%), Italian (1.5%), Arabic (1.4%), Cantonese (1.3%), and Greek (1.3%). The community serviced by Western Health in Victoria is one of the most culturally diverse communities in Australia, with 38% speaking a language other than English at home, totaling over 150 languages and dialects.

In consultation with the Western Health language services manager, the number of occasions of interpreting service at Western Health were analyzed. The ten most common languages serviced by the Western Health language services were Mandarin, Cantonese, Vietnamese, Italian, Greek, Macedonian, Serbian, Croatian, Arabic, and Spanish, largely reflecting the common languages identified in the 2011 Australian Census. These ten languages were identified for inclusion in CALD Assist. Although the most unmet need at Western Health was for specific dialects such as Chin Hakka, the unmet need of this language was outweighed compared with the overall need of the most common languages.

Focus Groups: Understanding the Assessment Context and Content Requirements

Allied health assessment results inform treatment teams on manual handling, communication, and dietary plans, in addition to medical care plans. Delays in the provision of care and in discharging patients can increase the patient's length of stay, which inconveniences the patient and increases the cost of care.

Allied health assessments are usually conducted at the patient's bedside. Clinicians typically sit at the head of the bed and suggest that an iPad or similar device could be placed on a patient's table. Podiatrists differ from other allied health disciplines in that their assessment is conducted from the bottom of the bed as they examine the patient's feet. Podiatrists wear surgical gloves while conducting assessments and hold equipment such as scalpels. Thus, podiatrists identified the need for infection control procedures for use of the iPad and protocols to be introduced to ensure patient and clinician safety if both handling the device and their equipment. When questioned about suitable access to the intended CALD Assist app, all clinicians indicated a preference for the app to be available on each ward. A suggestion was made by a podiatrist that the

podiatry app could be located with the equipment that they carry to the patient's bedside.

Participants noted that in situations where an assessment of a CALD patient is required, but when an interpreter is unavailable, clinicians are resourceful and often attempt to gain some information from patients through the use of gesture and demonstration.

Physiotherapy, OT, and dietetic assessments require the patient to answer closed questions about their current, and often past, health status. Physiotherapy and speech pathology clinicians also observe patients doing actions such as walking, getting out of bed, climbing stairs, coughing, or swallowing as part of an assessment. The nature of the closed questions and instructions for physical assessments are well suited to a two-way communication app.

OT assessments are highly structured and gather detailed information on activities of daily living and the set-up of patient homes. Dietitians often complete a nutrition assessment that requires responses to open-ended questions. The detailed nature of both of these assessments limits the applicability of a full OT or dietetics assessment for this app, but participants agreed that an app could ascertain some useful basic information while waiting for a full assessment, or in determining if a full assessment is required.

Podiatrists assess patient's feet, and podiatry assessments typically include some treatment (eg, lancing a wound or debriding) that requires use of instruments such as scalpels and as such is more invasive than other discipline assessments. Thus, including the ability to gain consent from patients for podiatry input and being able to explain each stage of the podiatry assessment and intervention process to the patient were important factors.

All clinicians suggested that the app would facilitate broader communication than simply the assessment content. Participants noted the need for clinicians to be able to introduce themselves and to explain a little about the assessment and its purpose. Similarly, being able to exit an assessment, explain next steps, or inform the patient that they will return were considered important in increasing patient comfort and experience.

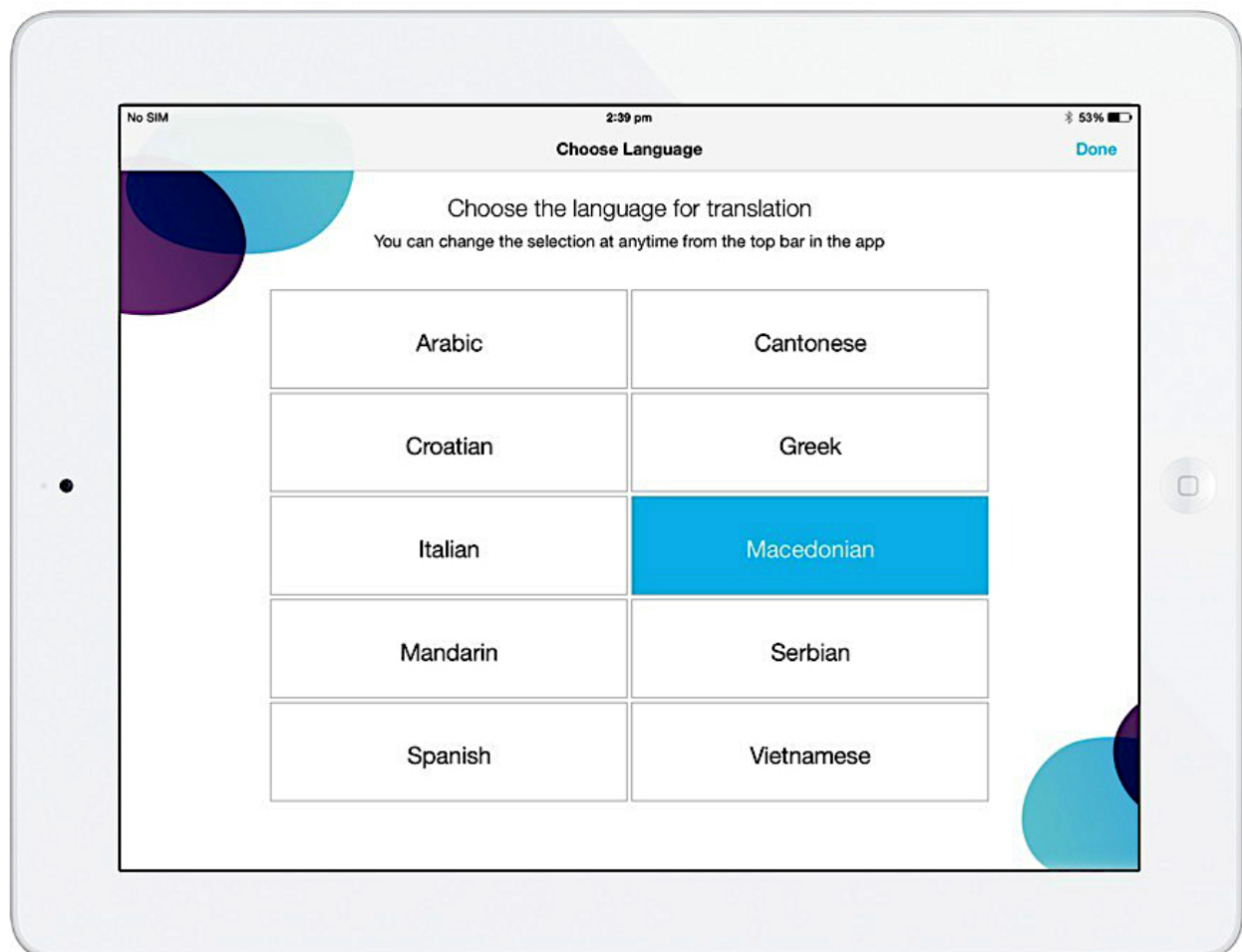
Participants also noted the value of being able to provide education or strategies to patients around precautions that they should be taking, given their conditions. These included safety precautions for a patient's time in hospital, such as not walking to the bathroom unaccompanied, eating slowly, and keeping wounds dry, and recommendations for use of equipment at home once discharged. Dietitians, speech pathologists, and OTs noted a desire to be able to show patients images to ascertain knowledge about preferences for food and drink, to communicate instructions, and equipment used at home. Speech pathologists and OTs suggested video content to demonstrate appropriate swallowing and movements. Further information on the focus groups is provided in the study by Albrecht et al. [10].

App Design Overview

On the basis of the outcomes of the user needs focus groups, CALD Assist was developed to be simple in design and function. To use the app in an assessment, the allied health clinician selects a language for use from the ten languages listed (Figure 1). The clinician then selects the group of phrases that they wish to access, grouped by discipline, and the type of phrase that they wish to use, grouped by section (Figure 2). Users can also search for a phrase using keywords. All phrases were translated using a professional translation service and reviewed by professional interpreters employed at Western Health. Audio for each phrase was recorded by the Western Health interpreters.

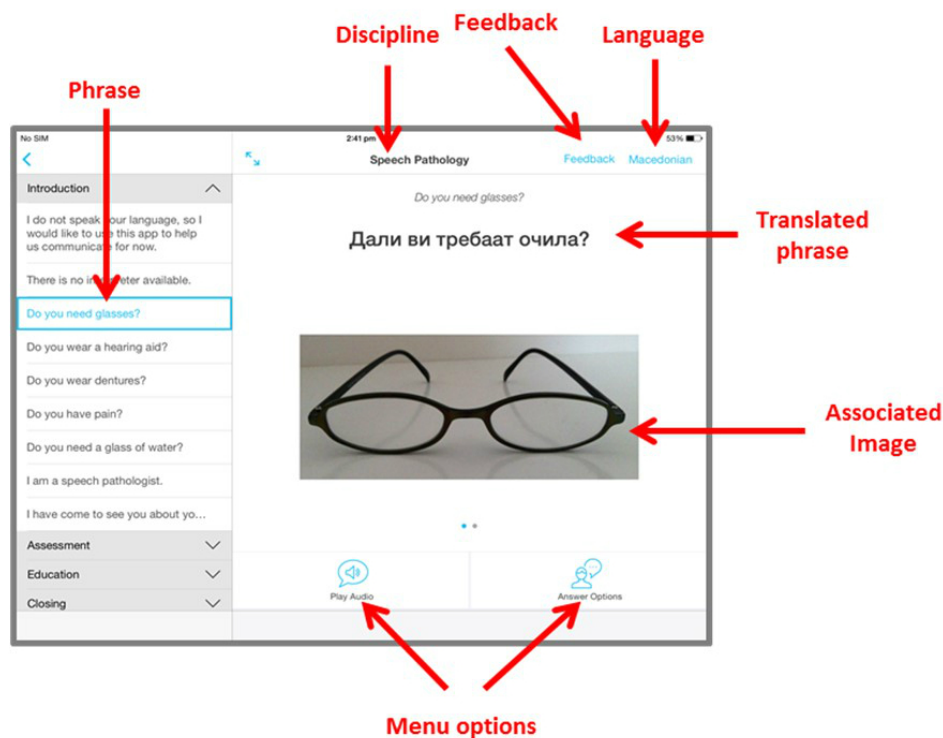
A total of four sections containing different types of phrases were identified for each discipline: introduction, assessment, education, and closing. A *general phrases* subsection was added to provide simple access to generic phrases for all disciplines, such as “Do you need glasses?” or “Do you have pain?” A sample of the phrases requested by the speech pathology participants is shown in Table 1.

Figure 1. CALD Assist language selection.



Upon selection of an individual phrase, the content (translated text and appropriate images or video) are displayed on the screen and can be shown to a patient (Figure 2). The menu options allow the clinician to play the audio for the phrase through the built-in iPad speaker. For many questions, gesture-based responses are expected from patients. Where the question has specific answers that cannot be conveyed through gesture, the clinician can display some “answer options” that include text and images. Where a phrase has follow up questions, these can also be accessed through the on-screen menu. All images can be enlarged, and users can swipe between images when more than one image or video is associated with a phrase.

For evaluation purposes, when a clinician completes an assessment, they can select the feedback option on screen. This brings them to the post assessment questionnaire where they can record their experiences using the app. CALD Assist was built as an iPhone operating system (iOS, Apple Inc) 8 compatible iPad app.

Figure 2. CALD Assist app overview.**Table 1.** Sample phrases from speech pathology participants.

Section	Phrase
Introduction	I am a speech pathologist.
	I don't speak your language, so I'd like to use this app to help us communicate for now.
Assessment	Do you cough when you eat or drink?
	Point to where the food is getting stuck.
Education	Sit up when you eat and drink.
	Eat and drink slowly.
Closing	I will return with an interpreter.

Baseline Data

A total of 45 assessment records of CALD patients were obtained by clinicians, with a balance of male ($n=25$) and female ($n=20$) patients, although not all clinicians answered all questions. The majority of patients (98%, 44/45) required an interpreter. The average age of patients requiring interpreters was 75.6 (standard deviation [SD] 15.5), with the youngest patient being 27 years and the oldest being 95 years. The reported time to complete assessments was 41.9 min (SD 16.39) (84% [38/45] of clinicians responded). In line with published data [11,12], participants noted that older CALD patients tended to have age-related sight or hearing impairments that needed consideration, and they may not be literate in their native language.

When clinicians were asked about their confidence that patients' understood their questions or instructions, 30 of 45 responded. Of these 30, 57% (17/30) responded that they had no confidence, 33% (10/30) responded that they had moderate confidence, and 10% (3/30) that they had complete confidence. It is noted that

those reporting complete confidence had the patients' family member in the room assisting with communication. Clinicians reported that only 50% (20/40 responses) of assessments were completed, with 24 clinicians giving reasons for non-completion including language barriers as the main barrier to completion (67%, 16/24), followed by health of the patient (13%, 3/24), and other (21%, 5/24).

CALD Assist's inbuilt logging captured all usage data during the live trial. A single session was defined as an episode of use, where at least one phrase is selected. Given the unsupervised nature of app usage, it is not possible to distinguish between app familiarity sessions and usage in real assessment sessions. Considering that as all participants were provided with training where they had access to the app before the start of the trial, we propose that the activity captured during the trial phase corresponds to usage in assessment contexts. A total of 32 sessions were captured in 23 weeks, indicating that CALD Assist was used to perform an assessment in the absence of an interpreter on average once a week.

Table 2 shows the uptake of CALD Assist on each of the eight wards on which it was deployed. The first four wards had iPads with CALD Assist supplied for 23 weeks, the remaining for 6 weeks. Equivalent usage levels were recorded in the wards included in the initial rollout, with each ward conducting between six and nine assessments in total, or between 0.26 and 0.36 uses per week. The length of session use varies between wards but SD is high, indicating a range of assessment times across each ward.

The app was used to provide support in a range of languages, with the most frequently selected being Greek, used in 27% (7/26) of the sessions. Vietnamese (19%, 5/26) and Cantonese (15%, 4/26) were also popular, followed by Italian (12%, 3/26), Mandarin (8%, 2/26), and Croatian (8%, 2/26). Spanish, Serbian, and Arabic were each used one single time, whereas Macedonian was not used at all. Language data for the remaining 6 sessions

is unavailable. Uptake of CALD Assist varied by clinician type. Speech pathologists used the app more frequently than other disciplines, with 13 sessions recorded (**Figure 3**). High uptake was also recorded by physiotherapists (ten sessions). Usage by dietetics, OT, and podiatry was low with less than six sessions recorded each.

Of the 95 phrases included in the app, 54 were used during the trial. The most frequently used phrase in the library was a phrase used to introduce the app to patients: “*I don't speak your language, so I'd like to use this app to help us communicate for now.*” This phrase was used twice as often as the next most popular phrase: “*Do you have pain?*” High usage of phrases used to explain the absence of the interpreter, “*There is no interpreter available,*” and to introduce clinician groups, “*I am a speech pathologist*” and “*I am an occupational therapist,*” are noted.

Table 2. CALD Assist usage during the trial period.

Trial period and ward	Sessions	Clicks	Duration (min) Mean (standard deviation)
Usage: 23 weeks			
Acute aged care	8	97	12.12 (16.99)
General medicine	6	36	6.00 (7.92)
Acute orthopedics and neurosurgery	6	83	13.83 (14.67)
Oncology and gastroenterology	9	67	7.44 (7.72)
Usage: 6 weeks			
Surgical	1	1	1 (0)
Neurology	0	0	0
General medicine	1	0	0
Respiratory	1	5	5.00 (0)

Figure 3. Sessions per discipline. Note that more than one discipline could have been accessed in a single session, according to the clinician needs. As a result, this figure represents more than the 32 total sessions.

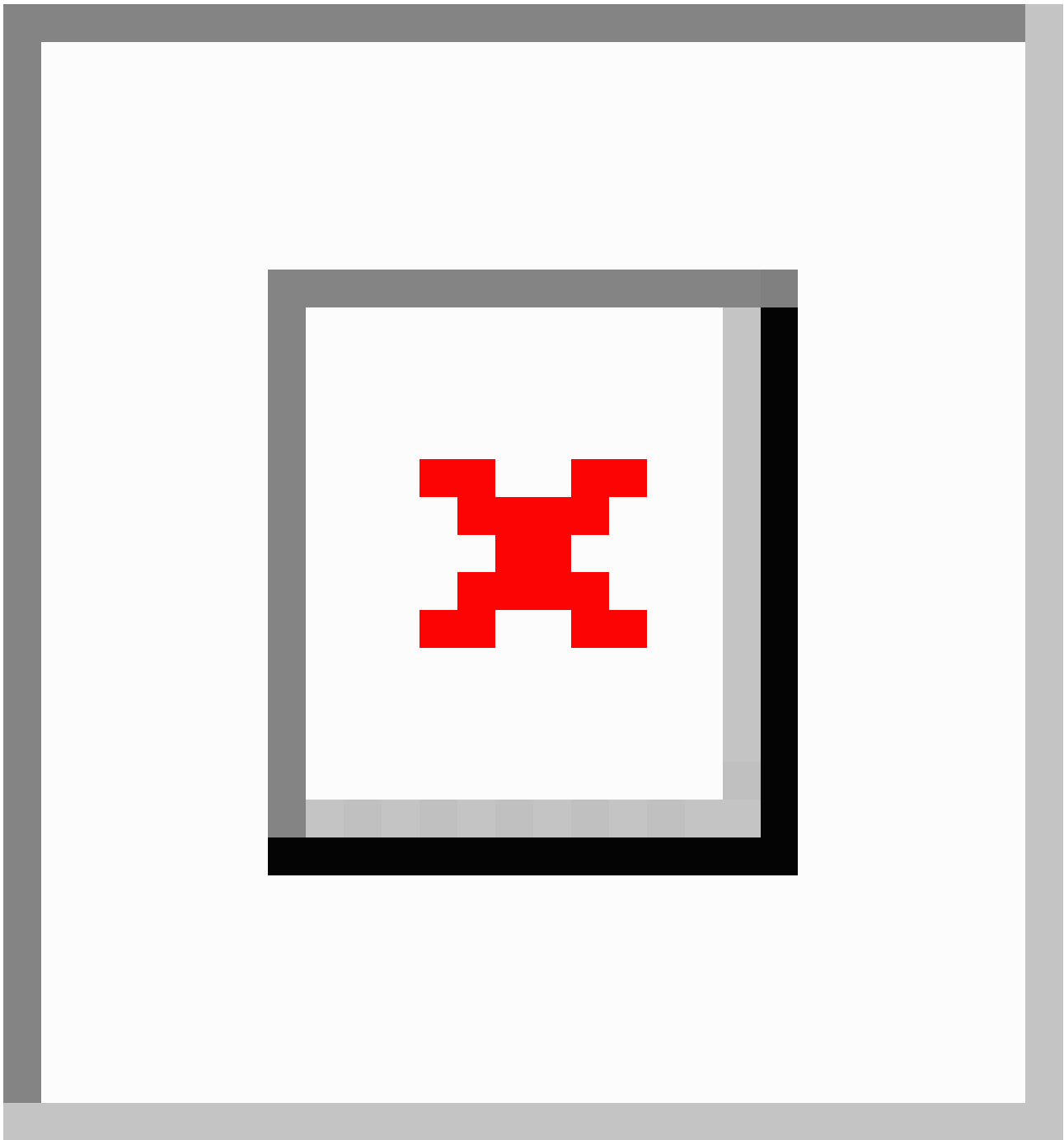


Table 3. CALD Assist top phrase usage. This list includes only the phrases that were used in at least four sessions.

Phrase	Discipline	Phrase type	Sessions
I don't speak your language so I'd like to use this app to help us communicate for now.	General	Introduction	12
Do you have pain?	General	Assessment	6
There is no interpreter available.	General	Introduction	6
I am a speech pathologist.	Speech pathology	Introduction	6
I have come to see you about your swallowing.	Speech pathology	Introduction	5
Copy me.	Speech pathology	Assessment	5
Do you use a frame or stick?	Physiotherapy	Assessment	5
Do you need help with bathing?	Occupational therapy	Assessment	4
Please swallow.	Speech pathology	Assessment	4
Do you wear dentures?	General	Assessment	4

In total, the 54 phrases were used 154 times. Of the phrases used, 61.6% (95/154) were assessment phrases, 29.2% (45/154) were introduction phrases, 7.1% (11/154) were education phrases, and 1.9% (3/154) were closing phrases. Grouping phrases by discipline shows high use of the speech pathology and OT phrases. General phrases, available in disciplines, were also common (Table 3).

The average number of phrases used in assessments varied with each discipline. A higher number of phrases (6.2 per session) were used in OT sessions, confirming the findings that OT assessments are detailed and require more questions. Speech pathology and physiotherapy used an average of 3.2 and 2.2 phrases per session, respectively.

Examination of the usage logs shows the selection of a phrase is the most popular task completed, followed closely by playing

the audio accompanying the phrase (Table 4). We see reasonable use of the swipe between image function, which is used to browse between multiple images relevant to a single phrase. The capability to show follow up phrases and answer options was rarely used. Low use of the search feature and phrase library list was noted.

Post Assessment Questionnaire

Clinician's had the opportunity to provide feedback using the feedback option on the screen (Figure 2). A total of 12 feedback questionnaires were provided by staff participants for assessments conducted with 5 male and 7 female patients in the age range of 21 to 94 years (average age=74 years). To identify the potential impact because of the introduction of the CALD Assist app, data from these questionnaires were compared with the data collected during baseline (Table 5).

Table 4. Functionality uptake.

Function	Uses	Sessions
Choose phrase	189	21
Play audio	125	17
Swipe image	86	10
Show feedback form	16	14
Phrase image tapped	12	6
Select feedback incomplete option	12	7
Show answer options	12	7
Choose phrase library phrase	7	4
Search	6	3
Do patient survey	4	2
Show follow-up questions	3	2
Choose full screen mode	2	1
Phrase movie tapped	2	2

Table 5. Improvement in efficacy in app-enabled assessments compared with standard assessment. Percentages are rounded to the nearest decimal and therefore may not add to 100%. Baseline data were completed by 45 clinicians, not all of whom answered every question. Post-trial data were completed in full by 12 clinicians.

Measures	Baseline	CALD Assist
Time to complete assessment (mins)		
Max	80	30
Min	10	2
Mean (standard deviation)	42.97 (16.34)	15.58 (8.61)
Confidence in assessment, n (%)		
No confidence	17 (57)	2 (17)
Moderate confidence	10 (33)	5 (42)
Complete confidence	3 (10)	5 (42)
Completed assessments, n (%)		
Yes	20 (50)	6 (50)
No	20 (50)	6 (50)
Reason assessment not completed, n (%)		
Language	16 (67)	0 (0)
Health of patient	3 (13)	2 (33)
Participation of patient	0 (0)	4 (66)
Other	5 (21)	0 (0)
Interruption	0 (0)	0 (0)
Phrase not available	0 (0)	0 (0)

Following implementation, improvements were seen in the length of time required to complete assessments, with the average time required falling from 42 min to 15.6 min. The number of noncompleted assessments was consistent before and following app implementation; however, the reason for noncompletion differed markedly. Before app implementation, 16 unfinished assessments (of the 24 for which reasons were given, 67%) could not be completed for reasons related to language, whereas after implementation, no clinicians cited language as a causative factor. Health and participation of patients were issues that were beyond the scope of the app to address.

Importantly, we see that clinician confidence in their assessment increased with use of CALD Assist. Assessments where no confidence was reported decreased from 57% (17/30) to 17% (2/12). Assessments where complete confidence was reported increased almost fourfold from 10% (3/30) to 42% (5/12). This demonstrates that clinicians believe that they are communicating more effectively with patients when using CALD Assist.

Staff Participant Feedback

Six responses were received from the Web-based *participant feedback questionnaire (staff)* at the end of the trial. Feedback was received from 3 speech pathologists, 2 dieticians, and 1 occupational therapist. Measures included choosing between a pair of descriptors and usability questions informed by discussions with clinicians. All respondents were female, with an average of 7.5 years of clinical experience. The majority of

participants used only positive terms to describe the app (Table 6), with only 1 participant using three negative terms: annoying, not enjoyable, and not effective.

There was greater variation in the self-report section of the *participant feedback questionnaire (staff)* (Table 7). In general, most participants agreed or were neutral to phrases about the app's ease of use, operation, and clarity. One participant disagreed with the statement that it was easy to get the app to do what they wanted. One participant suggested patients appeared to have problems when communicating with the app, 3 people were neutral, and 2 proposed that patients did not have problems when using the app.

The participant questionnaires also included a section for free text feedback; comments include the following:

- Expansion to include further phrases would be ideal.
- Expansion to include further languages would be ideal.
- It would be great to be able to play audio for instructions or questions that have a second lot of options
- Fantastic app and definitely helpful if no interpreter available. At times, difficult to use if patient is significantly cognitively impaired.
- Often would have loved to use it but required language not available on app.
- Access is a big barrier, it would be used more if the app was located more centrally.
- Excellent tool!

Table 6. Term options given to participants to describe the app during feedback (n=6).

Term pairs (negative — positive)	Negative respondents	Positive respondents
Unpleasant — pleasant ^a	-	6
Bad — good	-	6
Annoying — supportive ^a	1	5
Not enjoyable — enjoyable	1	5
Not effective — effective ^a	1	5
Useless — useful	-	6
Irritating — likable ^a	-	6
Worthless — valuable	-	6
Boring — exciting ^a	-	6
Ugly — attractive	-	6
Harmful — beneficial	-	6

^aThis subset of pairs of descriptors was used for patient feedback.

Table 7. Self-reported function and usability of the app (n=6).

Question	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
I found the app easy to use	-	-	1	2	3
I enjoyed using the app	-	-	2	1	3
I found it easy to get the app to do what I wanted	-	1	1	2	2
Learning to operate the app was easy for me	-	-	-	2	4
I found it easy to become skillful at using the app	-	-	2	2	2
My interaction with the app was clear and understandable	-	-	2	3	1
Patients did not appear to have problems when communicating via the app	-	1	3	1	1
The app was useful as a communication tool when interpreters were not present	-	1	2	-	3
All of the phrases that I needed were available in the app ^a	1	1	-	2	1
All of the images or videos that I needed were available in the app ^a	1	1	-	2	1
All of the languages that I needed were available in the app ^a	-	2	-	-	3
The app contain phrases that are appropriate for me to carry out initial assessments ^a	-	1	-	-	4

^aOne participant did not answer this question.

Patient Participant Feedback

A 74-year-old male who spoke Croatian consented to participate by completing the *participant feedback questionnaire (patient)*. He strongly agreed with all questions assessing effectiveness of the app (I was comfortable with the app being used for my assessment, the iPad app helped me communicate with my therapist and was useful as a communication tool, I understood what the therapist was trying to say, because they used the iPad app, I could clearly hear the audio that the iPad app played, and I could clearly see the screen of the iPad app). When asked to choose descriptive terms for the app (see descriptor pairs in Table 6), he choose four positive terms (pleasant, supportive, effective, and likeable), but when presented with a choice between boring and exciting, he chose boring.

Discussion

Principal Findings

Our key findings show that CALD Assist was used, on average, once a week to complete an initial assessment. Through its use, a number of patients from non-English speaking backgrounds received timely initial assessments and subsequent care, in line with their English speaking peers. Thus, CALD Assist can be seen to have contributed to the goal of the delivery of equitable health care. Additionally, CALD Assist was positively accepted by clinicians who reported increased levels of confidence when communicating with non-English speaking patients when they had access to the app.

We note the high utilization of introductory phrases that allow clinicians to introduce themselves, explain their purpose, and that interpreters are unavailable, which was not possible to achieve before CALD Assist. We also note high usage of a variety of assessment phrases used and high usage of the audio and image cues. This domination of assessment phrases is expected, as the main aim of the app is to facilitate assessments. In most sessions, a number of phrases are used in succession rather than a single phrase used in an ad hoc manner. Finally, the app was used more by the speech pathology clinicians and physiotherapists than the other disciplines. This is not surprising as our needs analysis uncovered the detailed nature of assessments in OT and dietetics domains, the complicating factors of a podiatry assessment requiring the wearing of surgical gloves, and the clinician being positioned at the patient's feet. We note that although podiatry and dietetics did use the app, their assessments typically only included a single phrase. It is possible that these clinicians initiated assessments but were unable to complete them using the app. We expect that through increased familiarity and promotion campaigns, we will see increased usage of CALD Assist in those disciplines.

CALD Assist does not aim to replace interpreters but to assist in communication when interpreters are unavailable. Thus, we note the rise in clinician confidence in communicating with patients in the absence of an interpreter following the introduction of CALD Assist. We have shown that clinicians are more confident that patients have understood their requests and that language is no longer the main barrier to the completion of assessments. Outside of our formal data gathering, clinicians reported several success stories for CALD Assist not captured through our formal data collection procedure.

Through use of CALD Assist, a speech pathologist determined that ear, nose, and throat (ENT) specialist input was required for a patient who was receiving a swallow assessment, and a referral to the ENT team was made immediately. With use of CALD Assist, it was also determined that a follow-up review was not required. The speech pathologist commented that without CALD Assist they would not have been able to determine the need for ENT and would have needed to return to complete a swallow review the following week when an interpreter was available. In this case, appropriate care was determined through use of CALD Assist when a significant wait time for an interpreter was estimated.

On a separate occasion, a speech pathologist reported advantages of using CALD Assist with patients who are cognitively impaired, a situation where we'd expected the app not to be used. The clinician reported that without CALD Assist the patient was easily distracted; however with CALD Assist, the patient was able to easily attend to the instructions and information provided by the speech pathologist. Although cognitive impairment may impact communication in general, but specifically communication with the app, this example shows that not all cognitive impairments are barriers for CALD Assist use and that benefits of focused delivery through an app exist in health care situations. There were also cases where sufficient information was gathered from a patient with CALD Assist to no longer warrant a full assessment with an interpreter, and the

research team had repeated requests from clinicians on nontrial wards to gain access to CALD Assist for their patients.

Negative responses to content feedback (Table 6) suggest that now that the app has been used, refinement of the phrases, images, and languages is recommended. Five participants agreed that the app had appropriate content for their assessments, but negative feedback pertaining to the app having all the phrases and languages needed suggest that additional phrases and languages are desirable, and additional images and videos for existing phrases should be considered. This is supported by the comments, several of which relate to potential refinements. Despite the research protocol specifying that an iPad be located on each ward for clinicians to use, one comment suggests that the iPads were not centrally located. This could explain low usage on some wards and would need to be rectified before commercialization. Additionally, 1 participant disagreed with the ease of use of the app, suggesting that a need for additional training or a revision of design may be needed.

It was identified that other languages may have more prominence in other metropolitan catchments of Australia. For example, there is a greater need for Hindi interpreters in southeast Melbourne and a greater need for Aboriginal dialects in Queensland and the Northern Territory. However, there may be reduced generalization when comparing with Australia-wide trends and needs.

Although it is clear that the app improved the delivery of equitable health care for patients through the reduction in consultation times and provided additional benefits from the perspective of the clinicians, only one feedback questionnaire was obtained from patient participants. Although the responses to this questionnaire were generally positive, alternative methods to obtain additional patient feedback would be required in future research to gather a deeper understanding of the patients' perception of the app that could inform future developmental stages.

Challenges

Despite receiving mostly positive feedback, the introduction of CALD Assist was not without its challenges. Throughout the project, a number of hurdles were faced that impacted on uptake of the app and the level of feedback received during the trial.

First, the hospital performing the trial underwent significant organizational change immediately before the trial, which included the opening of a new intensive care unit and cardiac care unit and a reorganization of wards or units. This included staff in the 2 campuses included in the trial. It is hypothesized that this significant change in ward, service, and staff location impacted on the use of CALD Assist. Many staff participants were required to relocate to new workplaces or clinical areas, and priority was duly given to meeting organizational strategic priorities rather than implementing a new technology. We saw great levels of enthusiasm in the user needs analysis of the trial, and details on 45 assessments were gathered in the 3-month baseline data gathering phase, illustrating that clinical staff were keen to inform the development of the app and participate in this research before organizational change. Despite a 23-week trial period, only 12 assessment details were recorded, and low

responses to feedback questionnaires were received. Second, clinicians are busy people with many patients under their care, and because of ethics constraints, we were unable to directly follow up with participants other than to send a reminder email encouraging feedback.

Third, the introduction of new clinician-focused technology in a hospital environment was also a challenge faced by the project team. Many experienced clinicians reported that they found it challenging to change established behaviors or practices. As a result, they may enter an assessment session without considering CALD Assist as a tool to facilitate assessment. Further promotion of the CALD Assist app will continue during the next 12 months to further embed its use in current practice.

Finally, CALD Assist was used successfully to conduct assessment with many patients. However, it was challenging to collect meaningful feedback about the app directly from patients. It is hypothesized that this was largely because of patients being acutely unwell in an unfamiliar and often overwhelming hospital environment. Obtaining patient feedback proved to be more difficult than expected. Many of the patients who had assessments conducted with the assistance of the CALD Assist were suitably aware for the app to be used effectively for the assessment; however, they were unable to provide feedback during clinical review because of cognitive impairment and an inability to recall the use of the app. The delay between use of the CALD Assist and collection of feedback may have contributed to patient's recall of the app; however, this delay was largely unavoidable because of the need for an interpreter to assist with the collection of feedback.

Comparison With Prior Work

CALD Assist is unique in facilitating two-way communication between patients and clinicians. Although MediBabble, Canopy, and xprompt include questions and phrases for clinicians to communicate with patients, there is no functionality for the patient to respond effectively to the questions or instructions if they do not have proficient verbal skills in English. The omission of responses for questions with simple yes or no answers can be overlooked, but when clinicians require responses to open

questions, existing apps do not assist patients in responding. Patients' only response option is to answer in their native language, which the clinician is unlikely to comprehend. This scenario is likely to frustrate the patient and the clinician. CALD Assist provides translations of response options through both images and text. When asked what type of walking aid they have in their home, patients can browse a set of images to identify an aid similar to the one which they own. When asked how long they have been experiencing pain, they can indicate on a timeline of days, months, or weeks annotated in their own language. The ability to seek detailed information from patients through two-way communication is a key advantage in an environment where accuracy is relied upon. We believe that the inclusion of images and video demonstrations in CALD Assist increased the ability to communicate with patients and overcome age- and literacy-related barriers.

As is the case with many mobile apps, neither MediBabble and Canopy nor xprompt provide evidence on their efficacy. Little information is available on the efficacy of mobile technology in the health domain [13-17], which causes reluctance by policy makers and clinicians to include the mobile apps in standard practice. Although not yet clinically evaluated, available technologies suggest that a mobile app may be used to assist patient-clinician communication when interpreters are unavailable; reducing inequity in service delivery, improving staff confidence, and patient care. Nonetheless, a number of gaps need to be addressed before this technology can be effectively used in a clinical setting, including the provision of high grade audio-visual and pictorial resources, a design that is practical and easy to use by clinicians, and allowance for patient responses.

We hope that by providing evidence in the design and evaluation of CALD Assist that we have addressed these gaps and will instill confidence in allied health clinicians in the use of the app as part of their care delivery. We look forward to comparing the patient experience with CALD Assist to other apps in the market in future studies. CALD Assist is available for download to iPads via the Apple App Store.

Conflicts of Interest

None declared.

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Abbreviations

- CALD:** culturally and linguistically diverse
ENT: ear, nose, and throat
OT: occupational therapy
PI: principal investigator
SD: standard deviation

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Original Paper

A Web-Based Platform for People With Memory Problems and Their Caregivers (CAREGIVERSPRO-MMD): Mixed-Methods Evaluation of Usability

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Abstract

Background: The increasing number of people with dementia (PwD) drives research exploring Web-based support interventions to provide effective care for larger populations. In this concept, a Web-based platform (CAREGIVERSPRO-MMD, 620911) was designed to (1) improve the quality of life for PwD, (2) reduce caregiver burden, (3) reduce the financial costs for care, and (4) reduce administration time for health and social care professionals.

Objective: The objective of this study was to evaluate the usability and usefulness of CAREGIVERSPRO-MMD platform for PwD or mild cognitive impairment (MCI), informal caregivers, and health and social care professionals with respect to a wider strategy followed by the project to enhance the user-centered approach. A secondary aim of the study was to collect recommendations to improve the platform before the future pilot study.

Methods: A mixed methods design was employed for recruiting PwD or MCI (N=24), informal caregivers (N=24), and professionals (N=10). Participants were asked to rate their satisfaction, the perceived usefulness, and ease of use of each function of the platform. Qualitative questions about the improvement of the platform were asked when participants provided low scores for a function. Testing occurred at baseline and 1 week after participants used the platform. The dropout rate from baseline to the follow-up was approximately 10% (6/58).

Results: After 1 week of platform use, the system was useful for 90% (20.75/23) of the caregivers and for 89% (5.36/6) of the professionals. When users responded to more than 1 question per platform function, the mean of satisfied users per function was calculated. These user groups also provided positive evaluations for the ease of use (caregivers: 82%, 18.75/23; professionals: 97%, 5.82/6) and their satisfaction with the platform (caregivers: 79%, 18.08/23; professionals: 73%, 4.36/6). Ratings from PwD

were lower than the other groups for usefulness (57%, 13/23), ease of use (41%, 9.4/23), and overall satisfaction (47%, 11/23) with the platform ($P < .05$). Qualitative comments related to both improvements for functionality and the platform interface.

Conclusions: Although caregivers and professionals were overall satisfied with the platform, further adaptations were recommended by PwD. This reiterates the importance of the involvement of end users in the development of Web-based interventions. Recommendations from users in this paper apply for the interface and functionality of a wider range of Web-based support interventions.

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KEYWORDS

dementia; technology; social support; caregivers

Introduction

Background

The increasing number of people with dementia (PwD) and its progressive nature has led researchers to explore tools to provide support to larger numbers of PwD and their caregivers. A range of Web-based support interventions have been designed and evaluated including websites providing material and training for caregivers [1,2] and Web-based portals to enable communication with health care professionals [3]. Other Web-based support interventions combine educational material, communication with health care professionals, and monitoring of PwD well-being through Web-based questionnaires [4].

To aid the development of successful Web-based support interventions, researchers utilize user-centered designs to refine devices and technology to meet the needs of the targeted population [5]. A continuous and iterative involvement of users (eg, through focus groups or interviews) is widely seen vital in the design of technological solutions [6]. Usability in this context is measured as the user-friendliness (eg, ease to learn) and perceived usefulness in addressing users' needs [7].

In a recent study, a Web-based portal (the Digital Alzheimer Center; DAC) was developed in Netherlands for PwD and caregivers [8]. DAC provides information on dementia, promotes peer support and communication, and enables communication with health professionals. The usefulness and usability of the DAC was assessed through evaluation from PwD and caregivers. Both the participant groups found DAC useful. Involving users in the development and evaluation of Web-based support interventions enables researchers to understand their unmet needs and increase user autonomy [9]. Other projects developing technological devices for PwD and caregivers have also taken into account the perceived usability from the perspective of end users. In the Skills Training and Reskilling (STAR) project [3], a Web-based training portal was developed to offer learning opportunities to caregivers, as well as peer support and contact with care professionals. Informal caregivers, volunteers in dementia care, and professional caregivers rated the STAR Web-based portal as useful and user-friendly. In the Rosetta project [10], 3 previously developed tools were merged, the COGKNOW Day Navigator [11], the Emerge system [12], and the Unattended Autonomous

Surveillance system. This platform is offered through a touch screen and provides reminders for activities, a phone dialing system with pictures, a radio button, activity support for performing everyday tasks (eg, preparing coffee), and safety warnings (eg, the door is open). The platform also offers monitoring and emergency function with sensors monitoring daily activities, as well as automatic detection of emergencies. Data from PwD, informal caregivers, professionals, and dementia experts were collected to rank the usefulness of the Rosetta functions and to collect information about improving the system.

Aims and Objectives

This study aims to explore the usability and user-friendliness of the CAREGIVERSPRO-MMD platform [13] through evaluations performed by PwD or mild cognitive impairment (MCI), informal caregivers, and health and social care professionals. The CAREGIVERSPRO-MMD platform targets the dyad of PwD or MCI and their informal caregivers, alongside their health and social care professionals. The platform is being developed based on a user-centered approach identifying (1) the characteristics of PwD and caregivers affecting their ability to use Web-based tools and (2) the user requirements for the platform functionality. The platform is being piloted at 4 centers in Italy, Spain, France, and the United Kingdom. One innovation of the CAREGIVERSPRO-MMD platform is that it integrates many features that have previously been tested individually, namely: (1) peer-to-peer social contacts through circles of friends, (2) forums or cafes for open discussions, (3) practical information about dementia and local resources, (4) open monitoring of user well-being through Web-based questionnaires and activity measures through interactions with the platform, and (5) guided personalized educational material about living with dementia or MCI and caregiving. The platform integrates a gamification engine designed to increase user engagement. Behind the platform, a machine learning engine will attempt to present the features of the platform to users to maximize the benefit. The aim of the platform is to improve the quality of life for PwD or MCI and reduce caregiver stress. Secondary aims are to delay institutionalization for PwD, reduce care costs, and reduce administration time and costs for professionals. The functions available in the early version of the platform in the usability test are presented in [Table 1](#).

Table 1. Platform functions tested in this usability study.

Name	Activity of platform functions
Home page	Sharing and replying to messages
My Network	Creating a network of peers
My profile	Uploading personal information
My Agenda	Recording appointments and events and setting reminders
Invitations	Reviewing invitations sent from other users
Café (Forum)	Sharing information, tips, and support in a social networking forum
My Health	Completing Web-based questionnaires to monitor health and well-being
Local resources	Seeking information about local services that offer help and support
Create user profiles	Creating accounts to enroll people with dementia (PwD) and caregivers to the platform (for professionals only)
Managed users	Reviewing the profiles of PwD ^a and caregivers (for professionals only)

^aPwD: people with dementia.

The aim of this study was to test the usability of the early version of the platform (usefulness, ease of use, user satisfaction) for PwD or MCI, primary caregivers and professionals. A secondary aim was to generate recommendations from users that could be utilized to further improve the platform.

Methods

Design

The study employed a mixed methods design and included the collection of both quantitative and qualitative data. This is in line with the previous studies that have employed a combination of qualitative and quantitative methods to measure the usability of Web-based support interventions. In the COGKNOW project [7], data for the user-friendliness, the usefulness, and the effectiveness of the intervention were collected through qualitative interviews and questionnaires. In a similar way, the researchers in the DAC project [8] collected usability data through observation, a Web-based survey, and semistructured interviews. The mixed methods designs combine the benefits from both quantitative and qualitative approaches and increase the validity of results [14]. This is because the mixed method designs capture the understanding of participants for a topic or a concept through closed, quantitative questions and provide a deeper understanding for the responses of participants through open, qualitative questions. Data for mixed methods designs can be collected through a questionnaire including both closed and open questions [15,16]. Therefore, the participants in this study completed questionnaires with both closed questions about the perceived ease of use, usefulness and their satisfaction with each function of the platform, and with open questions in the

event that participants were not satisfied with one or more of the platform functions.

Following a convergent parallel design [14], the researchers in this study collected quantitative and qualitative data simultaneously and then merged both types of data to interpret the results. Examples of platform functions are presented in [Figures 1](#) and [2](#). Ethical approval for CAREGIVERSPRO-MMD project is obtained from the Ethics committee of the Faculty of Health and Social Care (United Kingdom), the Comitato Etico Regionale delle Marche (Italy), the Centre Hospitalier Universitaire de Rouen (France), the Comité de Protection des Personnes (France), the Fundació Universitària del Bages (Spain), and the Comité de Ètica de Investigación Clínica Fundació Unió (Spain).

Participants and Recruitment

Users were recruited in Ancona (Italy), Hull (United Kingdom), Manresa (Spain), and Rouen (France) from local health and social care providers and community support groups. Inclusion criteria for PwD or MCI (N=24) were (1) to have a self-reported diagnosis of dementia or MCI, (2) to be at least 50 years old, and (3) to have an informal primary caregiver who agreed to participate too. All PwD or MCI were retired from work. For primary caregivers (N=24) and professionals (N=10), the inclusion criteria required them to be older than 18 years and have adequate language skills in the country of testing, and for the caregivers to be an informal, unpaid carer supporting PwD or MCI. A total of 12 caregivers were employed on a full-time basis in addition to their caregiving responsibilities. Another 12 caregivers were retired from work. Demographic characteristics are presented in [Table 2](#).

Figure 1. The "My Agenda" function.

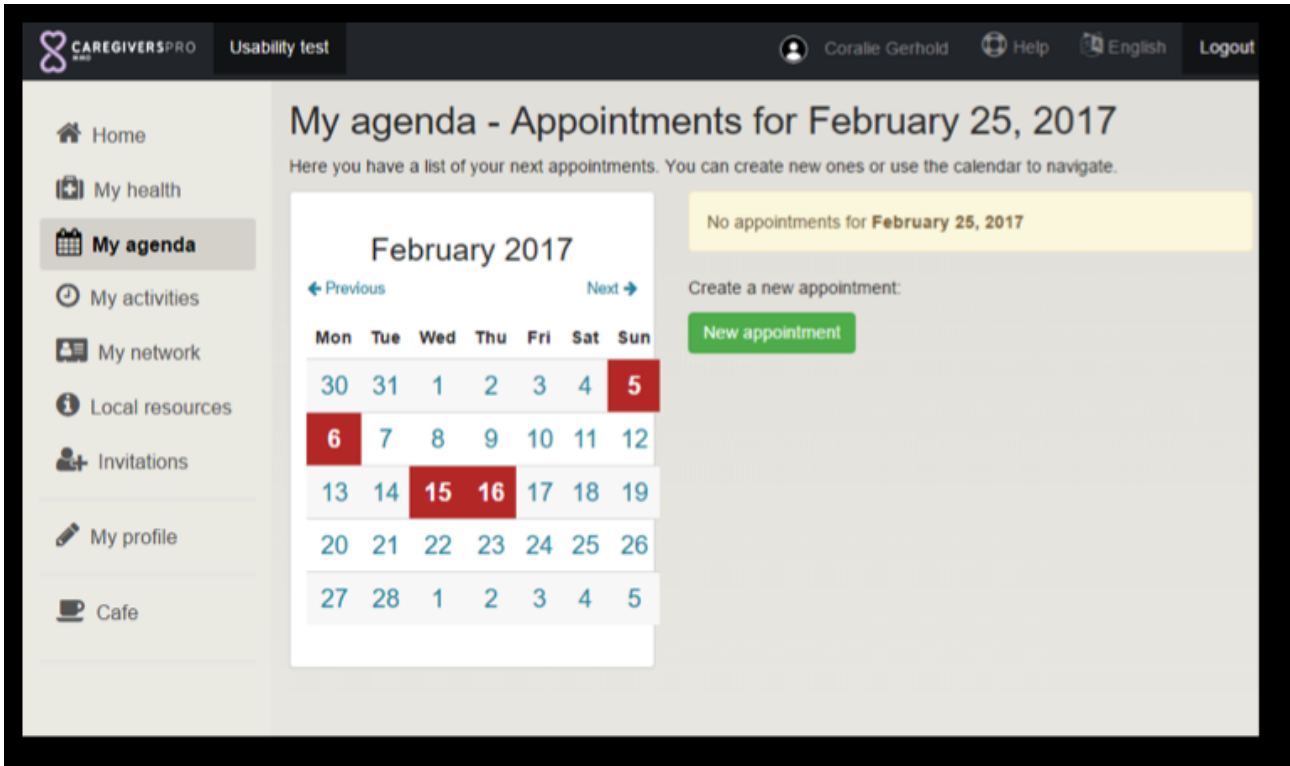


Figure 2. The "Café" function.

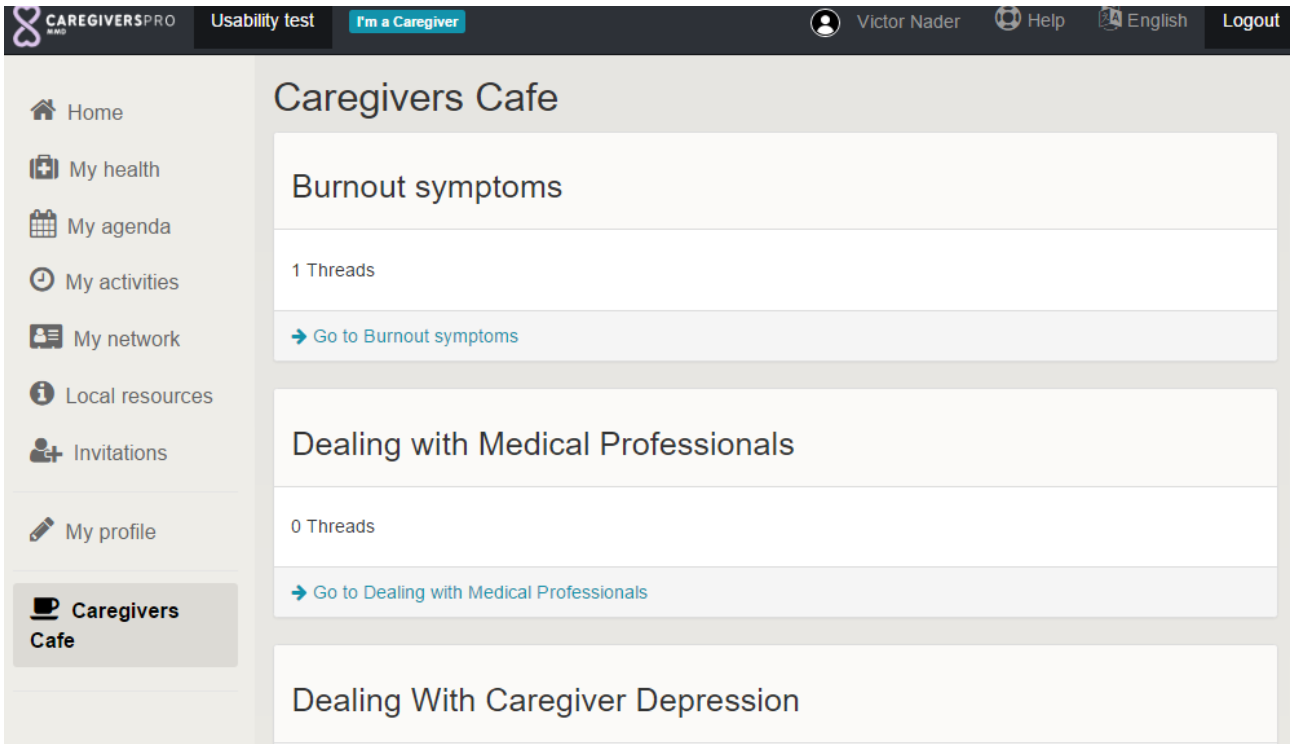


Table 2. Demographic characteristics.

Characteristic	Value
Age in years, mean (SD, age range)	
PwD ^a /MCI ^b (n=24)	78.30 (9.70, 55-91)
Caregivers (n=24)	53.58 (13.71, 30-77)
Professionals (n=10)	40.78 (10.44, 26-53)
PwD/MCI gender, n (%)	
Males	10 (41.67)
Females	14 (58.33)
Level of education for PwD/MCI, n (%)	
No qualifications after school	9 (37.5)
Higher education qualifications	12 (50)
Other training (ie, vocational)	3 (12.5)
Diagnosis for PwD/MCI, n (%)	
Alzheimer's disease	14 (58.33)
Mixed dementia (Alzheimer's disease and vascular dementia)	3 (12.5)
MCI	3 (12.5)
Vascular dementia	1 (4.17)
Other	3 (12.5)
Years living with the diagnosis, n (%)	
Up to 5 years	8 (33.33)
5-10 years	2 (8.33)
More than 10 years	5 (20.83)
Unknown	9 (37.5)
Caregivers gender, n (%)	
Males	4 (16.67)
Females	20 (83.33)
Level of education for caregivers, n (%)	
No qualifications after school	8 (33.33)
Higher education qualifications	16 (66.66)
Other training (ie, vocational)	0 (0)
Caregivers relationship with PwD, n (%)	
Spouses	9 (37.5)
Children	11 (45.83)
Grandchildren	1 (4.17)
Other relatives	3 (12.5)
Hours of caregiving per week, n (%)	
2-14 hours	9 (37.5)
15-25 hours	1 (4.17)
40 hours	1 (4.17)
56-168 hours	7 (29.17)
Unknown	6 (25)
Professionals gender, n (%)	
Males	3 (30)

Characteristic	Value
Females	7 (70)
Professionals job role, n (%)	
Doctors (neurologists and geriatricians)	5 (50)
Psychologists	3 (30)
Social workers	1 (10)
Nurses	1 (10)

^aPwD: people with dementia.

^bMCI: mild cognitive impairment.

Materials

All testing material was developed initially in English and subsequently translated by the researchers of the project into the other languages (French, Italian, and Spanish). These materials included printed information sheets for participants, consent forms, demographic sheets, usability questionnaires for each user group (PwD/MCI, informal caregivers, health and social care professionals), and a short user guide for the platform.

A usability questionnaire was developed for each user group based on the different platform functions designed for each group. The questionnaires for PwD and caregivers consisted of 30 items, and the questionnaire for professionals included 15 items. The questionnaires were developed based on usability questions from the previous research [3,7] and from questions emerging from the previous stages of the project. Thus, the questionnaires included questions about the ease of use and usefulness of each platform function, as well as about user satisfaction. They were designed to be administered by researchers. The questionnaires also included questions about the willingness of users to use the platform in the future and to recommend it to others. Responses were recorded on a 5-point Likert scale from 0 to 4 indicating strong disagreement to strong agreement. When users provided a neutral or negative score (2 or less on the Likert scale), they were asked by researchers to provide further information and suggestions for the improvement of the platform function.

Procedure

Once users consented to participate in the study, researchers created individual accounts and demonstrated the platform. During the demonstration of each platform function, users were verbally asked to rate the ease of use, usefulness, and their satisfaction with the platform. When users provided a neutral or negative response to the quantitative questions, they were immediately asked to provide qualitative feedback about this function. This method was used to avoid confusion, that is, by asking feedback for all platform functions together. Scores were collected by researchers through the usability questionnaires at baseline and the 1-week follow-up to measure the usability of the platform before and after users had access to it for 1 week. Participants were tested at the Rouen University Hospital (France), at the Sant Andreu Hospital of the Sociosanitari Foundation of Manresa (Spain), at the Centro Diurno Anziani Licio Visintini (Italy), or at their own environment (United

Kingdom). Technical support was available via phone or home visits.

Data Analyses

Demographics were analyzed with descriptive statistics. Quantitative data from the questionnaires were analyzed with nonparametric tests to show differences in the perceived usefulness and usability of the platform between baseline and follow-up testing, and differences between the user groups.

Data from qualitative questions were analyzed with thematic analysis [17]. PZ, EW, CW, and RD read and reread the interview transcripts and identified the emerging themes. The themes were discussed until consensus was reached and are presented in the Results section. Qualitative data aim to support the quantitative findings and to provide a deeper understanding of the quantitative responses from participants. Therefore, quantitative and qualitative data are merged for interpretation in the Discussion section [14].

Results

For analysis, the mean and percentages of users within each group, who agreed with the statements supporting the platform functions (responding 3 or 4 on the Likert scales), are presented in Table 3. When users were asked more than 1 question per platform function, the mean of satisfied users was calculated. Of all users, 6 users (1 PwD, 1 informal caregiver, 4 professionals) participated only at baseline testing and were excluded from further analysis.

At baseline, the platform was considered useful by the majority of PwD (65%, 15.5/24), informal caregivers (87%, 21/24), and professionals (85%, 8.45/10). Satisfaction rates were also positive from most of PwD (58%, 13.92/24), caregivers (83%, 20/24), and professionals (65%, 6.45/10). Ease of use scores did not follow the same pattern, with 48% (11.58/24) for PwD finding the platform easy to use. In contrast, 85% (20/24) of caregivers and 84% (8.36/10) of professionals appreciated the ease of use of the platform.

Scores from the follow-up indicated that the perceived usefulness, ease of use, and satisfaction with the platform increased for professionals after using the platform for 1 week. The ease of use and user satisfaction declined for PwD and caregivers, as well as in perceived usefulness for PwD.

Usability Scores at Baseline and Follow-Up Visits

To enable comparisons between the usability scores at baseline and after 1 week of platform use, the means and standard deviations of usefulness, ease of use, and satisfaction for all platform functions were calculated for each user group (Table 4).

Mann-Whitney *U* tests did not confirm significant differences between baseline and follow-up usability scores for PwD, caregivers, or professionals.

Tables 3 and 4 reveal a discrepancy between the baseline and follow-up scores for PwD. Although usefulness means are increased for PwD at the follow-up compared with the baseline (Table 4), fewer PwD find the platform useful (Table 3).

Usability Scores Across the Three User Groups

Kruskal-Wallis *H* tests revealed significant differences at baseline between PwD, caregivers, and professionals in usefulness ($H(2)=12.1, P=.01$), ease of use ($H(2)=14.4, P<.001$), and satisfaction ($H(2)=12.1, P=.01$). Post hoc tests showed these differences to be between PwD and carers in usefulness

($P<.001$), ease of use ($P<.001$), and satisfaction ($P<.001$). Differences were also found between PwD and professionals in the ease of use ($P=.02$).

The results from the follow-up data also revealed significant differences between the user groups in usefulness ($H(2)=16.6, P<.001$), ease of use ($H(2)=18.5, P<.001$), and satisfaction ($H(2)=12.0, P=.01$). These differences were found between PwD and carers in usefulness ($P<.001$), ease of use ($P<.001$), and satisfaction ($P<.001$). Differences were also found between PwD and professionals in usefulness ($P=.01$), ease of use ($P<.001$), and satisfaction ($P=.045$).

Usability for Platform Functions and Suggestions for Improvement: Overall Feedback and Guidance for Technology Projects

Interface

PwD and caregivers preferred bigger color contrasts and font sizes, as well as images and icons rather than text menus. Emoticons were used in the platform to like or not-like messages, but both PwD and caregivers found this confusing.

Table 3. Number of users and percentages (in parentheses) agreeing with the usability of CAREGIVERSPRO-MMD platform functions.

Usability variables	PwD ^a /MCI ^b , n (%)		Caregivers, n (%)		Professionals, n (%)	
	Baseline	1-week follow-up	Baseline	1-week follow-up	Baseline	1-week follow-up
Usefulness	15.5 (65)	13 (57)	21 (87)	20.75 (90)	8.45 (85)	5.36 (89)
Ease of use	11.58 (48)	9.4 (41)	20 (85)	18.75 (82)	8.36 (84)	5.82 (97)
Satisfaction	13.92 (58)	11 (47)	20 (83)	18.08 (79)	6.45 (65)	4.36 (73)

^aPwD: people with dementia.

^bMCI: mild cognitive impairment.

Table 4. Baseline versus follow-up usability scores for all user groups.

User group/usability variable	Baseline, mean (SD)	Follow-up, mean (SD)
PwD^a/MCI^b		
Usefulness	2.40 (1.03)	2.43 (1.09)
Ease of use	2.09 (1.20)	2.08 (1.11)
Satisfaction	2.34 (1.00)	2.22 (1.07)
Caregivers		
Usefulness	3.22 (0.55)	3.39 (0.48)
Ease of use	3.16 (0.83)	3.16 (0.88)
Satisfaction	3.18 (0.67)	3.17 (0.70)
Professionals		
Usefulness	3.13 (0.43)	3.44 (0.53)
Ease of use	3.13 (0.60)	3.59 (0.27)
Satisfaction	2.85 (0.61)	3.18 (0.70)

^aPwD: people with dementia.

^bMCI: mild cognitive impairment.

Additional Functions

PwD suggested including cognitive training games in the platform to train their memory. Caregivers wanted an easy way to send instant messages to health and social care professionals.

Language Used

Caregivers commented on the language used on the platform. They felt that terms such as “dementia” should be avoided in favor of *memory problems*.

Privacy

All users were concerned with the privacy of information that PwD and caregivers insert in the platform. They suggested using short explanations in each page of the platform to remind users who will see each piece of information.

Feedback per Platform Function

Home

The major social-network function of the platform allows users to publish messages to circles of friends and to reply to messages. At baseline there was wide acceptance that these functions would be useful and had been implemented in a way that made them easy. For caregivers and professionals, this perception either remained the same or was reinforced by use of the platform. However, PwD were less convinced and this did not increase with experience (Tables 5 and 6). PwD found it difficult to find previous published messages and pictures.

My Network

The My Network feature allows users to establish their circle of friends with whom they can share information and posts. This process involves the sending and possible acceptance of an invitation. PwD rated this feature lower than the other user groups, especially for the ease of use. Caregivers would prefer to receive notifications about invitation requests to the PwD they care for. Caregivers suggested that no notification was better than a reject notification, if an invitation was not accepted, to avoid upsetting users. They also suggested they would like to be able to find new contacts through common interests such as hobbies. Professionals required more information about PwD and the ability to download a file containing all the uploaded information and the responses to questionnaires by PwD.

My Profile

PwD provided the lowest usability scores and satisfaction rates among the 3 user groups for updating personal information. PwD and caregivers were concerned about privacy settings and who had access to the information they uploaded.

My Agenda

Caregivers and professionals rated higher, than PwD, the usability of the agenda function for noting appointments and events. All user groups reported that they would like to control who can see their own appointments. PwD and caregivers also

suggested that the upcoming appointments should be presented in a chronological order (with the closest appointment on the top of the page). PwD also suggested having options for selecting which appointments are displayed, for example, appointments could be selected to be displayed on a monthly, weekly, or daily basis.

Invitations

The majority of caregivers and professionals appreciated reviewing invitations from other users. PwD would prefer a standout notification, such as a notification in red color. Caregivers would prefer to be able to click on notifications to read them, as well as to show notifications in the home page to alert them for a request.

Café (Forum)

The forum was rated lower by PwD than by other user groups. The majority of PwD expressed their concerns about a possible inappropriate use and the need for the forum to be monitored by administrators. PwD and caregivers also suggested that they needed information about who can see information in the forums and the need to keep the individual forums for PwD, caregivers, and professionals separate. However, in contrast, professionals suggested that their user group should have access to all forums.

My Health

This platform function for uploading health and medical information for PwD and caregivers appears as *Manage users* to professionals and was the least appreciated of all the functions. Professionals reported that important information about PwD, including their cognitive level, is missing (see Create User Profiles and Manage Users). PwD underlined the need to include only user-friendly questionnaires with general questions, such as generic questions about their mood. PwD and caregivers requested a record of scores from completed questionnaires. Caregivers were concerned about who can see their information.

Local Resources

The majority of people in all user groups expressed overall satisfaction with the information provided about local resources. This platform function was the most appreciated function by PwD and caregivers. PwD and caregivers suggested a comment box under each local resource to leave feedback for other users should be available. Caregivers suggested that users should be able to upload new local resources.

Create User Profiles and Manage Users

Scores from professionals indicated their satisfaction with creating profiles for users, while they gave a lower rating for the platform function for monitoring PwD and caregivers. Professionals suggested that scores for PwD cognitive ability should be provided. They also suggested a “user summary” to be generated for them, including information about the health and current emotional well-being of PwD and caregivers.

Table 5. Number of satisfied people with dementia (PwD), mild cognitive impairment (MCI), and caregivers for each platform function, excluding the sign in function.

Platform functions	Usefulness (mean)		Ease of Use (mean)		Satisfaction (mean)	
	Baseline (N=24)	1-week follow-up (N=23)	Baseline (N=24)	1-week follow-up (N=23)	Baseline (N=24)	1-week follow-up (N=23)
Home						
PwD ^a /MCI ^b	17	17	14	13	19	17
Caregivers	21	22	19	18	19	19
My Network						
PwD/MCI	14.5	12	12.5	9.5	14	10
Caregivers	20.5	21.5	21	18.5	21	18
My Profile						
PwD/MCI	14	12	11	8	13	9.5
Caregivers	20	20.5	20	18.5	21	18
My Agenda						
PwD/MCI	14.5	13	11.5	10	12	10.5
Caregivers	19.5	18.5	20.5	17.5	19	16
Invitations						
PwD/MCI	17	14	10	8	15	11
Caregivers	21	21	19	17	18	17
Café (Forum)						
PwD/MCI	15	12	9	7	10	9
Caregivers	22	21	22	22	16	16
My Health						
PwD/MCI	18	12	11	10	16	11
Caregivers	21	20	20	19	21	18
Local Resources						
PwD/MCI	21	17	11	10	16	12
Caregivers	24	23	22	21	24	21

^aPwD: people with dementia.

^bMCI: mild cognitive impairment.

Table 6. Number of satisfied professionals for each platform function, excluding the sign in function.

Platform functions	Usefulness (mean)		Ease of Use (mean)		Satisfaction (mean)	
	Baseline (n=10)	1-week follow-up (n=6)	Baseline (n=10)	1-week follow-up (n=6)	Baseline (n=10)	1-week follow-up (n=6)
Home	7	5	9	6	6	5
My Network	9.5	5.5	8	5.5	5.5	3.5
My Profile	8	6	8	5.5	3.5	2.5
My Agenda	9.5	6	8.5	6	8.5	6
Invitations	9	6	9	6	8	6
Create User Profiles	10	6	10	6	9	5
Managed Users	7	3	6	6	4	3
Café (Forum)	7	4	9	6	9	5

Discussion

Principal Findings

This study explored the usability of the current version of the CAREGIVERSPRO-MMD platform through ratings and feedback provided from PwD or MCI, primary caregivers, and health and social care professionals. The results revealed significant differences in the usability scores of the 3 user groups, with caregivers and professionals rating the platform more useful and easy to use than PwD. Differences in scores between baseline and 1 week after using the platform were not statistically significant. However, although the mean of perceived usefulness of the platform for PwD was increased in the follow-up testing, the number of users finding the platform useful was decreased. Analysis of the individual functions of the platform showed that the 3 user groups held different opinions of the usability of the platform functions. Professionals considered the function to connect with users in the platform for peer support a necessary function and providing information about themselves as professionals to be less useful. PwD and caregivers considered the information for local resources to be the most important function of the platform for them and the peer support forum to be the least important. PwD appreciated some functions of the platform, such as the social networking service, and showed their interest to communicate with others; however, their scores for the ease of use of these functions underline their inexperience with technology. Suggestions for further platform functions for PwD and MCI concern games for cognitive training and instant communication with health and social care professionals through the platform. Professionals suggested including important health information about PwD and caregivers that is currently missing. These findings show that priorities differ between the 3 user groups and thus, platforms for each user group should be designed to fit the needs of each particular group. Findings from this study can be used for the development of future Web-based interventions, as well as for the further development of CAREGIVERSPRO-MMD platform.

Developing Web-Based Interventions Based on User Characteristics

PwD evaluated the platform as less useful and easy to use than caregivers and professionals. This difference may reflect the age difference between the mean ages of the user groups since PwD were 20 to 40 years older than caregivers and professionals. This finding is in line with the literature [18], where older adults needed more time than young adults to perform tasks using touch screens. The decline of cognitive functioning for PwD and MCI may be another explanation for the low usability scores. Literature suggests that PwD prefer less cluttered webpages, with less information per page, requiring less cognitive effort than other user groups [8].

Another possible explanation of the variability in the evaluation of the 3 groups concerns their experience with technology. The majority of PwD reported no previous knowledge of accessing the Web. Evidence suggest that older adults are keen to use technology devices when they are trained to use them [19], when they are aware of the benefits [20], when technology

enables their communication with other people, and when they have previous experience with computers at work [21].

The discrepancies between the usability scores of the 3 user groups can also be explained by the different needs of these groups. The lower scores of PwD indicate the need to adapt the interface and functionality of the platform to meet their needs, such as to simplify the interface for this group. The need to adjust the interface according to personal preferences is in line with the previous research [10] as individual preferences vary.

Guidance for Technology Projects

Qualitative results from this study may act as a guide for developing future Web-based support interventions for PwD or MCI and their caregivers.

Interface

The need of PwD and caregivers for less busy pages in the platform, more images, larger font size and color contrasts, and fewer colors on each page shows the importance of platform adaptation and adjustment for each user group. The technology design for older people needs to be adjusted to their motor, sensory, and cognitive abilities, including their visual and auditory capacity [6] because age-related impairments are likely to affect older adults' engagement with computer systems [18].

Content and Functionality

PwD and caregivers were concerned about the privacy of the platform. They requested explanations about who has access to their information and underlined the importance of monitoring the platform for an inappropriate use.

The variability in the importance of each platform function between the user groups, such as PwD finding Web-based questionnaires not useful but professionals needing more questionnaires, suggests that the dyads of PwD and caregivers have different needs and interests than those which may be anticipated by professionals and developers. This finding underlines the importance of involving end users in the development of Web-based support interventions to meet their needs [9].

The main limitation of this study was the lack of privacy and security arrangements in the early version of the platform. Future projects should consider the suggestions provided by PwD and caregivers in this study when developing technological interventions. Simpler interventions can be developed for PwD with uncluttered interfaces and an appropriate number of functionalities so that end users will engage with the interventions. Privacy issues about sharing information on Internet can be addressed with short statements explaining who can see this information while implementing in the platform all the regulations related with data protection and privacy at the European and national levels. Future research on technology-based platforms can also collect data about the usage of the platform. In a similar way, data for the number of visits per platform page could show the preferences of users.

Conclusions

Involving end users in the development of Web-based support interventions is necessary to understand their needs and

preferences. The discrepancies in the evaluations from PwD, caregivers, and professionals highlighted that these needs and preferences vary in each group. The different preferences have been identified both in respect of the interface and the content of the platform. The feedback collected through this study will

not only inform the development of CAREGIVERSPRO-MMD platform but also provide valuable suggestions for the development of Web-based support interventions for PwD and caregivers.

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Authors' Contributions

PZ designed the experiment. All authors served as scientific advisors in the design of the study. PZ, KP, RD, MA, FC, FS, IL, LM, XG, and MQ contributed to data collection. PZ, KP, and JT analyzed the quantitative data. PZ, EW, RD, and CW analyzed the qualitative data. PZ authored the manuscript. All authors reviewed the manuscript at all stages.

Conflicts of Interest

None declared.

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Abbreviations

- DAC:** Digital Alzheimer Center
MCI: mild cognitive impairment
PwD: people with dementia
STAR: Skills Training and Reskilling

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Original Paper

Factors Affecting Patient Portal Use Among Low-Income Pregnant Women: Mixed-Methods Pilot Study

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Abstract

Background: Patient portals offer patients personalized and secure Web access to their medical information and enable patients to manage their health care online. However, there is a lack of information about patient acceptance and use of patient portals among low-income pregnant women.

Objective: This formative research aims to assess the potential of a patient portal, MyChart, for improving prenatal health care and pregnancy outcomes, and identify the barriers and facilitators of MyChart use among low-income pregnant women.

Methods: A mixed-methods study was conducted with a convenience sample of 18 low-income pregnant women comprising low- and high-risk patients enrolled in a prenatal clinic in eastern North Carolina. MyChart use, patient demographics, and pregnancy information were collected by reviewing electronic medical charts. Health literacy was measured. Reported use and attitudes toward MyChart were collected using a semi-structured interview.

Results: Although 39% (7/18) of participants interviewed signed up for MyChart, only 22% (4/18) of them became active users. Another 33% (6/18) had never heard of MyChart or was unsure of how to access it. Users primarily accessed test results and appointment schedules. The main facilitating factors for patient portal use were information and motivation from health care providers and concerns about pregnancy due to a history of miscarriage. Reported barriers were lack of educational resources, lack of care provider encouragement, and technical difficulties possibly exacerbated by low health literacy. Participants also suggested improvements for MyChart, especially the provision of discussion-based support for pregnant women.

Conclusions: The one-time verbal introduction of MyChart does not meet current patients' needs. Data reveal the need for more consistent patient education and support programs, tailored to patients' previous pregnancy histories. The clinic also needs to facilitate better provider-patient communication about the importance of MyChart use.

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KEYWORDS

patient portals; digital divide; pregnancy; poverty; health literacy

Introduction

Patient Portal Use

A patient portal is a secure website through which patients can access their personal health information as a real-time, patient-centered record that makes information available instantly wherever and whenever it is needed [1]. The rates of patient portal adoption varied across different clinics among patients enrolled in AthenaHealth networks, with obstetrics and gynecology (OB/GYN) rates at 50% and pediatrics much lower at 23% [2]. Electronic patient portals are underutilized, particularly among low-income and minority populations [3-6]. A recent review reported that although 60% of patients enrolled in federally qualified community health centers registered with a patient portal system, only half of them used the account twice or more in 2 years [5], suggesting that patient portal activation does not necessarily lead to meaningful use among low-income populations.

Digital Divide

A cohort study in a managed care organization found that about one third of patients registered with an available portal, and whites had higher rates of use than African Americans [7], leading the authors to confirm the existence of a digital divide and to argue that the expansion of patient portal use has the potential to widen disparities in health and health care. The digital divide may be caused or exacerbated by low health literacy [8,9]. Diabetes patients with self-reported limited health literacy had lower use of patient portal compared with those with adequate health literacy, independent of the effects of education and access to the internet. Considering the well-documented disparities in diabetes and other chronic diseases outcomes suffered by low-income populations, this digital divide in patient portal use may further exacerbate these trends. For that reason, disparities in patient portal use [3,10] were considered a barrier to meeting the Healthy People 2020 goals on health communication and health information technology [11]. A recent state of the science review on patient portals calls for future research focused on identifying specific populations and contextual considerations that would benefit most from patient portal use and analyzing the contextual factors that encourage or inhibit such use [12].

To date, there has been a lack of information and understanding of patient portal use among low-income pregnant women. It is known that a lack of patient-provider communication during prenatal visits and a lack of access to vital prenatal care information are risk factors for poor pregnancy outcomes [13,14]. Therefore, a patient portal may be an important technology-based health care communication venue to improve prenatal care delivery, especially in a rural area where mobile phone use is the norm, but access to physical health care is often limited due to a lack of transportation.

This exploratory study targeted low-income pregnant women and examined the reasons for and barriers to MyChart use, the characteristics of patients who became users, and the factors

that patients suggested would increase their likelihood of use. These data provide an essential baseline for future MyChart patient education program design and implementation as well as for the development of prenatal clinic educational materials to be disseminated to improve patient adoption rates among low-income pregnant women.

Methods

Study Setting

The study site is an outpatient prenatal clinic affiliated with an academic medical center in a largely rural region characterized by high poverty rates in eastern North Carolina. *MyChart*, an Epic Systems Corporation (Verona, WI) patient portal, was introduced by this health system in October 2014. A nurse who was in charge of MyChart training program in the Center for Information Technology trained clinic staff once before MyChart implementation began. After a brief verbal introduction to MyChart, a nurse then followed a standard protocol to assist patients with enrolling in MyChart. There was no specific patient education program except for the distribution of an informational flyer with a helpline phone number and list of key features of the patient portal. Patients were given an activation code at their first appointment. They either had to then ask their health care provider (HCP) to activate the account while in the clinic or use the code themselves to activate the account from a home computer or mobile device. The activation code remained enabled for 6 months or until the patient declined MyChart use. After 6 months, the code expired and patients had to request a new one. Patients who made return visits to the clinic or any other HCP using MyChart were also offered new activation codes at those visits.

This study was undertaken as an exploratory sub-study of the ongoing Healthy Moms Study (HMS) being conducted by the authors. The HMS goal is to improve prenatal care by introducing a Facebook group as an intervention approach. To be eligible for the study, women had to be English-speaking, over the age of 18 years before the third trimester, and recipients of Medicaid insurance (an indicator of low-income status). A convenience sample of 24 women was invited to join the MyChart study during their HMS baseline assessment. Moreover, 4 patients dropped out, due to nonresponse (18% attrition rate), and 2 voice recordings were lost due to technical difficulties.

Study Participants

The analytic sample of participants included 18 women, with the average age of 26.1 (20-37) years. Non-Hispanic, African American women accounted for 61.1% of participants. The average gestational age of mothers was 23.7 (SD 8.1) weeks pregnant at the time of recruitment, and 2 of the women were pregnant for the first time. In addition, 5 women were recruited from the high-risk clinic and 13 from the low-risk clinic. MyChart exposure time ranged between 3 and 41 weeks, with an average of 16.6 weeks among those who had activated their account during the observation period.

Textbox 1. MyChart interview questions.

Have you ever used MyChart? (Why or why not)

(If used) How often do you interact with MyChart?

Do you find it useful? (Or do you think it will be useful?)

What is most useful about it? (What would make it more useful?)

What do you like most about MyChart?

What do you like least about MyChart?

Would you say that your health care providers motivate you to use MyChart?

When you have a question about something happening with your pregnancy, who do you talk to first? Is there a particular site you use for finding prenatal information?

Do you use any electronic social networking such as Facebook, Twitter, Instagram, or blogs that have provided you with information about your pregnancy?

Ad hoc questions: When you think about your life right now what are the three biggest worries that you have? What are your top three priorities?

Data Collection and Analyses

A semi-structured interview assessed characteristics of MyChart users, perceptions and attitudes toward MyChart, and whether and how HCP encouraged MyChart use (Textbox 1). In addition, respondents were asked about sources consulted for prenatal advice and health information, and about participation in any prenatal support groups or classes, both online and offline. Interviews were conducted at the study clinic or over the phone at a later time between February and May 2015 before study participants enrolled in a Facebook intervention. The answers were digitally recorded and transcribed and checked by an investigator before being uploaded into N-Vivo (V.10; QSR International, Melbourne, Australia) for analysis. The East Carolina University Institutional Review Board approved this study.

MyChart themes were coded in the following categories by 2 coders: MyChart functions, improving MyChart, and participant-reported use of MyChart. These were divided into subcategories featuring functions and utilizations mentioned (easy access to health information, prescription refills, HCP communication, lab results, and appointments), reasons for using or not using MyChart, HCP motivations to use MyChart, and awareness of MyChart.

An electronic health records (EHR) review was conducted to collect information regarding age, race, pregnancy history, intent to breastfeed, as well as detailed information regarding MyChart activation and use, number of physical prenatal visits, and providers seen. After starting the study, the health literacy test and interview questions about life and pregnancy priorities and concerns were added to refine study aims as posthoc study measurements. The Newest Vital Sign Health Literacy Scale [15] was added after the study began to assess health literacy among 13 participants. Moreover, 7 mothers (53.8%) scored at the high level of adequate literacy, 4 (30.8%) scored at a moderate level of limited literacy, and 2 (15.4%) scored a low

level of limited literacy. These scored groups were compared with rates of MyChart use.

Actual rates of MyChart activation and use were retrieved from the EHR review. Data included the date the portal was activated, declined, or expired and any communication between patient and HCP, viewing test results, number of physical visits, number of phone calls between patient and provider, and number of letters sent to the patient. By combining the interview and EHR data, participants were split into 4 MyChart *use* categories: *Active Users*, defined as those who activated their MyChart accounts and used them at least once before the end of the observation period; *Inactive Users*, those who activated their MyChart accounts but had not used them since activation; *Nonusers*, those who had heard of MyChart but had not activated their accounts; and *Unaware Users*, those who did not have a MyChart account and had never heard of MyChart or did not know how to access it.

Descriptive statistics were performed on the quantitative data because of the small sample size. The group differences in quantifiable information between MyChart use and pregnancy risk were tested by *t* test or Wilcoxon rank sum test depending on the distribution of the data (Table 1). The selected variables of prenatal care use are presented in Table 2.

Results**MyChart Users and Their Characteristics**

Only 4 participants (22%) were active users, whereas 3 participants (17%) activated their account but did not use MyChart. Another 5 participants (33%) were unaware of MyChart or unsure how to access it (Table 1). None of the 5 nonusers (28%) activated their accounts. About 75% of active users reported that they logged in every time they received an email that test results were available, and one used MyChart to keep up with her health information after appointments. The inactive users had not logged in since activating their accounts.

Table 1. Participants' characteristics by MyChart use.

Characteristics	Active users (n=4, 22%)	Inactive users (n=3, 17%)	Nonusers (n=5, 28%)	Unaware users (n=6, 33%)
Age, mean (SD)	27 (4.32)	23.3 (3.51)	25.8 (6.53)	25.5 (5.53)
Total parity, mean (SD)	0.5 (0.58)	0.66 (1.15)	2.6 (1.34)	2 (1.10)
African American, rate	50	100	60	50
Poor pregnancy history ^a , rate	100	0	80	83
Current pregnancy risk, high risk, rate	0	0	60	33

^aPoor pregnancy includes miscarriage, ectopic pregnancy, and premature birth.

Table 2. The average number of prenatal care use by MyChart use and pregnancy risk.

Characteristics	Total physical visits	Doctor visits	Midwife visits	Ultrasound visits	Lab test visits	Phone calls	Letters to patient
MyChart use, mean number (SD)							
Active users (n=4, 22%)	11.8	1.5	5.3	1.5	3.5	2.0	0.5
Nonusers (n=5, 28%)	19.2 ^a	8.6 ^b	1.4 ^b	4.0	5.2	6.4 ^c	1.4
Current pregnancy risk, mean number (SD)							
High risk (n=5, 28%)	17.8	8.4	0.8	4.6	4.0	13.8	1.6
Low risk (n=13, 72%)	12.2 ^b	2.0 ^b	4.5 ^b	1.7 ^b	4.0	3.1 ^b	0.3

^aThe mean differences between the 2 groups were detected at P value $<.05$ by t test or Wilcoxon rank sum test.

^b $P=.08$.

^c $P=.08$.

Women With a History of Poor Pregnancy Are More Likely to Use MyChart

According to EHR, 13 (72%) of the women had experienced poor pregnancy histories such as miscarriage, preterm birth, and ectopic pregnancy. All active users experienced miscarriage, and 3 of the nonusers had a preterm delivery (Table 1). One active user said she checked her account weekly and after every appointment, "to make sure I'm not missing anything." For another participant, keeping track of her prenatal care was a top priority due to a previous miscarriage and a bad experience at a different clinic where she was misdiagnosed as ectopic. Another 4 participants (40%) who had miscarried previously were unaware of MyChart and 2 participants (20%) were nonusers. Two participants were pregnant for the first time and both were inactive users.

On average, nonusers had more physical visits than active users and made 7.1 times more physical visits to doctors (Table 2). Active users saw 3.9 times more midwives, suggesting a possible difference in the type of provider consulted.

MyChart Use Difference Between Low-Risk and High-Risk Pregnancies

Although 54% (7/13) of participants recruited from the low-risk clinic had activated their MyChart accounts, only 31% were active users. None of the patients recruited from the high-risk clinic were using MyChart (Table 1). All active users were in a low-risk pregnancy, although they had poor pregnancy histories such as previous miscarriages. Out of 13 low-risk patients, 8 had poor pregnancy histories. It is noted that all 5

patients recruited from a high-risk clinic had a poor pregnancy history, but none of them used MyChart. Patients seen in the high-risk clinic had, on average, 5.6 times more physical visits and saw 6.4 times more medical doctors than patients on the low-risk side of the clinic (Table 2). High-risk patients also had 10.7 times more phone calls than low-risk patients. Although slightly over half of the low-risk pregnancy participants used MyChart, none of the high-risk pregnancy participants used MyChart and they made more medical office visits.

Health Priorities and Concerns

In addition, 10 out of 11 mothers said their health or their baby's health was a top priority and 6 out of 11 listed their health or their baby's health as a top concern in their life situation. Other top concerns and priorities included financial concerns, looking for a job, parenting, and family. All 4 active users put either their baby's or their health as a priority and 3 listed it as a top concern; the fourth listed her top concerns as related to finances, work, and family.

Technical Difficulties and Unknown Expiration Dates Are Barriers

MyChart activation was listed as pending for 5 participants (28%); 3 of these women had never heard of it and another did not know how to activate an account. Moreover, 4 women (22%) had actively declined to use MyChart, disabling their activation code, but 2 of these women claimed they had never heard of MyChart, indicating some possible miscommunication between providers and patients. One woman who had a MyChart account but did not use it said she never received a confirmation email and did not use it due to technical difficulties; however, the

EHR lists her account as online and active, indicating there was no technical difficulty. Although the study clinic has a telephone hotline for MyChart problems, no one brought up the helpline in the interview.

Low Health Literacy Is a Possible Barrier

Health literacy was assessed among 13 of the 18 participants. All assessed active users scored at high or moderate levels of health literacy. Both participants who were low-level literacy were either in the inactive or unaware group. These limited results suggest that health literacy could potentially have an impact on MyChart use, with those scoring moderate to high being more likely to use MyChart when they are aware of the service.

MyChart Features and Functions Among Users

Lab Test Results Are the Most Used Function

All of the active users mentioned test results as the key feature and all accessed their results. One of the inactive users mentioned that she thought it would be useful to check her lab results, but none of the nonusers mentioned the availability of test results. Medical records confirmed that MyChart was primarily used for tracking test results. Nonusers were more likely to mention wanting convenient access to health information, but few could name any specific features, and when asked how to improve MyChart, 2 responded suggesting services that are already available.

Scheduling Is the Second Most Popular Function

Active MyChart users mentioned appointment scheduling as well, with 3 users (75%) checking appointments. Only 1 nonuser (20%) mentioned access to appointment scheduling as a feature of MyChart, and 1 other nonuser thought that appointment information and scheduling would make her more likely to use the service, seemingly unaware that it was already available.

Communication With Health Care Providers

A total of 2 users (50%) mentioned the ability to communicate with their HCP online, but neither had used this service at the time of interview, although 2 had submitted feedback about their care through a patient satisfaction survey. Some respondents still mentioned communication with providers as a convenient option or “ just-in-case ” back up. One woman said:

It is super convenient...there is this little part where you can go and ask questions. I don't know how quickly you get replies but I like that.

She later used this function to ask the nurse a question about taking iron supplements during pregnancy.

Prescription Refills and Medication Lists

Prescription refill was mentioned least often, with 1 nonuser admitting she had not used it yet, but thought that MyChart would be useful primarily for prescription refills and appointment scheduling. However, her activation code expired before she accessed these features. One active MyChart user mentioned the convenience of being able to access a list of her medications online but did not request refills.

Improving MyChart

Health Care Providers Are the Strongest Facilitating Factor

A total of 7 women (39%) reported that their HCP did not motivate or encourage them to use MyChart, whereas 2 active users, 1 inactive user, and 1 nonuser said their HCP talked with them about MyChart but did not necessarily motivate them. One active user explained:

I feel like they had said something to me maybe once or twice about it...I guess it's not really encouraged as much as they let you know that the option is there and they leave it up to you to decide.

Another said her HCP did “ not usually ” motivate her to use MyChart, but explained, “ It's always a different provider every time I go out there, which doesn't make it any better. ”

Lack of Patient Education and Inconsistent Provider Models Are the Main Barriers

Although MyChart users were mostly satisfied with the services provided, 2 of them (50%) thought it was not always easy to understand or access the information. One woman wanted clearer instructions and another found the information presented to be difficult to understand, which may relate to low health literacy. One inactive user and one unaware patient felt that if access to MyChart was easier or if they had better instructions, they would be more likely to use it. Other requests from nonusers included services they were not previously aware were available, such as doctor's notes and appointment information.

Participants Use the Web for Prenatal Information But Not All Use MyChart

A total of 16 participants (89%) used the Web to look for prenatal information and advice and another 8 used social networking sites (SNS) to find prenatal information. Both the women who did not use the Web at all for prenatal information reported that they had never heard of MyChart. All active MyChart users used the Web to look for prenatal information and 75% of them used SNS. One inactive mother and 2 nonusers regularly used both the Web and SNS to look for prenatal information, indicating that access to the Web is not a barrier to MyChart use.

Participants Prefer to Seek and Share Information With Other Pregnant Women

A total of 14 (78%) of participants preferred to talk to other pregnant women or mothers or to read their comments and stories online over MyChart use. When asked how they verified information found online or where they went when they had a question about their pregnancy, 12 (66%) of participants said they talked with their HCP, whereas others said they would go on the internet or ask family or friends first. One MyChart user (20%) responded that she always talked to her doctor, whereas 3 others (75%) said they would talk with other mothers or check the internet first if it was a minor thing, then confirm with a doctor or nurse. Moreover, 4 nonusers (80%) turned to the internet first, then would confirm with a doctor, nurse, or more experienced mother.

Those Who Use Prenatal Support Are More Likely to Use MyChart

Half of active and half of inactive MyChart users were currently involved or planned to be involved in a face-to-face prenatal support group or class for their pregnancies. In addition, 2 (40%) of nonusers and 2 (33%) of unaware patients had been involved with a prenatal class or support group during a previous pregnancy. In addition, 69% of participants joined a Facebook group for prenatal support and education after receiving an invitation to do so, including 3 of the active MyChart users (75%). These findings suggest that mothers who proactively seek out either face-to-face or SNS prenatal support and educational opportunities may be more likely to use MyChart.

Discussion

Underused Patient Portal and Characteristics of Mothers Who Use Patient Portal

This is the first mixed-methods study to explore the use of and expectations about a patient portal among low-income pregnant women. We found that 39% (7/18) of participants interviewed signed up for MyChart, but only 22% (4/18) of participants were active users. Another 33% (6/18) had never heard of it or were unsure how to access or use it. This use rate is lower than previous studies for low-income populations [3,5] and lower than the OB/GYN clinics [2] but consistent with other general population surveys [12]. As patient portal adoption is one of the recommended measures of health care quality and safety [16], this study adds exploratory, qualitative information about some of the potential factors responsible for a digital divide among high- and low-income populations.

Among the patient characteristics of MyChart users, previous and current pregnancy problems were evaluated as patient portal adoption was higher among patients with high and moderate morbidity in the general population [9,17]. Our results are interesting; mothers who had poor pregnancy histories were more likely to use MyChart, but these women were all defined as low-risk patients during the current pregnancy at the time of the study. In contrast, women in high-risk pregnancies with previous poor pregnancy histories did not use MyChart. Although the sample size is very limited, we interpret this finding to reflect differences in communication preferences. Those women in current high-risk pregnancies made nearly twice as many medical office visits as low-risk patients. Therefore, they had more opportunities to ask questions and to receive specific health information face-to-face rather than relying on online means of health care communication as the low-risk patients did. Moreover, high-risk patients usually saw rotating physicians and residents rather than midwives, which is common in academic medical centers serving low-income populations. This lack of provider continuity and type may also contribute to inconsistent communications about the importance and use of the patient portal, which was one of the barriers women mentioned to MyChart use. As we did not measure care providers' practices and attitudes about MyChart use based on pregnancy risk profile, it is not clear whether provider type (rotating HCP vs same HCP) or current and previous pregnancy risk best account for the difference in MyChart use.

The Stage 2 Meaningful Use requirements define patient adoption as downloading or viewing health information and communicating with a health care provider via secure messaging services [16], whereas other researchers use the initial sign up to define use, making direct comparisons among studies difficult. We confirmed that MyChart sign-up does not equal MyChart use. Although all active users in our study used MyChart to check test results, and 1 inactive user was anxious to do so, none of the nonusers mentioned this feature as an option. The perceived usefulness of available medical information and ease of site navigation played an important role in patient adoption and use [18]. Mothers who are online users are more likely to use MyChart. Almost every woman in the sample consulted online resources and several used SNS, similar to other reports of high Web use among pregnant women. Even the sources used to verify prenatal information varied [19]; we found that mothers who use SNS, including Facebook, blogs, discussion boards, and chat sites, were more likely to use or be interested in MyChart and to want to join a Facebook group designed for pregnant women only. Due to the small sample size, it is difficult to generalize, but low level of health literacy seems to be a systematic barrier as both patients with low literacy did not use MyChart. Limited health literacy may affect patients' abilities to activate and navigate the particular features of MyChart, which involve more technical and knowledge-based literacy than SNS sites that draw on personal experience and opinion sharing. A recent qualitative study reported that limited health literacy seems to be a fundamental barrier among low-income patients and caregivers with chronic disease [20].

Lack of Patient Education and Communication in Prenatal Health Care

The accuracy of internet information was judged based on relevance to the participant's own symptoms and condition. Instead of using dry but informative articles, these women preferred to read about the experiences of other pregnant women. In their eyes, this information was "more accurate" because it was more relevant to them. This preference should be expected to carry over to MyChart use as it is an extension of internet engagement, allowing women to track their test results and appointments and to talk to their HCP if needed. Yet, few had actually used MyChart to communicate with providers, and the portal does not provide much patient-friendly information and support. These findings suggest that a redesign of key features and more active participation by HCP's might make MyChart more attractive to pregnant women.

The communication style of care providers with patients played an important role in enhancing patients' self-care behaviors among diabetics [21] and those with chronic disease, including their assessments of subjective health status [22,23]. Prior studies consistently reported that the use of patient portal systems enhanced patient-provider communication [24,25], decreased missed appointments among traditionally disadvantaged groups [12], and had the potential to improve health or medication adherence [26]. Our study supports that provider interaction seems to have a positive effect on MyChart use [12], as those who were prompted by their HCP to use MyChart were more likely to have activated their accounts. Lack of patient education about MyChart—what it was, what

services it offered, and how to use it—is the most common barrier across the MyChart user groups. One of the nonusers said :

I haven't asked anybody how to do it...they mention it but I haven't heard anything else about it. They were just saying that you can go on MyChart and look up your information

One nonuser thought it would be helpful if appointment information was included, and another thought she would be more likely to use it if the pictures and notes from ultrasounds were posted. Appointment information is available through MyChart, and ultrasound photos are not always posted. The notes are available through MyChart as well, indicating a lack of patient education and miscommunication or misunderstanding of MyChart function.

This study has limitations. We did not assess health care providers' experiences and attitudes about MyChart use or their compliance rates with MyChart introduction protocols. The small sample size and relatively short period of observation time for MyChart use limited the interpretation of the results. Especially, the noted group differences by descriptive statistical tests may be due to chance only. Moreover, we did not ask how patients understand and consider offline visits in comparison with communication through MyChart. Access to the internet might be an important barrier to MyChart adoption. However, a majority of the women in our study reported seeking prenatal health information online. Furthermore, data from a previously conducted needs assessment at the study clinic found that only

1 patient (1%) out of 86 pregnant women lacked access to the internet on a regular basis. Thus, internet access does not appear to be the critical barrier for today's low-income pregnant women.

In conclusion, low-income mothers relied on general internet sites and the advice of family and friends for their prenatal health information instead of the secure online patient portal offered by their HCP. Although most patients who did use the portal reported satisfaction with MyChart's features, some found the information difficult to understand, and users and nonusers alike wished for clearer instructions to understand lab test results. In addition, these data show that low-income mothers want more than factual information delivered electronically. They indicated a clear preference for a discussion place, either on SNS or in person, so they could share and learn from other mothers who experiencing similar health issues, which suggests the need to redesign the patient portal to incorporate more diverse functions. The findings also suggest that pregnant women with previous poor pregnancy histories may be more likely to use patient portals and to engage in monitoring their prenatal health status. In addition, in-depth research is warranted to examine more systematically the dynamics of patient portal use among pregnant women enrolled in a high-risk clinic who are already experiencing a large number of office visits. Finally, there seems to be a gap between patients and providers in health communication with MyChart. Future research should focus on the best ways to provide a patient-oriented communication channel via patient portals that fits a group care model.

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Conflicts of Interest

None declared.

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Abbreviations

- EHR:** electronic health record
HCP: health care provider

HMS: Healthy Moms Study
OB/GYN: obstetrics and gynecology
SNS: social networking sites

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Original Paper

A Spiritually-Based Text Messaging Program to Increase Cervical Cancer Awareness Among African American Women: Design and Development of the CervixCheck Pilot Study

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Abstract

Background: Although Hispanic women have the highest cervical cancer incidence rate, African American women account for a disproportionate burden of cervical cancer incidence and mortality when compared with non-Hispanic white women. Given that religion occupies an essential place in African American lives, delivering health messages through a popular communication delivery channel and framing them with important spiritual themes may allow for a more accessible and culturally appropriate approach to promoting cervical cancer educational content to African American women.

Objective: The aim of this paper was to describe the design and development of the CervixCheck project, a spiritually based short message service (SMS) text messaging pilot intervention to increase cervical cancer awareness and Papanicolaou test screening intention among church-attending African American women aged 21 to 65 years.

Methods: Through focus group interviews (n=15), formative research was conducted to explore facilitators, motivators, and barriers to cervical cancer screening. The interviews were also used to identify logistical factors that should be considered when developing the CervixCheck intervention. Culturally appropriate and spiritually grounded SMS text messages were developed based on the analysis of focus group data and the review of previous studies that incorporated technology into health behavior change interventions. After the CervixCheck intervention was developed, cognitive response interviews (n=8) were used to review the content of the SMS text messaging library, to ensure that the content was acceptable and understandable, particularly for church-attending African American women aged 21 to 65 years.

Results: Design and development of the SMS text messages involved consideration of the content of the messages and technological specifications. Focus group participants overwhelmingly reported cell phone use and an interest in receiving spiritually based SMS text messages on cervical cancer prevention and early detection. Findings from the cognitive response interviews revealed that the content of the SMS text messaging library was acceptable and understandable with the target population. The revised SMS text messaging library currently includes 22 messages for delivery over 16 days, averaging 11 texts per week, with no more than two messages delivered per day. Initial usability testing also showed early feasibility.

Conclusions: The design and development of the CervixCheck intervention provides important insight into what may be considered an overlooked minority population and missed opportunity in health information technology research. With increased internet penetration through the use of mobile phones, it is appropriate to investigate the viability of technology as a means to reach minority communities and to reduce health disparities.

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KEYWORDS

short message service; text messaging; African Americans; women's health; cervical cancer; health status disparities; pap test; cancer screening; health information technology; spirituality; community-based participatory research

Introduction

Background Information

Although cervical cancer incidence and mortality rates have drastically decreased in the United States over the last few decades [1,2], particularly because of Papanicolaou (Pap) testing, some populations still continue to bear a larger burden of the disease [1,3,4]. On a national level, African American women experience the second highest incidence rate of cervical cancer (11.4/100,000) and the highest death rate (4.9/100,000) [2]. When compared with white women in the general population, African American women have a 34% higher incidence of cervical cancer and are twice as likely to die of the disease in the United States [1,3,4].

Despite the similarities in cancer screening habits between African American and white women, the former is still more likely to be diagnosed with advanced stage of cervical cancer [4-6]. Although these racial differences are evident, several studies have indicated that race is not a predictor of cervical cancer; the effect of race diminishes as other factors such as education and socioeconomic status are taken into account [5,7]. A Massachusetts study found that these racial differences could possibly be caused by inadequate education for patients and providers, fear and mistrust of the health care system, cultural differences in health-seeking behaviors, and challenge in diagnostic testing after an abnormal Pap test [8,9]. Another study by Schwartz and colleagues (2003) found that socioeconomic status accounts for most of the diagnosis stage disparity between African Americans and whites for cervical cancer [10]. Other studies have attributed the differences in cervical cancer mortality rates between African American and white women to the quality of screening and follow-up after abnormal screening that African American women receive [4] and to higher disease stage upon diagnosis [4-6,11].

It has been evident that in the last three decades that there has not only been an increase in mass education both in rural [12] and urban areas [13] but reductions in financial difficulties with Pap tests covered by the majority of health insurance plans including Medicaid as well. Regardless of these reductions in educational and financial barriers, disparities in cervical cancer screening have persisted, with African American women being one of the populations that continue to bear a disproportionate burden of the disease. Fortunately, cervical cancer is one of the most preventable types of cancer, and women in the age range of 21 to 65 years can get screened for it with a routine Pap test [3,4]. Current screening guidelines recommend that women should have regular cervical cancer screening starting at the age of 21 years till at least the age of 65 years. For women of average risk, current screening guidelines recommend getting screened with the Pap test every 3 years. For women ages 30 years and older, cotesting (a Pap test with human papillomavirus [HPV] test) every 5 years is also recommended (either that or routinely getting the Pap tests every 3 years should still

continue) [14,15]. Identifying opportunities to improve Pap test screening utilization and adherence are critical to reduce the cancer burden in African American women [3,4].

Religiosity or Spirituality and Health in the African American Community

Screening and early detection, particularly by identifying opportunities to improve Pap test screening utilization, are critical components in eliminating the aforementioned disparities in health outcomes for African American women [3,4]. There are a number of social and cultural factors that relate to prevention and screening behaviors that impact cancer mortality rates. Religious involvement is one of these factors [16-21]. Extensive research has shown that religious involvement plays an important role in the African American community [16-22]. In particular, older African American women have been found to be more religiously involved than other groups [17,19].

The relationship between religiosity or spirituality and health has gained much consideration in recent scientific literature, as well as amid lay audiences [23-26]. Research has extensively examined the relationship between religious involvement and a wide variety of physical and mental health outcomes [27]. These relationships are generally agreed to be positive in nature [28,29], suggesting a beneficial impact on health. Theoretical models and literature proposes that the reason religiously involved individuals tend to have good health outcomes is because they have healthy lifestyles and behaviors that align with their religious beliefs. This perceived religious effect on health behavior [30] may reflect religious doctrine, or the common belief that the body is the temple of the holy spirit [31], and include greater engagement in health behaviors such as physical activity (PA), diet, and screening [29], while avoiding behaviors such as drinking alcohol excessively and risky sexual practices [28,31].

Religious involvement has been associated with cancer beliefs, screening, risk, and prevention behavior and has great potential for use in the development of cancer prevention and screening communication interventions for this group [16-21]. Due to the popularity of church-based cancer screening programs for African Americans and the well-established association between religious involvement and health in the literature [16-21,32,33], it is logical to consider health promotion programs that engage faith-based institutions and that are spiritually based to address the health needs of the African American community. Given the relatively high relevance and frequency that religion plays in the daily lives of African American women [34], it is important to explore how religious beliefs and behaviors may influence an individual's perception, initiation, engagement, and participation in cervical cancer screening prevention.

Text Messaging as an Intervention Communication Delivery Channel

Mobile phone technology represents a nearly universal form of communication and is a promising new medium of intervention

delivery in health research [15]. The National Institutes of Health (NIH) Consensus group defines mobile health (mHealth) as the use of mobile and wireless devices to improve health outcomes, health care services, and health research [35,36]. Literature relating to short message service (SMS) text messaging has revealed that SMS text messages may be an effective strategy for stimulating behavior change or supporting behavioral interventions [37-39]. Periodic cues through this type of communication medium have been also been found to be effective in reinforcing healthy behaviors [37], including sensitive health-related issues such as sexually transmitted infection (STI) prevention [40-42]. For example, combined social media and SMS text messaging interventions have been used to successfully promote weight loss [43-45] and various health behaviors (ie, PA and dietary behaviors) [45-47] in previous research and have several benefits compared with mailed print-based or traditional face-to-face health interventions. Specifically, SMS text message reminders have established popularity with patients and have been shown to be more cost-effective than paper- or telephone-based reminder strategies [48]. Such evidence implies that SMS text messaging can be an effective medium to deliver health information and promote preventive behaviors.

Results across recent studies on cancer-specific SMS text messaging interventions for minority populations have already demonstrated both participant interest in SMS reminders for cancer screening appointments and a positive effect on screening rates [49,50]. For example, in a study of younger Korean American women where a 7-day SMS text messaging program for cervical cancer screening was created to stimulate increases in knowledge and behavior pre-post intervention, preliminary results showed that 23% of participants received a Pap test after the intervention [51]. In addition, in a pilot single-group study with a pre-post design, Spark and colleagues also yielded positive results from their cancer-specific SMS text messaging intervention [52]. In this study, Spark and colleagues investigated whether a 6-month extended contact intervention delivered through highly tailored SMS text messages would support long-term weight loss, PA, and dietary behavior change in breast cancer survivors (vs usual care). Results from this study supported the feasibility, acceptability, and provided preliminary evidence on efficacy of an SMS text message-delivered extended contact intervention to promote the maintenance of weight loss and PA among a predominately older female subgroup. On the basis of a recent systematic review of SMS text messaging interventions on cancer screening rates [53], the absolute screening rates for SMS text message recipients were found to be 0.6% to 15.0% higher than for controls, whereas the unadjusted relative screening rates for individuals who received SMS text messages were 4% to 63% higher compared with controls. It was also reported that SMS text messaging interventions seemed to moderately increase screening rates for breast and cervical cancer, while having a smaller effect on colorectal cancer screening. Benefits were shown across several countries, including non-English-speaking and resource-poor populations.

Although the use of SMS text messaging interventions in cancer prevention and control is growing in the general population and

is emerging among minorities and the medically underserved, the number of studies that specifically focus on African Americans remain limited. In one study of predominately African American women, findings revealed that this group was receptive to receiving SMS text messages that focus on cancer and health information [54]. Similarly, some feasibility and positive acceptability of using SMS text messaging in a prostate cancer research project were also found for older African American men in the age range of 40 to 69 years [39]. In the Men's Prostate Awareness Church Training project, SMS text messages were added to a men's health intervention that aimed to increase informed decision making on prostate cancer screening. To the authors' best knowledge, and aside from Yuan and colleagues' work where study findings are still pending [55], this study was the only research found to date that utilized SMS text messaging as a means to reach mature African American men. Moreover, there does not appear to be previous research using this technology to increase cervical cancer prevention among African American women, particularly as a stand-alone intervention that uses a spiritually based approach. This study will provide important insights regarding the feasibility, acceptability, and initial efficacy of a spiritually based SMS text messaging educational intervention in the promotion of cervical cancer prevention information for what may be an overlooked minority population and missed opportunity in health information technology research [45,56-60].

Active Users of Text Messaging

With respect to SMS text messaging behavior, there are several groups that text on a daily basis at higher-than-average levels [61]. On the basis of cell phone owners who use SMS text messaging among a sample of 2277 adults (18 years and older) who were telephone interviewed by Princeton Survey Research Associates International from April 26, 2011 to May 22, 2011, the average number of SMS text messages sent or received on a normal day is approximately 41.5, with the median user sending or receiving 10 SMS text messages per day. Although women send and receive SMS text messages more frequently (mean 42.0/day; median 15/day) than men (mean 40.9/day, median 10/day), African Americans send and receive SMS text messages on a more frequent basis (mean 70.1/day; median 20/day) than their non-Hispanic white counterparts (mean 31.2/day, median 10/day) [61]. Although the use of SMS text messaging decreases by age group, it is evident that a majority (73%) of American adults use this mobile-based technology to communicate. The higher-than-average levels of SMS text messaging in women (mean 42.0/day; median 15/day) and African Americans (mean 70.1/day; median 20/day), as well as the indication that most Americans across all age groups engage in some frequency of SMS text messaging (for those aged 18-64 years: mean >11.4/day; median >3/day), suggest the potential suitability of delivering a SMS text messaging-based health intervention to African American women aged 21 to 65 years.

SMS text messaging was selected as the primary delivery channel for the current intervention because of its popularity and high use among African American women. Nationally representative data show that African American adults are more likely to own a mobile phone (87%) when compared with

non-Hispanic whites (80%) [62]. Additionally, African Americans, in general, are more likely than their non-Hispanic white counterparts to use their mobile phones to send and receive SMS text messages [56,63-65] and to access social media websites (ie, Twitter, Facebook, etc) [56,65,66]. The most recent data from the Pew Internet and American Life Project reports that 80% of African Americans and 80% of all women use mobile cell phones for sending or receiving SMS text messages [64]. The low cost and widespread use of mobile phones and the convenience of SMS text messaging further suggest the potential suitability of employing this type of mobile-based medium for delivering health promotion interventions to African American women.

This Study

The purpose of this three-phased multiple methods study was to develop, pilot-test, and evaluate the feasibility, acceptability, and initial efficacy of “CervixCheck,” a spiritually based SMS text messaging intervention for the promotion of cervical cancer early detection among church-attending African American women in the age range of 21 to 65 years. Given the high levels of technology use in African Americans and substantial evidence suggesting that technology-based health promotion efforts are effective for stimulating behavior change and supporting behavioral interventions [45,56,57,60], the minimal previous research on SMS text messaging as a means to promote cervical cancer early detection represents a missed opportunity to reducing cervical cancer mortality rates in this population. Although there is a growing body of literature reporting positive outcomes of SMS text message-based communication with STIs [40-42] and cancer prevention [39,55,67-70], few focus on cervical cancer screening [51] or African American women [54], and none of these SMS text message interventions for cervical cancer prevention focus on African American women or use a spiritually based approach, making this intervention unique. Spiritually based SMS text messages on health allows for a more culturally appropriate technology-based approach to promoting cervical cancer early detection educational content to African American women and can potentially serve as an effective intervention strategy to reach this population.

This paper reports on the formative research (phase 1) that was conducted to inform the development of the CervixCheck intervention. We also report on the iterative process of intervention and delivery system development (phase 2). Phase 3 of this study, reported elsewhere, was used to determine the feasibility, acceptability, and initial efficacy of SMS text messages in the delivery of cervical cancer early detection educational content to African American women.

Methods

Ethical Approval

This research was reviewed and approved according to the University of Maryland Institutional Review Board’s procedures for research involving human subjects (866903-1).

Study Overview and Design

The CervixCheck project was conducted in three phases. Phases 1 and 2, completed in February and March 2016 and reported in this paper, involved the development and initial usability testing of a SMS text messaging intervention and automated distribution system (Figure 1).

First, two semistructured focus group discussions (n=15) were conducted to explore knowledge, beliefs, attitudes, barriers, facilitators, and motivators in cervical cancer screening for church-attending African American women in the age range of 21 to 65 years. They were also used to identify factors (eg, message content and timing) that should be considered when developing a spiritually based SMS text messaging intervention targeted at women such as themselves. Next, culturally appropriate and spiritually grounded SMS text messages were developed based on the analysis of our focus group data, feedback from our community advisory board, and review of previous studies that incorporated technology into health behavior change interventions [37-48,51-55,67-70]. Finally, after the CervixCheck intervention was designed and developed, cognitive response interviews (n=8) were used to assess the content of the SMS text messaging library. The compilation of SMS text messages in the library database were ultimately refined and incorporated into an automated SMS distribution system and was piloted for feasibility, acceptability, and initial efficacy in phase 3 (reported elsewhere).

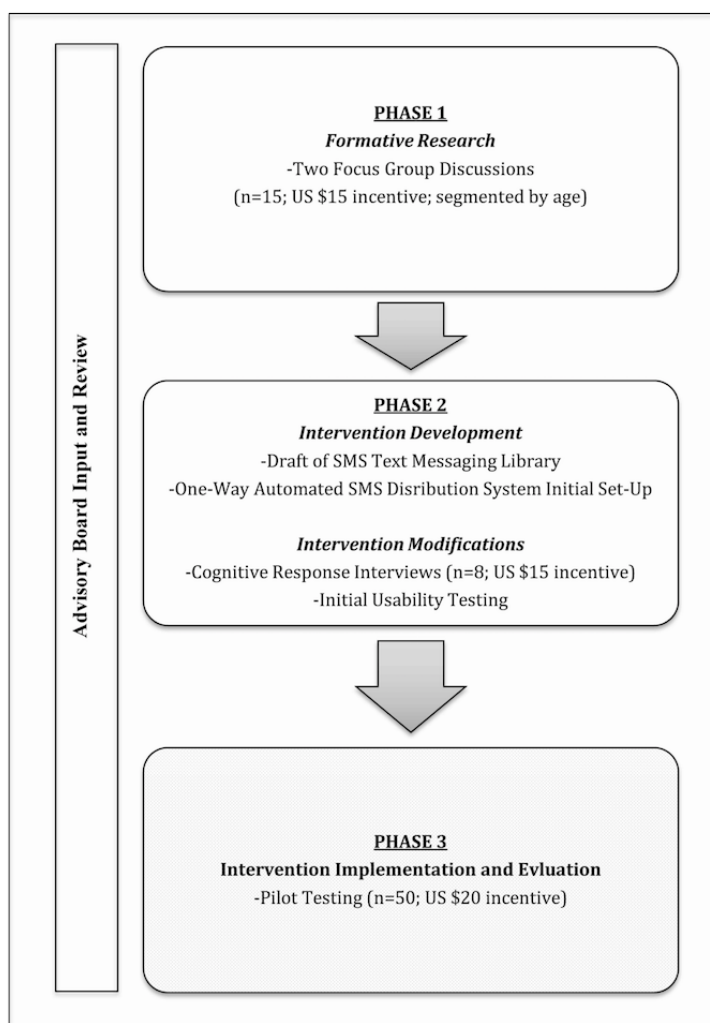
Community-Engaged Approach

Community-engaged research requires partnership development, collaboration, and negotiation, as well as the commitment from both the community and academic researchers to addressing local health issues. Community-engagement activities involved in this study included the following: (1) conducting formative research for intervention development; (2) setting the study in the community, at an agreed-upon location and time of convenience to the study participants; (3) securing buy-in and recruitment or retention support from pastors and community health advisors; (4) forming a community advisory board; and (5) building in and carrying out member checks throughout the study.

Community Advisory Board

Members of the priority population were identified and approached by the principal investigator (PI) to serve on a community advisory board. The six board members were in the age range of 22 to 61 years. All members were church-affiliated African American women. Four indicated that they either were currently serving or had previously served in a leadership capacity within their local congregations (eg, head of a health or women’s ministry and previous community health advisor). This advisory board contributed to the development of the intervention materials and provided recommendation for other aspects of the project (eg, recruitment strategies and SMS text messaging content and delivery time or format).

Figure 1. Intervention development process. Phase 3 of this study is reported elsewhere.



Participant Eligibility, Recruitment, and Sample

African American women aged 21 to 65 years were recruited from the research team's professional networks and from current collaborations with faith-based organizations in Prince George's County, MD. Participants were also recruited through social media (Facebook), emails sent to numerous listservs, flyers posted at churches, workplaces and campuses, and snowballing techniques during the months of February 2016 and March 2016. Those responding to the recruitment materials were screened for eligibility before being scheduled for either a focus group discussion or a cognitive response interview.

Phases 1 and 2 of the CervixCheck intervention were limited to self-identifying church-attending African American women who were in the age range of 21 and 65 years and who had indicated that they reside within Prince George's County, MD. Only individuals who had not had a past medical history of cervical cancer or hysterectomy (ie, the surgical removal of the corpus uteri) were considered for the study. Eligible participants who were interested in participating in phase 1 or 2 of the intervention must have also been willing to discuss topics surrounding culture, technology use, and cervical cancer prevention and education. Participants were expected to meet in person at an agreed-upon location and time of convenience.

This often meant meeting in the community during the evenings and weekends to enable those who worked during the day to participate. Individuals in the focus group discussions and cognitive response interviews received US \$15 each for their involvement. Participants were only eligible to participate in either the focus group discussions or the cognitive response interviews.

Focus Group Discussions

Before intervention development, formative research was conducted through two semistructured focus group discussions to inform the development of the CervixCheck intervention. The discussions qualitatively explored African American women's beliefs and attitudes about cervical cancer prevention and education and assisted in determining factors that would be needed to be considered when developing the spiritually based SMS text messaging educational intervention aimed at increasing Pap test screening intention in church-attending African American women. The focus groups were segmented by age (21-35 years and 36-65 years) to facilitate more open discussion and identify any age group differences. The sessions followed a semistructured format and lasted approximately 90 min. All participants (n=15) received written information about the study and signed individual consent forms.

Short Message Service Text Message Development

Findings from the focus group discussions informed the format (eg, frequency or timing) and content (eg, messaging) for the SMS text messaging intervention. Methods to develop the SMS text messaging strategy also included the following: (1) review of previously published literature, (2) examination of successful SMS text message interventions presented at national and local conferences and events (eg, 2015 Society of Behavioral Medicine Conference, NIH mHealth listserv, and research forums), (3) review of existing spiritually based SMS text messages, (4) review of health-related Biblical scripture, and (5) recommendations from a community advisory board. Frequency and timing of the SMS text message delivery were determined by the preferences and needs of the target audience. SMS text message content was determined before initiation of the pilot study. A total of 18 short project-specific SMS text messages that were health-related and spiritually themed were developed by the PI and initially reviewed by members on the community advisory board. To ensure suitability for delivery via a SMS text message, each message was two to three sentences long.

Cognitive Response Interviews

Once the spiritually based cervical cancer SMS text messaging educational intervention was developed, cognitive response interviews (n=8) were used to assess the content of the SMS text messaging library, to ensure that the content was acceptable and understandable, particularly for church-attending African American women in the age range of 21-65 years. Cognitive response procedures involve intensive one-on-one interviews in which participants may be asked to think aloud about the content they have read, paraphrase the information, and respond to other planned inquiries and probes [71,72]. On the basis of suggestions from the participants, the research team revised the texting curriculum following findings from the cognitive response interviews. The final product was a programmed spiritually based SMS text message library on cervical cancer prevention and early detection to be delivered over a 16-day period.

Initial Usability Testing

Initial usability testing of the pilot program then ensued. During the initial usability testing, the PI and the two research assistants (RAs) beta tested the revised system and used this time to identify and correct some initial programming issues. An invitation for beta testing was also extended to members on the community advisory board and to the participants who previously participated in the focus group discussions during phase 1. The spiritually based cervical cancer SMS text messaging educational intervention was then finalized for subsequent feasibility testing (described elsewhere).

Data Analysis

The focus group discussions and cognitive response interviews were digitally recorded, and the audiotapes were transcribed verbatim. The PI reviewed each of the transcripts for transcription accuracy. Each of the focus group transcriptions was also combined with two sets of observers' detailed field notes and summary reports.

Data from phases 1 and 2 of the CervixCheck intervention were qualitatively analyzed using standard text analysis. Data-driven content analysis was used to explore the findings with the PI and two trained RAs identifying themes independently. Themes were identified in accordance with the methods described by Owen [73]. In an iterative analytic process, the three researchers independently read and reviewed the transcripts to generate impressions. Together with the research questions that shaped the discussion and interview guides, these impressions then formed the basis of the initial coding framework. Participants from phases 1 and 2 were also extended an opportunity to review the findings and to confirm the main themes and specific phases that demonstrated them.

Results

Focus Group Characteristics

The 15 focus group participants ranged in age from 23 to 58 years, with a mean age of 39.57 years (SD 14.17; median 45.50). One participant had less than a high school education, 3 had a high school diploma or general equivalency development credential, 1 had attended some college, 6 had a bachelor's degree, 3 had a master's degree or higher, and 1 did not answer the question. Six participants were currently single, 5 were married or living with a partner, 3 were separated or divorced, and 1 was widowed. Nine participants were employed full time, 1 was not employed at the time, 1 was receiving disability, 4 were employed part time, and 1 did not answer the question. One participant reported being a breast cancer survivor, 9 reported having a family history of cancer, and 14 reported having been screened for cervical cancer at some point in their lives, whereas one had not. Of the 15 women who participated in the discussions, approximately half (n=8) indicated that they had undergone a Pap test within the previous 3 years, with 5 out of 8 of these women reporting that they had received their most recent Pap test within the last 12 months. All but one reported having some form of health insurance coverage (Table 1).

Focus Group Findings and Recommendations

Although general access to health care (eg, having coverage through health insurance or access to a regular doctor nearby) was mentioned as a reason as to why women in their communities may not get screened for cervical cancer, the participants overwhelmingly expressed how the lack of screening within their communities may actually have more to do with the lack of general knowledge, awareness, and communication around this particular type of cancer. Women across both focus groups mentioned how cervical cancer and Pap testing get minimal attention in their community, especially in comparison with other cancers such as breast cancer and prostate cancer. One woman shared how:

...[she] kn[ew] a lot of people who don't get diagnosed sometimes until it's too late because a lot of people just don't think about it. They think of all the other cancers first before they think of cervical cancer.

Table 1. Sociodemographic characteristics and Pap test screening behavior of focus group and cognitive response testing participants (N=23).

Sociodemographic characteristics and Pap test screening behavior	n (%)
Age (years)	
21-35	8 (35)
36-50	10 (43)
51-65	5 (23)
Education	
Less than high school	1 (4)
Some high school	0 (0)
High school graduate or General Equivalency Development	3 (13)
Some college	5 (22)
Bachelor's degree	8 (35)
Master's degree or higher	5 (22)
Missing ^a	1 (4)
Marital status	
Single	9 (39)
Married or living with partner	7 (30)
Separated or divorced	6 (26)
Widowed	1 (4)
Employment	
Full time	11 (48)
Part time	6 (26)
Not currently	2 (9)
I'm disabled	1 (4)
I'm retired	2 (9)
Missing ^a	1 (4)
Insurance	
Private	15 (65)
Public	7 (30)
None	1 (4)
Religion	
Christian	13 (100)
Other	0 (0)
Ever had a Pap test	
Yes	22 (96)
No	1 (4)
Received a Pap test within the previous 3 years	
Yes	14 (64)
No	8 (36)
Received their most recent Pap test within the last 12 months	
Yes	9 (64)
No	5 (36)
Family history of any type of cancer	

Sociodemographic characteristics and Pap test screening behavior	n (%)
Yes	15 (65)
No	4 (17)
Not sure	4 (17)
Cancer survivor	
Yes	1 (4)
No	22 (96)

^aData are missing for 1 participant because the participant did not answer this question.

Another woman shared:

...you just don't hear too many people talk about cervical cancer...a lot of people may not think "ok look, let's go get tested"...how are we supposed to know to go get screened [cervical cancer] if we don't even hear people around us talking about it?

When asked why the women believed this was the case in their community, one woman stated:

...well, it's the generations too...the conversations are not there. My mom never talked to me about it. Everything that I've learned regarding maintaining my body as a woman...[it was] derived from or what I was exposed to in school and things of that nature...and they didn't talk about it because she wasn't comfortable or she didn't know...I truly believe it is from education, direct communication.

Another woman in the same focus group also shared how:

...well, and there's the fear of cancer...no way'...I don't want [the doctors] to tell me that I have it...it's really important for us to get tested so we know what is going on with our bodies and so that we can know what our options are...

to which the majority of her fellow focus group participants nodded in agreement. Participants in both focus groups agreed that the lack of general knowledge, awareness, and communication about cervical cancer is a contributing factor to why many women in their communities do not often get screened or treated until it is too late.

As the focus group discussions naturally transitioned over to whether or not the participants have ever gotten Pap test screened and what their experiences were like, the following additional themes surfaced: (1) discomfort (eg, most of the participants described getting the Pap test as being invasion, awkward, painful, cold, and uncomfortable); (2) intergenerational relationships (eg, the older generation, the parents, are not discussing these issues with their children; there is a lack of conversations around cervical cancer and Pap testing within the family setting); (3) confusion regarding current screening recommendations (eg, some of the women did not know when you should start getting the Pap test and how often you should get them); and (4) patient or provider relationship and communication (eg, doctors need to actively let their patients know the importance of getting a Pap test, the risk of not getting one, and patiently walk their patients through what the procedure is like). With regards to general knowledge around

the Pap test, a little over half of the focus group participants indicated that they were unaware that it was a screening procedure for cervical cancer. One woman emphasized this concern by sharing the following:

...when you came into womanhood, I mean, it was my understanding that part of your normal yearly thing was, you go get a Pap smear, but I never connected it to cervical cancer...I just assumed it was part of my physical exam...now I'm wondering how often I actually got these Pap smears done.

Moreover, there was a lot of confusion across both of the focus groups when the women were asked whether they knew what the screening recommendations currently were for cervical cancer. Although all of the participants from phases 1 and 2 reported familiarity with the Pap test, 83% (19/23) of the women were unable to correctly identify what the current Pap test screening recommendation was for cervical cancer. These individuals were unable to identify when (ie, at what age) a woman should begin to get Pap test screened and how often these screenings should take place.

During the last portion of the focus group discussions, participants were asked to share whether they thought a spiritually based SMS text messaging educational intervention would be appealing for the promotion of cervical cancer early detection among church-attending African American women, and if so, what factors should be considered when developing this type of program (ie, what would the program look like). Across both focus groups, the women enthusiastically shared their support for such a program. For example, one woman responded:

Yes, of course it will because it is something that will provide us encouraging [and] positive messages... just like the ones we get in church. Then, when we get [the messages], we can even share it with the next 10 ladies on our list...pass it right around.

Another woman from the same focus group added:

I know for our church, we have been doing a lot with making health a priority. Just having [that] information has helped our church tremendously...so, I would agree with her that having similar messages and reminders like that, even when we are away [from the church setting], is just a plus.

Women who expressed positive attitudes regarding the intervention's potential ease and convenience were often drawing comparisons to their prior experiences with similar

SMS text messages that they were already getting from their congregation and health care providers (HCPs). Statements comparable with the ones shown above were always followed along with the majority of our participants nodding in agreement and elaborating on the topic.

Additionally, the women in our focus groups also expressed how a spiritually based SMS text messaging intervention to promote any health topic would “definitely get [their] attention” because “it is just a natural fit.” When we probed further and asked our participants what they meant when they refer to an intervention, such as ours, being a “natural fit,” one participant shared:

Well, you know right...God, the Bible, our religion...all of that is important for so many of us. That's why we are in church...we go to church. Getting religious prayers [and] reminders, if you can tie that back to something else important to us, like our health, you get our attention. You know? Like, I mean, why not?

Another woman, who was slightly older, also responded positively about why such a program would be a “natural fit,” stating the following:

Yes! It absolutely is [a natural fit] because it will just add to what my church is already doing...my church, you know, we have helping and healing...and they have brought up cervical cancer prevention before.

The general consensus was that an intervention that is actually spiritual in nature, through message framing or content, would be more effective for women like themselves. One young woman stated:

Even if I didn't care right away [about cervical cancer prevention], when the text pops up on my phone, you know...it'll just catch my attention right there and then...I already have something like that called InstaPray. It has prayers and spiritual messages so, of course, if it was something like that, I would definitely use it. It's like a mix of Instagram and Twitter. You can change how many notifications you get too!

Other participants in that focus group all nodded in agreement, acknowledging that when spiritual individuals such as themselves are presented with spiritual messages, their receptivity and perceived relevance of the underlying health topic is increased. They overwhelmingly voiced support for a spiritually based SMS text messages on cervical cancer prevention because of their comfort and familiarity with religion already being a large part of their everyday lives. They perceived benefits associated with not only early detection and the need to get checked, but also with the concept of how faith can be used to get them through their life experiences and to ease any anxiety that a woman may feel when “the big C” is mentioned, if ever directly. Considering and getting a Pap test was seen as “easier” when one is calmed by their faith. This prompted a number of our focus group participants to tell personal stories of either their own or a loved one’s illness and how their religion and faith helped them through the varied experiences.

Understanding the role of faith in cancer screening and whether these women desired a spiritually based intervention through these focus groups, reaffirmed what we had learned from our previous studies [32,33,39]. However, to further grasp what influences our participants to go in to get their Pap test and the type of channels, message framing, and content that would specifically work for them, we continued to probe our participants and asked them to elaborate on how they would go about educating and encouraging individuals, such as themselves, to get Pap test screened. They were initially asked about their current access, use, and preference for various technology-based programs and platforms (Table 2).

All participants in the focus groups had text-capable phones, with 87% (13/15) indicating that they had unlimited usage plans. The participants overwhelmingly reported cell phone use and an interest in receiving spiritually based SMS text messages on cervical cancer prevention.

The participants were also asked to share their thoughts on what they felt would be the best way to deliver information about cervical cancer and the benefits of getting Pap smear screened as recommended and whether incorporating technology to some extent was a reasonable idea. Without hesitation, the majority (87%, 13/15) of the participants across the two focus groups ecstatically agreed that utilizing SMS text messages would be a great way to quickly get short health-related educational messages across to individuals in their community. Two women shared the following views:

...everyone has a [cell] phone and texts these days...like my mom texts me a lot...telling me to come over dinner or to remember to do something...she doesn't text as much as my daughter, but she does text...and come on, she's 62!...She still doesn't know how to use our tablet or computer though...

...who doesn't text? I may not [send] text much...you know, I'm almost 53, but I get them often. I get [text messages] from my family, church groups...and I like the ones that they send me about the traffic...or storms...and now my doctor, my dentist...I like those! I also like how if I forget or need to find something, I can go back to check some of my old texts to see if the information is still there.

Further recommendations from the focus group discussions regarding what an SMS text messaging-based program would look like included (1) Having a catchy project name that reflects the topic at hand, (2) Making sure the SMS text messages were not going to get delivered too early in the morning (ie, before 8 AM) or too late in the evening (past 8 PM), (3) Incorporating testimonials from women such as themselves or from famous celebrities that they can identify with, (4) Balancing the health-related educational messages with other messages that were broadly more positive and motivational in nature, (5) Ensuring that the faith-based messages included direct scriptures that most church-attending individuals can quickly recognize, and (6) Including local resources where individuals can go get screened for cervical cancer, especially if health insurance coverage is not a possibility.

Table 2. Technology access, use, and preferences for participants in the focus group discussions and cognitive response interviews (N=23).

Technology access, use, and preferences	n (%)
Contact preference	
Cell phone	22 (96)
Home phone	1 (4)
Do you use a cell phone?	
Yes	23 (100)
Is your phone a “smartphone”?	
Yes	17 (74)
No	6 (26)
Do you use a cell phone for text messaging?	
Yes	23 (100)
How often do you use text messaging to communicate?	
More than once a day	18 (78)
Once a day	2 (9)
2-3 times a week	2 (9)
Once a week	0 (0)
Less than once a week	1 (4)
Do you have a computer at home with internet?	
Yes	19 (83)
No	4 (17)
Do you have a Facebook account?	
Yes	15 (65)
No	8 (35)
Do you have a Twitter account?	
Yes	10 (44)
No	13 (57)

Although participants indicated the popularity of unlimited SMS text messaging plans within their communities, they stressed that the research team should never send out more than two messages per day. There were mixed feelings regarding receiving daily messages from the project. Some individuals indicated that they would appreciate the regularity and consistency of getting the daily messages, whereas others indicated that “it would be too much for me” or that “I kind of would like a break here and there.” In general, participants indicated that sending out several messages, a few days each week, would be completely acceptable, as long as it did not exceed two per day and that at least one of these two messages (within the same day) was not health-content heavy. To have some balance and to keep individuals such as themselves engaged, participants stressed the importance of having at least one of the messages be a more general spiritually or motivationally based message.

A final recommendation that surfaced during the discussions revolved around the project name. Though reasonably appealing, the originally proposed project name was ultimately replaced based on a suggestion that came from one of the focus group

participants. A proposed project name, CervixCheck, was favored by the majority of the participants across both focus groups, as well as all of the participants during the cognitive response interviews. All of the women in the first focus group enthusiastically nodded in agreement when one of their fellow participants stated:

...you need a sexy, like a catchy [project] name, something that gets straight to the point and tells us...we need to get specifically checked for cervical cancer...it's just something we don't really ever hear or talk about...but I mean, it's really important.

As opposed to having a generic project name stressing the idea of overall women's health, the appeal with the new project name was that it actually reflected the specific type of cancer that the project was trying to target.

Initial Draft of the Text Messaging Library

Through the focus group discussions, messages and wording preferences and recommendations for incorporation into the SMS text messages were recorded. On the basis of the information collected, the research team developed a 14-day

one-way SMS text messaging pilot intervention. The recommendations of the focus groups and the advisory board were reviewed by the investigative team and used, along with a review of existing cervical cancer educational materials, to develop draft content for the SMS text messages to be used in the intervention. The originally drafted SMS text messaging library comprised a total of 18 messages. The 18 draft messages included the welcome and closing messages to participants, as well as nine health-specific messages and seven spiritually based messages. Core content covered areas such as the definition of cervical cancer, cervical cancer's impact on the African American women population, the role of Pap testing in cervical cancer prevention and early detection, and information on where individuals can go for free or low-cost screening in their local communities. The spiritually based messages involved themes such as being a good steward over the body as a gift from God; personal responsibility for the life and body, which is a gift from God; being healthy so that one can serve God and those important around her; use of faith to get through cervical cancer screening; God will take care of us, but we must do our part and get screened; and various scriptures supportive of health. Selective examples of messages from the initial draft of the SMS text messaging library are shown in [Table 3](#).

Cognitive Response Testing Participant Characteristics

The 8 cognitive response testing participants were in the age range of 21 to 65 years, with a mean age of 41.67 years (SD 18.77; median 41.67). Four of the participants had attended some college, 2 had a bachelor's degree, and 2 had a master's

degree or higher. Three of the participants were currently single, 2 were married or living with a partner, and 2 were separated or divorced. Two of the participants reported that they were retired, 2 were employed full time, 1 was not employed at the time, 2 were employed part time, and 1 individual did not answer the question. None reported being a cancer survivor, and only 6 reported having a family history of cancer. All participants reported having been screened for cervical cancer at some point in their lives, and everyone also indicated that they had some sort of health insurance coverage during the time of their individual cognitive response interviews. Of the 8 women who participated in the cognitive response interviews, 75% (6/8) indicated that they had undergone a Pap test within the previous 3 years, with 4 out of 6 of these women reporting that they had received their most recent Pap test within the last 12 months.

Cognitive Response Testing Recommendations

Participants understood and found acceptable the vast majority of the content that was tested. A consistent concern that surfaced during the interviews was one about the first educational message (health 1) and when it should actually be presented in the program. Participants did not like the idea that the very first educational message from the project would be one that hones in on the devastating impact that cervical cancer has on women in their community. Although all of the women acknowledged the importance of including such a message, they did not feel that it was appropriate to start with a message that "invokes fear" or "is depressing."

Table 3. Selected examples of messages from the draft short message service (SMS) text messaging library.

Text order/#	Message type	Construct	Key message	Message text	Character # (without spaces)
1	Start	Welcome	Thank you for enrolling	(CervixCheck) Hi, (first name of participant). Thank you for being part of the "CervixCheck" Women's Health Project. If you are still interested in receiving text messages over the next two weeks from the "CervixCheck" project about cervical cancer, please reply to xxxxx with the response "YES."	276
2	Health 1	Knowledge	Impact; rates or statistics	African American women are at higher risk of dying from cervical cancer than other women. This is because too often the cancer is found later, after it has spread.	163
3	Spiritual 1	Knowledge	Taking care of health	"My People are destroyed from lack of knowledge."—Hosea 4:6	60
9	Spiritual 4	Subjective norms	Responsibilities	When it comes to our health, doing "our part" means that we take care of our bodies in general, and get the routine exams that we need. This includes getting a Pap test—the part we do so that God can do His part.	215
13	Spiritual 6	Perceived behavioral control	Self-motivation to take action	"I can do all things through Christ which strengtheneth me."—Philippians 4:14	78
15	Health 8	Cues to action	Resources: link to more information or free services	When are you due for your routine Pap test? Talk to your doctor to find out. No insurance? No problem. For more information and to see if you are eligible for free screening, go here: (short url).	195
16	Health 9	Social network	Spread the word; intergenerational communication	Spread the word and pass the wisdom down from one generation to the next. Share this information with the next generation like a good family recipe.	148

Table 4. Scheduling of short message service (SMS) text messages for the CervixCheck pilot intervention. N/A: not applicable.

Message #	Day	Day of week	Time	Interactive activity
1	1	Saturday	12:00 PM	Request for response 2 opt-in
2	1	Saturday	8:30 PM	N/A
3	2	Sunday	2:00 PM	N/A
4	2	Sunday	5:00 PM	N/A
5	4	Tuesday	12:00 PM	Link to supplemental website
6	4	Tuesday	4:00 PM	Link to image
7	5	Wednesday	12:00 PM	“True or false” question posed (prompt for a close-ended response); website link
8	6	Thursday	12:00 PM	N/A
9	6	Thursday	4:00 PM	Link to supplemental website
10	8	Saturday	12:00 PM	N/A
11	8	Saturday	4:00 PM	N/A
12	9	Sunday	2:00 PM	“Thoughts?” (prompt for an open-ended response)
13	9	Sunday	5:00 PM	“Agree or disagree” question posed; (prompt for an open-ended response)
14	11	Tuesday	12:00 PM	N/A
15	11	Tuesday	4:00 PM	Link to testimonial
16	12	Wednesday	12:00 PM	Link to testimonial
17	13	Thursday	12:00 PM	N/A
18	13	Thursday	4:00 PM	N/A
19	15	Saturday	12:00 PM	Link to resources
20	15	Saturday	4:00 PM	N/A
21	16	Sunday	2:00 PM	N/A
22	16	Sunday	5:00 PM	(Prompt for further questions)

One woman shared:

...[how] you should move this [message] to later in the program...you want to start with a more uplifting message...you want to catch our attention about cervical cancer and how it affects people like me, but an initial message like this would totally turn me off...it's important but it just sounds too scary.

Another concern that arose during phase 2 was how there was still some confusion as to where the cervix was and what the Pap test procedure included. To remedy these concerns, participants recommended that we include direct links to images and/or videos that would elaborate on the anatomy of the women's reproductive area. One woman explained:

...for those of us who want more information, at least you can have it right there and easily accessible...even if we don't look at what you send us right away, at least it'll be in our phones and we can return to it when we feel like it.

Other recommendations included the need to “really bring in the personal stories” and to place an emphasis on testimonials from women such as themselves. Some of the participants also provided direct edits on how to the research team could condense some of the draft messages that originally ran beyond the 160 characters limit. As system specifications limits text

content to 160 characters and spaces, our drafted messages needed to be redesigned to be concise. Finally, a message “sign-on” was recommended for any text that the project team was planning to send out. There was general consensus across the interviews that some sort of project branding was necessary to let participants know which messages were directly coming from the research team. It was also noted that a message “sign-on,” as opposed to a message “sign-off,” would be ideal because “you want [us] to know right away that that incoming message is from you, your project...If you start each message with your project's name, participants can get in the habit of recognizing them as soon as they come.” Beyond the recommendations mentioned above, other materials tested during phase 2 were found to be both understandable and acceptable, including the spiritual themes and scriptures.

In response to feedback from the participants in phase 2, we revised the texting curriculum to include four additional messages. The 22 “final” messages include the welcome and closing messages to participants, as well as 10 health-specific messages, four spiritually based messages, and six messages that were both health-specific and spiritually based in nature (Table 4). The messages now span across 16-days, averaging at about 11 texts per week, with no more than two messages scheduled for delivery per day.

The welcome or opt-in message is scheduled to take place on the Saturday before the first program message is sent off the next day (ie, on a Sunday). During the weekdays and on Saturdays, messages are scheduled for delivery at 12 PM (around lunch time) and/or 4 PM (before the end of a regular work day's shift). On Sundays, messages are scheduled for delivery at 2 PM (after most church services) and 5 PM (before dinner time). "Off days" are scheduled for every Monday and Friday, days of the week in which participants indicated that they would be "more swamped" and that it would not be ideal to receive program-related information. The closing message is also scheduled for delivery on a Sunday.

Discussion

Principal Findings

This paper reports on the design and development of the CervixCheck project, a spiritually based SMS educational pilot intervention aimed at increasing cervical cancer awareness and Pap test screening intention among church-attending African American women aged 21 to 65 years. This intervention situates health beliefs and behaviors in the context of culture and information technology [33,74]. Previous research has suggested that the development and implementation of culturally appropriate interventions through a community-based or community-engaged approach can be successful in addressing the underutilization of cancer screening among African Americans [33,75-77]. The process in developing this intervention involved substantial participation of the priority population in all stages of the intervention development. This participation is viewed as a necessary element of a culturally appropriate intervention, not only to allow for community ownership of the project but to ensure that the intervention is indeed culturally appropriate, and not based on assumptions from the research team that may or may not be accurate.

The findings showed that a culturally appropriate SMS text messaging intervention should be developed based on the target population's perspectives and input. The intervention development required collecting data from the participants regarding both the content and delivery formats of the culturally relevant health messages. In general, the participants felt that a cervical cancer educational program, framed within a spiritual context, was a good and innovative idea. The spiritual concepts generated by this group of participants were quite similar to those generated in previous cancer screening educational interventions, especially in qualitative projects examining spirituality and health beliefs [33,78,79]. To be additionally effective with the target population, the SMS text message content also needed to be encouraging, empowering, and thought-provoking, all while being short, informative, and direct. The focus group discussions suggest that the messages should focus on raising awareness and increasing general knowledge and acceptance of the Pap test to change attitudes, possibly before any specific behavior change [80,81]. There was also a general preference for the inclusion of culturally appropriate visual and motivational messages that emphasizes one's role in relation to God, family, community, and women such as themselves. Overall, these findings are consistent with the

Centers for Disease Control and Prevention's suggestions that to quickly engage the reader, messages need to be clear, give important information first, be action-based, and easy to understand [81,82].

Although expansive reviews of the literature describe the weight of the evidence of the relationship between spirituality and health as being largely positive [27,83], not all religious influences are positive, or adaptive, in nature [84-87]. For example, one negative aspect of religious involvement is the idea that some individuals believe that illness may be the result of punishment for their wrongdoings or sins [88-90]. Individuals who defy religious norms may experience feelings of shame or guilt, or they may fear punishment from God [89]. Research on this particular notion has suggested the idea that serious illnesses such as cancer may be viewed as being the consequence of punishment for sin [30,91,92] and thus, may translate to engagement in maladaptive health behaviors such as forgoing cancer screenings [89,90]. With regard to implications from this study that addresses such situations, where religion might act as a barrier for a woman to undergo a gynecological examination, this is where the development, implementation, and evaluation of a two-way spiritually based SMS text messaging intervention that incorporates counseling may play a role in working with individuals who may hold such beliefs, with a spiritual sensitivity and competence [93].

Conclusions

As mobile technology become more popular and advanced, a culturally appropriate SMS text messaging intervention could be an effective medium to deliver sensitive health information and eventually promote positive health behavior in underserved population. Studies investigating SMS-based interventions in minority populations have recommended more extensive research to better understand the most effective content of text messages to increase the benefits derived from mHealth apps [94-96]. This paper reports on formative research conducted to inform the development of an automated one-way SMS text messaging intervention to disseminate cervical cancer prevention and early detection education. The development of the SMS text messages not only involved consideration related to the content of the messages but also with technological specifications. The findings from phases 1 and 2 of this study show the importance of obtaining feedback about the content of SMS text messages and of pretesting the SMS text messaging distribution system before further implementation should take place.

SMS text message interventions should be carefully developed, tested, and refined before implementation, to ensure they are written in the most appropriate way for their target population. Although some may be tempted to rely on common sense and skip a formative stage before implementation of interventions, the process of iterative formative research to develop the content and logistics for developing this program was indispensable to identify challenges to be addressed before the implementation of the piloting phase (phase 3). This research provides insights into the appropriate number of messages to consider, the timing of when they should ideally be sent, and the educational content for consideration in an SMS text message-based intervention

to promote cervical cancer prevention and early detection information for African American women. Message development research is important for effective interventions, and public health practitioners need to pay close attention to how the messages will be received by the recipients.

The development, and ultimately the implementation and evaluation, of this CervixCheck spiritually based SMS intervention will provide important findings into what may be considered an overlooked minority population and missed opportunity in health information technology research [45,56-60]. Although there is a growing body of literature reporting positive outcomes of SMS-based communication with STIs and cancer prevention, there is still very little research about the integration of communication technologies with previously reported effective intervention approaches such as being spiritually based. By using important spiritual themes to frame cervical cancer educational content and by delivering these health messages through a popular communication delivery channel for this targeted group, cancer interventions can move one step closer to being more accessible and culturally appropriate for the African American women community.

Limitations

There are, however, some limitations to the approach used during the formative phases of this study. First, the process of working with church-attending African American women on message design and refinement was fluid and often nonlinear. The PI gave up her own sense of control over the project as it evolved into a partnership endeavor. Second, although the PI conducted quality control measures, the findings from this study may still be at risk for social acceptability bias. The focus group discussions and cognitive response interviews were conducted on the culturally sensitive topic of cervical cancer and Pap testing. This may have deterred our participants from sharing their true thoughts and feelings.

Third, despite efforts to recruit individuals with varying sociodemographic characteristics, participants from the focus group discussions and cognitive response interviews had fairly high education, with 74% having at least an undergraduate degree (17/23). Furthermore, the majority (96%, 22/23) of the participants indicated that they had some sort of health insurance coverage during the time that this study was conducted and that they had already been screened for cervical cancer at some point in their lives. The final make up of our convenience sample showed us that we were barely able to reach some specific subgroups, in particular unscreened African American women whose experiences would have enriched our findings. Thus, the lack of representativeness from the larger population of church-attending African American women may have potentially limited the generalizability of the findings. This could also, however, reflect the current nature of cervical cancer screening practices among church-attending African American women from Prince George's County, MD.

Finally, although the authors acknowledge the important role that the HPV vaccine holds in cervical cancer prevention, this study did not heavily focus on this approach. Even women who were vaccinated when they were younger need regular Pap test

screening because the vaccines do not protect against all cervical cancers. Additionally, previous studies have suggested that African American women are less accepting of the HPV vaccine [97-99]. Future studies should evaluate the acceptability of the HPV vaccine among the African American community and explore the feasibility of promoting HPV vaccine educational content through mobile-based technology.

Albeit the limitations presented here, it is important to note that the nonrandom sampling design for this study was also purposefully selected in consideration of cultural issues. As African Americans put high values on social relationships, being invited to participate in a study by people with whom they are familiar (eg, health ministry leaders, HCPs who work in the African American community, community health advisors, and/or organizational partners from the already existing community network) was proposed as a more of a reasonable recruitment approach than being contacted by a third-party telephone interviewer they do not know. Although this study utilizes a convenience sample, this culturally sensitive sampling strategy serves as the initial step to create some degree of capacity building among the African American women community and will ideally create a sustainable infrastructure to support future research and cervical cancer intervention programs similar to this one.

In the next phase of this project, we will pilot-test the CervixCheck program and will use baseline and follow-up surveys to assess the program feasibility, acceptability, and initial efficacy. The findings from this intervention will inform future research and practice in developing culturally appropriate health communication approaches for church-attending African American women. If this pilot intervention shows feasibility, acceptability, and initial efficacy for increasing cervical cancer awareness and Pap test screening intention, such a program can be adapted or further expanded and evaluated for its effectiveness in its contribution to the elimination of cancer disparities that negatively impact African American communities. Future studies using a more rigorous research design with a larger sample of African American women (eg, a randomized controlled trial with multiple follow-up time points where actual screening behavior can be taken into consideration) is therefore needed to validate the effectiveness of interventions such as the CervixCheck program.

From a public health standpoint, this study also informs the work of researchers engaged in efforts to meet the *Healthy People 2020* objectives to reduce the death rate from cancer of the uterine cervix (C-4) and to increase the proportion of women who are counseled by their providers about Pap tests (C-18.2). *Healthy People 2020* is a 10-year health agenda released by the US Department of Health and Human Services that is designed to guide national promotion and disease prevention efforts to improve the health of all people in the United States [100]. Technology-based platforms can, therefore, provide researchers the ability to reach a large number of people at a relatively low cost, which can ultimately lead to a greater public health impact with regard to cervical cancer early detection health promotion efforts.

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Conflicts of Interest

None declared.

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Abbreviations

HCP: health care provider
HPV: human papillomavirus
mHealth: mobile health
NIH: National Institutes of Health
PA: physical activity
Pap: Papanicolaou
PI: principal investigator
RA: research assistant
SMS: short message service
STI: sexually transmitted infection

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Original Paper

User-Centered Design of a Mobile App for Weight and Health Management in Adolescents With Complex Health Needs: Qualitative Study

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Abstract

Background: Growing research has been conducted into the deployment and evaluation of mobile technology interventions for weight management in adolescents. However, no work has yet been conducted toward the development of these technologies for adolescents with complex health needs receiving specialized tertiary-level health care.

Objective: The aim of this study was to conduct a user-centered needs assessment of adolescents interested in weight management with complex health needs requiring specialized health care services, their parents, and health care providers (HCPs) to inform the design and development of a mobile app for weight and health management.

Methods: A qualitative study design was employed. Participants were recruited from two tertiary health care centers. Separate audiotaped focus group interviews were conducted with adolescents aged 12 to 18 years, parents, and HCPs. Interviews were transcribed, and field notes were collected by research staff. Iterative simple content analysis was performed independently by 4 research team members using computer software NVivo (QSR International) 10.0.

Results: A total of 19 adolescents, 16 parents, and 21 HCPs were interviewed. Qualitative analysis revealed seven major themes related to app functionality: healthy eating, social support, self-monitoring, communicating with HCPs, supporting mental health, gamification and incentives, and user interface (UI) design. Adolescents provided several ideas related to each feature, whereas parents' views focused on assistance with meal planning and greater access to HCPs. HCPs viewed the app as a novel and more acceptable platform to connect remotely with adolescents than conventional methods. They also strongly endorsed the value of social support capabilities and the ability to connect with an HCP.

Conclusions: This is the first study to conduct a qualitative needs assessment in adolescents receiving specialized health care services toward the design of a mobile app for weight and health management. Our results indicate that core components of the app should include tailored meal recommendations and assistance with meal planning, social networking for peer support, customized and convenient tracking, remote access to HCPs, features to support mental health, and an attractive and engaging UI. These findings will be used to develop and evaluate a mobile app targeting adolescents with complex health needs.

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KEYWORDS

obesity; weight loss; adolescent; mobile apps

Introduction

Background

Obesity in adolescents remains a major public health concern owing to its high prevalence and association with significant adverse health outcomes in adulthood [1]. Clinical interventions for obesity in children and adolescents aim to improve behaviors related to diet and physical activity (PA) and are based on psychological and family-centered theories of behavior change [2,3]. Adolescents with complex health care needs such as those with severe or complex obesity, disabilities, and other chronic health conditions may be excluded from such programs and generally show poorer rates of long-term success maintaining weight control [4-7]. Adolescents with complex health care needs often require specialized approaches to weight and lifestyle management that also address managing comorbid conditions, mental health problems, medications, and activity limitations [4,5,8-15]. Evidence-based behavioral strategies for weight management in children and adolescents with complex health care needs generally require more intensive counseling with an interprofessional health care team to help individuals and families build skills around goal setting, reducing sedentary time, and developing healthy eating habits through stimulus control and positive reinforcements [7,16]. Generally, factors that have been identified in successful programs are those taking place over 6 to 12 months, are family-centered in approach, and include group-based activities with peers [17]. Despite these advancements, the efficacy of emerging behavioral approaches is unclear, and behavioral interventions generally show modest reductions in body mass index (BMI) over the short-term [7].

Information and Communication Technologies for Weight Management

Information and communication technologies have created opportunities to deliver accessible and cost-effective interventions for weight management that may help to sustain adolescents engaged in healthy lifestyle practices over the long-term. Mobile apps are being increasingly investigated for their potential to support long-term health management by providing more convenient and sustainable ways to implement health-related behavior change and access health care [18-20]. Mobile apps allow for users to track and interpret relevant health data, access information and resources, and to communicate with peer and health care provider (HCP) supports. Moreover, rapid advancements in remote monitoring capabilities and aggregated data analytics present new opportunities to develop more personalized, precise, and effective treatments for overweight and obesity [21]. Mobile apps can potentially serve as a medium to deliver accessible health care to young people in their community, as they comprise some of the most active users of this technology [22]. Moreover, adolescents of today are often described as digital natives having grown up surrounded by digital technology and demonstrate a natural capacity to process information in an electronic world [23].

A number of systematic reviews of technology-based interventions for overweight and obesity in adolescents found significant short-term (less than 6 months) reductions in BMI and improvements in dietary behaviors, PA, and self-monitoring

[24-26]. Evidence is generally stronger for interventions employing mobile technology as an adjunct therapy to comprehensive weight management clinic-based programs [27-29]. Although these studies describe apps that have been used in research and health care settings, our group has conducted prior work to characterize the commercial app market for weight management apps and found that the majority of the apps available do not include evidence-based strategies and have not been developed with input from patients and HCPs [30]. These findings are supported by Shoffman and colleagues who reported on 57 commercial apps for pediatric obesity prevention and treatment and found that most lacked evidence-based recommendations [31].

Despite advancements made, a number of gaps persist in the literature. Minimal research has been conducted toward the development and evaluation of mobile health (mhealth) technologies for weight management, specifically targeting adolescents with complex health needs that require more frequent contact with HCPs and more intensive engagement with services [7,32]. Virtually no studies to date have been designed specifically for weight and health management in young people with severe or complex obesity, disabilities, and comorbid conditions, whose complex health needs often require specialized health care services and may not yet be properly represented in current research on health apps [33,34]. Furthermore, very little research has been conducted within health care settings and developed with patients and providers input toward the design and implementation of mhealth interventions. Finally, the majority of interventions have been developed for and tested in adult populations, and very few randomized controlled trials (RCTs) have been conducted in children and adolescents [25]. More research is needed to rigorously develop and evaluate mhealth interventions for weight and health management in young people with complex health needs requiring intensive and specialized treatment. The goal of this study was to conduct a user-centered needs assessment to inform the design of a mobile app for weight and health management targeting adolescents with severe or complex obesity, physical and developmental disabilities, and comorbid conditions receiving tertiary-level health care and in specialized clinical programs.

Methods

Study Design

A descriptive qualitative research design, as described in the study by Sandelowski [35], was conducted from 2015 to 2016. This research design was used for exploring the perspectives of adolescents with complex health care needs interested in weight management, as well as their parents and their HCPs regarding the essential features needed in a mobile app for weight and health management. Separate focus group interviews were conducted across two sites with adolescents, parents, and HCPs.

Participant Recruitment

Purposive sampling of adolescents interested in weight management and healthy lifestyles was employed to collect information-rich cases that encompassed the diverse needs of

a heterogeneous sample of adolescents with different health conditions and obesogenic risk factors. Participants in the age range of 12 to 18 years were recruited from two pediatric hospitals in Ontario, Canada. Participants at site 1 were recruited from a specialized tertiary care outpatient behavioral weight-management program for adolescents in the age range of 12 to 17 years with severe or complex obesity. Patients referred to this program have a BMI over the 99th percentile or a BMI over the 97th percentile and a significant obesity-related comorbidity requiring subspecialty care. Participants at site 2 were recruited from specialized inpatient units at a tertiary care pediatric rehabilitation hospital for adolescents in the age range of 12 to 18 years with disabilities, including acquired brain injury, neuromuscular, orthopedic and developmental disabilities. The study was approved by the Research Ethics Boards of both participating hospitals.

Adolescent Selection

Eligible adolescents were introduced to the study by an HCP who was part of the client's circle of care and could verify their capacity to consent. Adolescents were provided information letters describing the study and asked if they wanted their contact details passed onto the research team. Those interested were contacted by a research assistant who met with the adolescent to explain the study and obtain consent. Adolescents were deemed eligible to participate if they were receiving care at either recruitment site, were interested in weight and health management, and were able to speak and read English. Adolescents were excluded if they had severe cognitive impairments (eg, unable to take turns and consider other viewpoints), or a major comorbid psychiatric or medical illness that precluded their capacity to consent and ability to participate in a group discussion (eg, severe depression or anxiety), as identified by a member of their immediate clinical team.

Parent and Caregiver Selection

Parents or caregivers of adolescents deemed eligible were also invited, though not required, to participate via the information letter. Parents or caregivers were required to speak and read English to participate. Parents were provided the option to participate with their spouse or on their own.

Health Care Provider Selection

HCPs were introduced to the study by program managers and recruited from the respective clinical programs serving adolescent participants. No limitations were placed on health discipline or type of clinical service provided. Trainees were excluded from the study because of limited knowledge of the population.

Interview Protocol

Study consent was obtained before each focus group interview. Adolescent and parent or caregiver participants completed two

questionnaires on demographic and health characteristics, as well as level of use and comfort with mobile apps. HCPs completed one questionnaire on demographic and occupational characteristics. All interviews were conducted at the two hospital sites by four research team members, two of whom facilitated group discussion and two who observed and took field notes capturing verbal and nonverbal behaviors.

Focus groups were semistructured in format and followed an interview guide created by experts in pediatric obesity and informed by current research and clinical experience. Guides for adolescents and parents or caregivers included topics regarding their general experiences with weight management in their clinical programs, school, and home, before moving into more specific questions regarding desired app features and design. Adolescent and parent or caregiver focus groups were conducted concurrently and separately. The HCP interview guide similarly started with general questions about their openness to a mobile app related to healthy lifestyles before moving into more specific questions regarding app features and integration within their clinical practice. Sample interview questions are provided in [Table 1](#).

Data Analysis

Demographic data were coded and analyzed using Excel (Microsoft) to determine measures of central tendency and the distribution of values for the sample. All interviews were audiorecorded and transcribed verbatim, which were imported into NVivo 10.0 for data management. Qualitative content analysis was conducted using the approach described by Sandelowski, 2000 [35] using focus group transcripts and field notes. The data were analyzed to produce a simple descriptive summary of participants' views, which is presented in everyday language [35]. More specifically, data for all participants were coded and organized into categories that reflected the emergent themes.

Three members of the research team coded the data (JR, TG, and MP). Study credibility and integrity were achieved using iterative questioning during interviews, frequent debriefing sessions with research team members, thick description, and prior examination of extant research in this area. Techniques were used to minimize the power differential between interviewer and respondents, including establishing rapport with ice-breaker questions using developmentally appropriate language, active listening, and relaxed body language. Data saturation was reached when no new codes were arising through iterative and open-ended questioning. The raw data were revisited regularly throughout the analytic process to ensure that the coding schemata reliably reflected the data. Discrepancies in coding were resolved with two senior members of the research team (JS and AM). Pseudonyms are used in place of participant names with quotes indicating the type of participant and the study site (site 1 or site 2).

Table 1. Sample interview questions.

Group	Broad questions	Program-specific questions
Adolescents	<ul style="list-style-type: none"> • Can you tell me how long you have been working on healthy nutrition or physical activity goals and what it has been like for you? • Why do you want to develop healthier lifestyle habits? • Who do you feel should be involved with helping you to make and stick to healthy lifestyle changes? 	<ul style="list-style-type: none"> • What do you think about having a website and smartphone app that could help you to better manage your weight and develop a healthy lifestyle? • Would you be interested in tracking your weight, what you eat, and your physical activities on an app? How about your mood, stress, sleep quality, and medications? • Would you want a function on the app to help you set healthy lifestyle goals?
Caregivers	<ul style="list-style-type: none"> • Can you tell me how long your child has been working on healthy nutrition or physical activity goals and what it has been like for him or her? • Do you feel like your child has the tools or resources needed to manage and stick with their healthy lifestyle independently? • Do you think your child wants to develop healthier lifestyle habits? Why or why not? 	<ul style="list-style-type: none"> • What do you think about having a website and smartphone app that could help your child to better manage their weight and develop a healthy lifestyle? • Does your child keep track of their weight, what they eat, and their physical activities on a regular basis (eg, paper or electronic diary)? Why or why not? • What information about managing your weight and developing a healthy lifestyle would you or your child want to learn more about to feel comfortable managing a healthy lifestyle?
Health care providers	<ul style="list-style-type: none"> • What would you say are the patients' and families' biggest challenges and barriers to developing a healthier lifestyle? • Do you feel like they have the tools or resources that they need to manage their healthy lifestyle independently? 	<ul style="list-style-type: none"> • What do you think about having a website and smartphone app that could help them to better manage their weight and develop a healthy lifestyle? • How do you see an app fitting in with their care plan? • Are there any other important features that we didn't talk about that could help them to become healthier?

Results

Study Participants

A total of 56 participants were included in the study. Three focus groups were conducted with adolescents (n=19), four with parents or caregivers (n=16), and three with HCPs (n=21). A total of 34 participants were interviewed at site 1 (adolescents: n=12, parents: n=10, and HCP: n=12), and 22 were interviewed at site 2 (adolescents: n=7, parents: n=6, and HCP: n=9). Demographic characteristics of adolescents, parents or caregivers, and HCPs are presented in [Tables 2-4](#). In general, most adolescents were female and in the age range of 12 to 16 years. The majority of parents were mothers in shared, middle income households. A range of HCPs were represented in our sample, including pediatricians, psychologists, social workers, registered nurses, dietitians, exercise coordinators, and occupational therapists.

App Functionality

Thematic analysis revealed seven app functionalities of a mobile app for weight and health management, endorsed by adolescents, their parents, and HCPs. The seven desired app functionalities were as follows: healthy eating, social support, self-monitoring, communicating with HCPs, supporting mental health, gamification and incentives, and user interface (UI) design. Similarities and differences in perspectives were compared between participant groups and outlined below. All participant

groups felt that a weight and health management app that is geared toward the unique needs of adolescents receiving specialized health care services to promote healthy weight-related behaviors would be beneficial.

Key Functionality Components

Support for Healthy Eating

Adolescents identified a number of features that they felt were crucial to support healthy eating, including meal recommendations, recipes, nutrition information, and meal tracking. Adolescents desired meal suggestions to be personalized to factors such as mealtime patterns, social activities, and health conditions.

For example, one respondent proposed meal suggestions specific to popular restaurants or frequented eating locations, as illustrated in the following quote:

So like a list of the most popular restaurants...You could even have a section where it gives you options if you go to that place. [Lily, adolescent, site 1]

Adolescents also desired a variety of new healthy recipes, as exemplified by the following quote:

Maybe food recipes is a big one, because we can eat healthy all we want but if we continue to eat the same grilled chicken breast, it will get boring. So maybe it could update all the time with different food recipes. [Sarah, adolescent, site 1]

Table 2. Demographic characteristics of health care provider participants.

Characteristics	Health care providers (n=21)
Type of health care provider, n (%)	
Pediatrician	2 (10)
Psychologist	3 (14)
Social worker	3 (14)
Registered nurse	3 (14)
Dietitian	2 (10)
Exercise counselor	2 (10)
Occupational therapist	6 (28)
Sex, n (%)	
Female	21 (100)
Experience as a health professional (years), mean (SD)	11.2 (8.0)
Experience working with children (years), mean (SD)	8.21 (6.6)
Experience in obesity or weight management (years), mean (SD)	5.23 (6.6)

Table 3. Demographic characteristics of teen participants.

Characteristics	Teens (n=19)
Gender, n (%)	
Female	13 (68)
Male	6 (32)
Average age (years), mean (SD)	14.7 (2)
Current grade, n (%)	
Grade 6	1 (5)
Grade 7	3 (16)
Grade 8	1 (5)
Grade 9	2 (11)
Grade 10	3 (16)
Grade 11	4 (21)
Grade 12	4 (21)
College	1 (5)
Work status, n (%)	
Not working	15 (79)
Part-time work	4 (21)
Medical conditions, n (%)	
None	7 (37)
Not sure	7 (37)
Asthma	3 (16)
Autism	1 (5)
Sickle cell	1 (5)

Table 4. Demographic characteristics of parent participants.

Characteristics	Parents (n=16), n (%)
Type of caregiver	
Biological mother	14 (88)
Biological father	1 (6)
Adopted father	1 (6)
Employment status	
Unemployed	2 (13)
Part-time	2 (13)
Full-time	11 (69)
Retired	1 (6)
Household income (CAN \$)	
Less than 25,000	3 (19)
25,000-49,000	1 (6)
50,000-74,000	2 (13)
75,000-99,999	1 (6)
100,000-150,000	6 (38)
Above 150,000	2 (13)
Do not want to answer	1 (6)
Education	
Some high school	2 (13)
Graduated secondary school	1 (6)
College or technical school	5 (31)
Some graduate school	2 (13)
Graduate degree	6 (38)
Marital status	
Single	2 (13)
Married or living common law	12 (75)
Separated	1 (6)
Divorced	1 (6)
Ethnic background	
Aboriginal	0 (0)
White	9 (56)
South Asian	0 (0)
Chinese	0 (0)
Black	1 (6)
Filipino	0 (0)
Latin American	0 (0)
Arab or West Asian	0 (0)
Southeast Asian	0 (0)
Korean	0 (0)
Japanese	0 (0)
Other (ie, Portuguese, Greek, or Italian)	3 (19)
Do not want to answer	3 (19)

Related to this, nutrition information for specific foods was desired to facilitate more convenient grocery shopping. One adolescent stated the following:

You brought up using barcodes, maybe you could be able to go to the grocery store, scanning a barcode and the nutrition facts popping up and maybe give you more information than is on the package and see if that is in your list of things that you could have. [Megan, adolescent, site 1]

The feedback provided by the app would ideally reflect their individualized healthy eating plan established between the adolescent and their health care team.

Adolescents and parents felt a meal-tracking feature would be beneficial, as a strategy for health-related behavior change, exemplified by the following quote from one adolescent:

Say you go out and eat something for fast food and we put it in [the app] and it notices that we have had that [food] too many times that it gives us a tip saying be careful. [Heather, adolescent, site 1]

One parent provided a real-world example of how such a feature might provide guidance to their adolescent, as illustrated in the following quote:

A reminder...I've had hamburger and French fries, okay well then have a hamburger and French fries in 4-5 days but not tomorrow. [Susan, parent, site 2]

Parents' priorities centered primarily on assistance with meal planning. Parents desired an app that would provide nutrition information and suggestions for healthy meals personalized to their child. One parent stated the following:

Yeah, I think [meal planning] is the biggest thing. Or on the app what are the good snacks and the ingredients and what they need to do, just so they have everyday planned out. [Margaret, parent, site 1]

Another parent wanted greater variety with food selection, as illustrated in the following quote:

What things you've discovered that you can eat other than apple sauce. [Lilian, parent, site 2]

HCP's responses centered on meal tracking and emphasized identifying adolescents' personal health goals and adapting self-monitoring practices appropriately to promote healthy eating. One HCP stated the following:

At least get a push notification saying we noticed your weight has gone up, try eating more fruit, based on if they were entering data regarding their diet, or depending on what their goal was...to help people make that connection between knowing and actually implementing what they know. [Kathryn, HCP, site 2]

Social Support

A key feature identified by the majority of adolescents was social support capabilities within the app. Social connection, or a way to maintain contact with peers, was frequently

discussed as a critical feature for app use. One adolescent stated the following:

I think what you could actually have is something that could keep you connected to everyone else in the program...we have known each other for 10 weeks and it is kind of sad that we are not going to see each other anymore. [Lily, adolescent, site 1]

An app could be used to prolong connection with peer social supports.

Encouragement and coping support were also discussed as potential benefits to a social support feature, which would allow for adolescents to share encouraging messages with peers and to seek out or offer advice regarding healthy lifestyles. For example, one adolescent commented the following:

Every once and a while you click on someone's name and send them a little private message or a little motivation thing. [Sarah, adolescent, site 1]

To facilitate social support, adolescents suggested linking to other social media platforms that are already in popular use, while also providing ways to engage in more private conversations with peers in similar situations (eg, participating in a weight management program). One adolescent stated the following:

It would be cool if we could have a section we could log into and it would just be for your group and there you could have a chat to stay connected. [Rebecca, adolescent, site 1]

The importance of social support to adolescents' motivation to adhere to healthy lifestyle change was reinforced by parents and HCPs who also identified social support frequently as a critical app feature. One HCP stated the following:

One thing we have heard back that people actually really like is the social [support]. [Dana, HCP, site 1]

Likewise, one parent commented the following:

Being here they're with their own, at least I feel my daughter feels more herself. Being able to talk to people with the same issue. [Margaret, parent, site 1]

HCPs and parents also endorsed using existing social media apps such as Instagram for motivation, entertainment, and encouragement, as illustrated in the following quote:

I'm really obsessed with the idea of having an Instagram with it...like look guys this is what [everyone] did today! [Maria, HCP, site 2]

Self-Monitoring

Adolescents supported tracking data such as meals, PA, sleep, mood, and general health and that tracking be made customizable and related to personal goals. For example, one adolescent stated the following:

You're able to pick from a list of things, like say that there is a list of 20 different things that you can track, but you pick maybe 8 of them. [Alice, adolescent, site 1]

Adolescents also described how tracking would facilitate greater awareness of unhealthy lifestyle behaviors. One adolescent commented the following:

Maybe track how much sleep I need...When I'm feeling really tired I can't [always] recognize it, it could tell me you need to go take a nap right now. Like when your body is really drained, go sit down. [Adolescent, site 2]

HCPs similarly supported tracking as an appropriate technique for understanding lifestyle patterns and identifying areas for improvement. One HCP suggested the following:

Recording [and] tracking patterns, because lots of times our kids will say right after school [is when] they breakdown. [Jessica, HCP, site 1]

However, both parents and adolescents expressed concerns that tracking aspects of health over the long-term can be difficult to sustain. One youth stated the following:

Just some personal experience with apps like this. I find that you start off really well with tracking, but overtime you forget or you don't put in accurate information. So it is really easy when it comes to tracking to lose focus. [Lily, adolescent, site 1]

Parents were particularly concerned that tracking all aspects of their life could be an emotional burden on adolescents, as was exemplified in the following quote:

[My daughter] tracked for a couple of years, and then she just had a meltdown. She refuses to track anything now. And my family doctor says she has every right not to want to track. Because they're telling you not to eat and then to write down everything you did eat, like continuously in your face. [Margaret, parent, site 1]

Finally, HCPs discussed the importance of setting realistic goals and considering the risk for unhealthy tracking, as demonstrated by the following quote by an HCP:

I think the danger is if they start using the app to expedite something. Their weight is going to be very tricky because we also want you to be comfortable with your weight. [Kathleen, HCP, site 1]

Communicating With Health Care Providers

Adolescents liked the idea of being able to keep in touch and communicate with their HCPs within the app. When considering the different features that could potentially be offered by the app, adolescents identified multiple ways that they would consider using to communicate with HCPs, such as video calling, SMS text messaging (short message service, SMS), and sharing health data. One adolescent stated the following:

Virtual check-ins would be pretty cool, almost if we could make our own little appointments...they could have a time slot and then we could be like "oh I'm free" so then we just add our own appointment. And then we just FaceTime. [Dianne, adolescent, site 1]

Adolescents endorsed the utility and convenience offered by remote access to interprofessional health care supports. This is demonstrated by one adolescent who suggested the following:

[Having] professionals you could talk to in case you have a problem or you're feeling down...At that moment in time, they could advise you and give you some strategies to help you. [Nicky, adolescent, site 2]

Furthermore, adolescents endorsed greater comfort and more efficient care with greater access to familiar HCPs, with one adolescent stating the following:

I think it would be cool to be able to connect with [our HCP] and ask them for advice because we have known the people we have been working with for a while. So it's more comfortable asking them. [Lily, adolescent, site 1]

Finally, data sharing with HCPs was suggested as many youths felt that this would provide a more accurate and up to date picture of their health, without constantly explaining what they were doing to maintain a healthy lifestyle. This was illustrated by a quote from an adolescent who stated the following:

Each time you go for your therapy, you wouldn't have to explain how you're feeling, or how you have been doing since the last time you saw them. You could just show them, or they could already have it written down. [Ian, adolescent, site 2]

However, adolescents still desired control over privacy in their communication, with one adolescent stating the following:

There could be an option to make it anonymous, or a direct message, or if you want you could put it to the group chat. [Heather, adolescent, site 1]

Parents also endorsed the benefits of having greater access to HCPs, whom many believed could provide needed emotional support to adolescents. One parent stated the following:

If they could talk with [a HCP], I think that would be the best thing, because sometimes [my daughter] just doesn't want to talk to me, she gets all frazzled and then I start getting mad, and it's just going to make it worse. [Mark, parent, site 1]

HCPs were also open to communication with adolescents using an app and acknowledged adolescents' comfort and adeptness with mobile apps, particularly as a communication tool over more traditional platforms such as email. One HCP stated that using an app can be "a way to communicate with [youth] that they are tapped into [and] that's groundbreaking. They are like, why do you want my email, what are you, 100 [years old]?" (Nadia, HCP, site 1). HCPs also described how sharing health data over the app would facilitate more personalized, targeted and consistent care, as illustrated in the following quote:

...with the app it's a nice kind of consistency. If I don't [see] you all the time but you wrote on the app "I'm sad today" then I can get you that support. So maybe I can get you someone from psychology or somebody from recreation that you have a good bond with to come talk to you. [Jacklyn, HCP, site 2]

However, HCPs still raised doubts about the practicality and enthusiasm held by adolescents for sharing their health data with their health care team, stating it would be “weird if you’re filling it out knowing a HCP is going to see it” (Tara, HCP, site 2).

Supporting Mental Health

Adolescents, parents, and HCPs all identified support for mental health as an important component of app function. Features that were suggested by adolescents included information about emotions, mood, and their impact on motivation, as well as healthy coping strategies such as relaxation, stress reduction, and building self-efficacy. Adolescents and HCPs both suggested inspirational messages, positive affirmations, reframing negative thoughts, and connecting with social supports as potential coping strategies facilitated by the app.

HCPs also viewed an app as an acceptable and useful tool for adolescents to self-monitor mental health, including mood and thought patterns, as exemplified by one HCP who stated the following:

You click on the app, first thing is “how are you feeling?” [Melissa, HCP, site 2]

HCPs also felt that the app would allow adolescents to more honestly report their mood and its impact on their lifestyle. One HCP stated the following:

I think they’d be more willing to say it on the app as opposed to telling us “I’m not having a good day today.” I think they’d be more open to doing it that way than verbally. [Lindsay, HCP, site 2]

Finally, parents and HCPs found it important that support also be provided to parents to promote mental wellbeing and positive self-image in their adolescent. One parent (Eleanor, parent, site 2). in particular claimed that her daughter’s mental well-being and self-image were the “most important things” to her, even over her daughter’s weight or adherence to diet. Another HCP (Darlene, HCP, site 2) suggested the “model of giving parents the tools they need to be the therapist with their adolescent. ”

Gamification and Incentives

Adolescents proposed games and rewards-based incentives to help motivate continued use of the app. Suggestions included a point systems, monetary rewards, as well as multi-player gaming. HCPs also endorsed games and rewards, particularly group-based games as strong motivators for adolescents. One HCP stated the following:

I think that’s really motivating, when you have a goal in mind and you want to [improve] every single day. I think for kids that’s a good way to do it too. They’re always trying to compete against their classmates so I think having a goal oriented program would be good. [Patricia, HCP, site 2]

User Interface Design

The most salient need in the UI design raised by adolescents was that it be attractive and entertaining to motivate its regular use. One adolescent’s quote encapsulates this notion, as stated in the following:

I feel like if we were to make an app, you have to make it entertaining...because even on the iPhone and the Android you automatically get a health app but almost no one ever touches it. [Julia, adolescent, site 1]

Some adolescents compared the need to design the app to be interesting and engaging in a similar fashion to popular social media apps such as Snapchat and Instagram, which are accessed frequently throughout the day by many teens. HCPs also stressed that the app be simple and easy to use, preferably with minimal reading. One HCP stated the following:

Simplicity, just keeping it simple, so no food entry or that kind of stuff. That is what drives people away from using it. [Carmen, HCP, site 1]

Discussion

Principal Findings

This qualitative study describes the perspectives of adolescents with severe or complex obesity or physical and developmental disabilities regarding the development of a mobile app to support weight and health management. Participants desired an app with features to enhance existing weight management practices and improve long-term maintenance of healthy behaviors. These features centered on healthy eating, social support, self-monitoring, communicating with HCPs, supporting mental health, gamification and incentives, and the UI design.

Healthy eating emerged across participant groups and included proposed features for meal planning, cooking, nutrition information, and more effective ways to self-monitor. The US Preventive Services Task Force considers a dietary component a critical aspect of comprehensive behavioral pediatric weight management programming [36]. However, a review of commercially available apps for weight management found only one-third included features to support healthy eating [30], whereas another review of apps specifically for the prevention of obesity in children found less than a third (27.4%) provided nutrition-related education, and only 11.2% assisted with meal planning [37].

Seventy-five percent of the top rated smartphone apps for weight loss are narrowly based on the energy-balance model of weight management and rely on a food database to track and control caloric intake [2,38,39]. In contrast, assistance with meal planning has not been widely reported in apps developed for weight management, particularly in young people [37]. Curtis et al have conducted preliminary work describing the design and theoretical development of a user-centered healthy eating app targeting parents for childhood weight management [40]. They identify time-saving and convenience with meal preparation as key characteristics desired by parents. Meal planning features such as recipes and nutrition information were strongly endorsed by both adolescents and parents in this study. Few apps targeting adolescents have been found to provide tailored assistance with meal planning and recipes for healthy eating, with most apps narrowly focused on dietary tracking and assessment [25,41]. Adolescents’ needs for healthy eating expanded beyond self-monitoring capabilities and included

more convenient and efficient ways to plan meals and make healthier food choices throughout the day.

Self-monitoring, which involves tracking relevant health data and analyzing trends, is argued to be a central strategy of effective weight management [42,43] and is one of the most common strategies incorporated into technology-based interventions for weight, diet, and health management [25,44]. Electronic devices can provide more convenient and accurate ways to monitor personal health data than paper methods, thus increasing the sustainability of behavior change [45]. The potential effectiveness of emerging digital technologies for self-monitoring and health management is based on the proposed capabilities for more comprehensive and precise measurement, allowing for more personalized feedback to be generated [2].

Studies of mobile device interventions in adults have demonstrated significant associations between frequency of dietary and PA self-monitoring and weight and health-related outcomes [44,46]. Cartel et al reported that those with the highest frequency of mobile app use for self-monitoring had a -6.4 kg lower follow-up weight at 6 months than those with the lowest frequency of app use. Studies in adolescents have shown mostly mixed findings [25], likely attributable to a lack of longer-term trials demonstrating the effectiveness of mobile device interventions beyond 12 months, as well as to large variability in intervention designs and adherence rates to mobile device health tracking [43]. Participants in our study perceived difficulties in sustaining tracking over the long term, but believed the information would benefit their understanding of their health and support making healthier lifestyle choices. Self-monitoring adherence remains a major problem with current mobile devices for weight loss [43]. Our findings suggest an app would be more effective and engaging if tracking was made personally relevant and tied to personal goals, thereby facilitating greater awareness and evaluation of goal attainment and reinforcing behavior change.

Social support was seen as an important app feature for adolescents to stay connected with peers they had met through their hospital. Peers were valued as major sources of motivation, confidence, and learning. Our findings reinforce the value of social support and relationships to adolescents' adoption of health beliefs and behaviors [47,48], including dietary and PA behaviors [49-53]. Smartphones and social media apps have reshaped how adolescents communicate with different peer groups on health-related topics [47]. The application of social media in health interventions has been examined in a systematic review of online social networks, which found mostly small and nonsignificant results [54]. These studies, conducted mainly in adults, used commercial websites such as Facebook and Twitter, as well as researcher-developed, health-focused social networks. Researcher-developed social networks were shown to be more effective for the users they retained over a period of time, suggesting that online social networks for health behavior change would be more useful for individuals already contemplating behavior change and are highly motivated [54].

Fostering supportive social relationships is a key strategy in pediatric clinic-based weight management programs, particularly in the maintenance phase of treatment [53]. The implications

for a social support functionality in a health app for adolescents with complex health needs include the potential for online social networks to enhance motivation and adherence with healthy lifestyle changes. In addition, social network apps can allow greater access to social supports that are known to positively influence health behavior change. For many adolescents in the study, supportive relationships were central drivers of change, thus creating opportunities to leverage existing social networking applications and technologies to enhance and sustain health behavior change.

Communication with HCPs using a mobile device has the potential to significantly expand access to professional support and reflects ongoing initiatives within telehealth to develop applications for remote health care delivery and monitoring. Although efforts to harness mobile technologies for remote health care delivery are growing rapidly [55], our findings expand on the perceived utility of these technologies not only for enhancing access to health care but also to enhance continuity of care between patients and providers most knowledgeable about their health. Several adolescents viewed their HCPs as important resources for information about nutrition and healthy meal ideas, as well as for support during times of emergency or crisis. They ascribed greater comfort and openness to interacting remotely with providers they are familiar with regarding their progress and setbacks with weight management, suggesting that maintenance of the therapeutic relationship can serve as a major driver of adolescents' adherence to healthier lifestyle change.

Telehealth interventions to extend therapeutic contact for children and adolescents with overweight and obesity have incorporated telephone, email or Internet, and mobile device SMS [56-61]. The underlying aim and rationale of these technologies is to improve health care service coordination and continuity through client education, health information transfer, and real-time assistance with self-management [62]. More recently, [25] systematically reviewed studies of mobile device technologies for adolescent weight management and describe pilot RCTs by Nguyen et al [63] and Patrick et al [64]. Nguyen and colleagues [63] employed SMS, email communication, and telephone coaching for adolescents with overweight or moderate obesity to connect them with a registered dietician who was trained to provide additional therapeutic support. In the study by Patrick et al the researchers also used SMS, Internet, and telephone calls to provide adolescents at risk for type 2 diabetes access to a health counselor for support. Neither study found significant effects of the intervention on weight loss. However, Nguyen and colleagues point out there are few theories or frameworks to inform the structure, frequency, and duration of communication with HCPs [63]. Turner et al [25] in their review describe several usability and design studies showing improvements in diet, sedentary behavior, adherence to treatment, and self-monitoring with remote access to HCPs. Large-scale RCTs of differing systems and arrangements outlining remote HCP communication for adolescents are needed to better inform design of an optimal program structure.

The implication of our findings on future research and development of mobile device health provider communication suggests such a feature would be more effective when used by

patients and their regular health providers with whom trust and a therapeutic alliance has been established. This way, more personalized and meaningful support can be provided, particularly for adolescents with complex health care needs. Furthermore, protecting privacy and ensuring security of personal health information is paramount to the utility, effectiveness, and safety of any mobile health intervention. Ultimately, our findings suggest that a mobile app can enhance or expand an existing health care service arrangement, rather than establish a new arrangement, and must be appropriately, safely, and securely implemented. Adolescents and parents view their HCPs as important sources of information and support and would benefit from easier access to them.

Support for mental health incorporated ways to feel motivated and increase self-efficacy. Adolescents, parents, and HCPs discussed the importance of emotion, motivation, and positive self-image for weight management success. Adolescents specifically touched on managing stress and mood as important components to making healthier lifestyle changes. Some specific strategies related to supporting mental health using the app included guided relaxation and mindfulness practices, access to personal supports, and speaking to an HCP. HCPs suggested storing affirmation statements, distraction techniques, and behavioral activation (eg, prompts) be incorporated into the app. Many of these strategies reflect components of emerging medical and commercial apps that have attempted to employ psychological theories into their design, mostly centered on cognitive behavioral therapy techniques such as mindfulness, relaxation, and emotional control, as well as providing tailored recommendations and information related to mental health and coping [65]. A recent review by Bakker et al [65] demonstrates that mental health smartphone apps can be effective for managing psychological problems, including depression and anxiety [66]. Fewer studies describe the integration and impact of psychological theories and psychotherapeutic techniques into the design and development of mobile apps for adolescent weight management [67].

Finally, the app interface should be simple and interactive, enjoyable to use, and intuitive. HCPs stressed the importance of designing the app to be very simple to use, whereas adolescents highlighted the importance of designing the user experience to be interesting, fun, and entertaining. Turner et al [25] reviewed usability studies of mobile technologies for pediatric obesity, which have provided some direction to future designs of app interface and the user experience. Ease of use and reduced demands on the user [68,69], reward-type incentives, social connection, and multiplayer gaming were

proposed as major usability requirements by participants and researchers [20]. Studies have also pointed to motivational and personalized feedback as important features of the user's interaction with the device [70]. Hamine et al [21] describe automation, motivational content, health challenges, and data analytics as main features of most mhealth tools for chronic disease management. In summary, the features discussed should be effectively integrated within the app's program architecture to ensure that usability is simple, convenient, interesting, and entertaining. Potential app designs can employ strategies for gamification and social engagement to drive behavior change, while customizing app functionality to the user's goals and preferences.

Limitations

This study presents preliminary findings toward the development of a mobile app for weight and health management using a qualitative research design. Hence, findings reflect the subjective perspectives of adolescents with complex health care needs in specialized clinical programs and should not be generalized to adolescents in the general population who are not as intensively engaged with the health care system and may not benefit from enhanced health care support through a mobile app. More research using quantitative and qualitative research designs should be used to substantiate these results and to evaluate and improve on proposed app designs. Second, it should be noted that the majority of adolescent participants in this study were girls, potentially limiting proper description of the unique needs of boys in a mobile app for weight and health management. Further work is needed to characterize the views of adolescent boys and actively involve boys and girls in the design and implementation of the tool.

Conclusions

The findings presented here describe the core functional components of a mobile app for weight and health management in adolescents with complex health needs. These findings highlight the lack of such a tool for adolescents in frequent contact with specialized health care services who could potentially benefit the most from more accessible health support through this technology. Remaining questions to be addressed center on how to best design these features into an app that is useful, interesting, as well as engaging for adolescents. Future directions for this research will be to develop the app and conduct iterative cycles of usability and feasibility testing before undergoing a pilot RCT to examine preliminary measures of effectiveness.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
HCP: health care provider
mHealth: mobile health
PA: physical activity
RCT: randomized controlled trial
SMS: short message service
UI: user interface

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Original Paper

MedFit App, a Behavior-Changing, Theoretically Informed Mobile App for Patient Self-Management of Cardiovascular Disease: User-Centered Development

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Abstract

Background: The MedFit app is designed to facilitate participation of people with cardiovascular disease (CVD) in an exercise-based rehabilitation program remotely. This paper details the development for the MedFit app.

Objective: The aim of this research was to develop a behavior change, theoretically informed exercise rehabilitation mobile app for adults with CVD by following the early stages of the formative research: development and feasibility testing.

Methods: Adhering to the mobile health (mHealth) development evaluation framework, the stages of the formative research process including (1) development and (2) feasibility were undertaken. The content and format of the MedFit app were developed based on (1) theory, (2) usability testing, and (3) content design.

Results: A systematic review of the literature was undertaken to identify the most appropriate theories from which to develop the app. This led to the creation of the MedFit app. The app went through iterative rounds of usability focus group testing with adults with CVD to provide feedback on the app. This process was framed by the unified theory of acceptance and use of technology model. Feedback was then translated into feasible technical improvements to be executed through close collaboration with the technical team, who adapted and made modifications to the app based on this codesign process.

Conclusions: The formative research process of the app development involved theoretical underpinning, usability testing, and content design. mHealth interventions may play a key role in the future of health care, potentially addressing the barriers to participation in cardiac rehabilitation. This work will provide guidance for future research aiming to develop mobile apps by incorporating a best practice framework for mHealth intervention development and a user-centered design approach.

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KEYWORDS

app development; cardiac rehabilitation; telemedicine; exercise; mHealth; focus groups; usability testing

Introduction

Background

Cardiovascular disease (CVD) is the leading cause of mortality worldwide, accounting for 17.3 million deaths per year, which is expected to rise to more than 23.6 million by 2030 [1]. With the prevalence of CVD on the rise, secondary prevention methods to battle this condition have never been so important. Cardiac rehabilitation (CR) is a secondary prevention program. It is defined by the World Health Organization as the “sum of activity and interventions required to ensure the best possible physical, mental, and social conditions so that patients with chronic or post-acute cardiovascular disease may, by their own efforts, preserve or resume their proper place in society and lead an active life” [2]. CR involves exercise training, education on heart-healthy living, and counseling to reduce stress and help return to an active lifestyle. CR can be delivered within a hospital-based program and also via community-based programs to enhance long-term maintenance of CR participation. As physical activity (PA) has been shown to improve quality of life (QoL) and reduces mortality in patients with CVD, PA counseling and exercise training are the core components of the program. A Cochrane systematic review of exercise-based CR found that all-cause mortality was reduced by 26% (RR 0.74, 95% CI 0.63-0.87) [3]. CR has also been associated with reduced hospital admissions and improvements in psychological well-being and QoL [4].

Although the benefits of CR have been well documented, adherence to these programs is generally suboptimal. Across a number of surveyed countries, only 14% to 43% of cardiac patients participate in rehabilitation programs [5-8]. Poor uptake of CR has been attributed to several factors such as physicians' reluctance to refer some patients, particularly women and people from ethnic minorities or lower socioeconomic classes, and a lack of resources and funding [9]. Furthermore, less than 50% of those who participate in CR maintain an exercise regime for as long as 6 months after completion of the program [10,11]. Results from a Cochrane systematic review revealed that common barriers to adherence to CR programs include accessibility and parking at local hospitals, a dislike of group environments, and work or domestic commitment [12]. This suggests that current CR programs do not suit all patients and that alternative modes of rehabilitation should be available. Mobile health (mHealth) technologies may hold the key to this new mode of CR delivery.

mHealth is a component of electronic health (eHealth) defined by the Global Observatory for eHealth as “medical and public practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDA's) and other wireless devices” [13]. According to Kailias and colleagues (2010), there are more than 7000 documented smartphone health apps available to the public [14]. mHealth technologies use techniques and advanced concepts from a multitude of disciplines such as computer science, electrical and biomedical engineering, health sciences, and medicine [15]. Technology-enabled health behavior change interventions are designed to engage people in health behaviors that prevent or

manage disease [16]. mHealth may therefore address the previously cited poor uptake of CR and act as a useful tool in supporting the self-management of chronic disease [17,18]. Indeed, some of the core barriers as stated above (ie, accessibility, social unease, and difficulty engaging with CR because of work or domestic commitments) can be addressed through flexible mHealth solutions. The Institute of Medicine has even called to increase the design and testing of health technologies [19], with research into the effects and mechanisms of behavior change interventions also crucial [20]. mHealth solutions deliver many additional behavior change techniques (BCTs) that are not possible with standard pedometers, such as goal setting, social support, and cues to action [21]. These new techniques embedded within an mHealth framework may move toward helping to tackle one of the key issues of long term CR (ie, less than 50% of those who participate in CR maintain adequate levels of PA post 6 months).

Recent findings from Gallagher and colleagues [22] echo results from the Technology Usage Questionnaire [23] highlighting a high level of technology ownership or use within the CVD population. Previous research has found that most (77%) CVD patients indicated an interest in CR support through the Internet, 68% through the mobile phone, with many reporting interest in game-based CR (67 %) and virtual rehabilitation (58%) [23]. Therefore, mobile technology offers an important opportunity to improve access to secondary prevention for cardiac patients, particularly when modified to suit subgroups [22]. Advantages of mobile technologies for secondary prevention include access to psychoeducation at appropriate times, real-time tracking of behavior, and cues to action. Serious gaming designs can also be incorporated to highlight key healthy lifestyle behaviors across the lifespan [24,25]. Patients may also access health information and connect with health professionals and other cardiac patients more directly. Patients and health care professionals may benefit from a rich source of data, which can be in turn used to evaluate effectiveness. When mHealth avenues are incorporated or offered as an alternative to *traditional* CR (ie, hospital-based programs prearranged at set dates and times), improvements in multiple risk factors occur, and mortality benefits have shown to be equal for both modes of delivery [26].

Despite these potential benefits, it is extremely important to consider aspects of acceptance and engagement with mHealth interventions. This study adopts a multidisciplinary approach to development of the MedFit app, drawing on theories from engineering, computer science, and health psychology. For example, the development of the MedFit app has been underpinned by social cognitive theory [27] and the behavior change wheel (BCW) [28], as well as the unified theory of acceptance and use of technology (UTAUT) model [29]. These two models of health behavior change have been used to design how the best practice guidance and content will be delivered to the end user, whereas the UTAUT theoretical model aims to provide general determinants of technology acceptance, with previous research demonstrating how it can provide insight into key relevant predictors for technology acceptance [30].

It is vital to appropriately and adequately explore attitudes toward, as well as acceptance and usage of these devices [31].

However, there currently exists little research in relation to these emerging technologies and a community-based CR population who are aiming to maintain adequate recommended levels of PA in a long-term maintenance phase of CR. The aim of this study was to test usability and acceptance of the MedFit app and to test feasibility of app usage among the target CVD population. [Multimedia Appendix 1](#) depicts the phases of intervention development and how the underpinning theory is related to the BCTs used, the focus group feedback, and feasibility field testing.

Description of Alpha Medfit App (Preuser Testing)

MedFit is an mHealth app and is designed to allow people with CVD to participate in an exercise-based rehabilitation program remotely through an Android app. MedFit offers the potential to make exercise-based rehabilitation programs more effective by making them more accessible, more personalized, and more interactive by providing real-time support and feedback for participants.

The app comprised three central sections: exercise, progress, and my healthy lifestyle. Within the exercise section of the app, preset exercise programs were incorporated into the app. These programs consisted of a warm-up, main phase, and cool down, all of which can be performed in the comfort of the user's own home. Local muscular endurance exercises as well as stretches were also incorporated into the programs. The dimensions of the exercise follow British Association for Cardiac Rehabilitation guidelines [32] for health-enhancing PA, including the minimum of 150 min of moderate intensity PA per week. Therefore, the general prescription for exercise will be based on the frequency, intensity, time, and type principle: frequency=variable (depending on time available to the patient), intensity=moderate or above, time=minimum of 150 min per week, and type=recommended aerobic exercises for CVD patient. These exercises are shown using exemplar videos that have been recorded by a qualified gym instructor.

The exercise section contained a *test yourself* function whereby users could do a 6-min walk test to test their progress. The *progress* section of the app contained user feedback displayed in charts and graphs so that the users could track their progress over time, for example, track step count. The *my healthy lifestyle* section of the app provided tips and recommendation on lifestyle factors such as healthy eating, alcohol consumption, PA, stress management, medication adherence, smoking cessation, and sexual functioning.

The app works in conjunction with a *Fitbit Charge HR* device and objectively measures PA and heart rate. Patients also received short message service notifications about their activity levels.

Methods

Overview of Methods

This iterative development process encompassed two key phases, each with sub components. Phase 1 consisted of the systematic review and consultation with the advisory panel, whereas phase 2 involved usability and acceptability testing

(using the UTAUT, focus group user testing and feasibility testing). See [Figure 1](#) which depicts this process.

Phase 1: Systematic Literature Review

The mHealth development and evaluation framework has been used to develop the app. The framework begins with the conceptualization phase. This phase in the MedFit apps development involved conducting a literature review. The MedFit research team conducted a systematic review [33] and identified what BCTs are used in PA eHealth interventions for people with CVD. The top three most frequently used BCTs included information about health consequences, goal setting (behavior), and joint third, self-monitoring of behavior and social support (practical). These BCTs were implemented within the MedFit app design to enhance user engagement and efficacy. From this review, the app content was designed and developed in line with the most frequently used groups of BCTs in the effective interventions. In tandem with this systematic review phase of the apps development, an advisory panel was established to review the proposed content emerging from the systematic review and to make recommendations. This advisory panel consisted of a multidisciplinary research team of experts in the areas of sport science, biomechanics, PA, electronic engineering, and health behavior change. Regular brainstorming sessions (ie, monthly) on how to best translate the theory and evidence into practical methods and techniques were held, whereby author OD generated content based on the current evidence base, and the advisory panel provided feedback before user testing within phase 2.

Phase 2: Usability and Acceptability Testing of the MedFit App

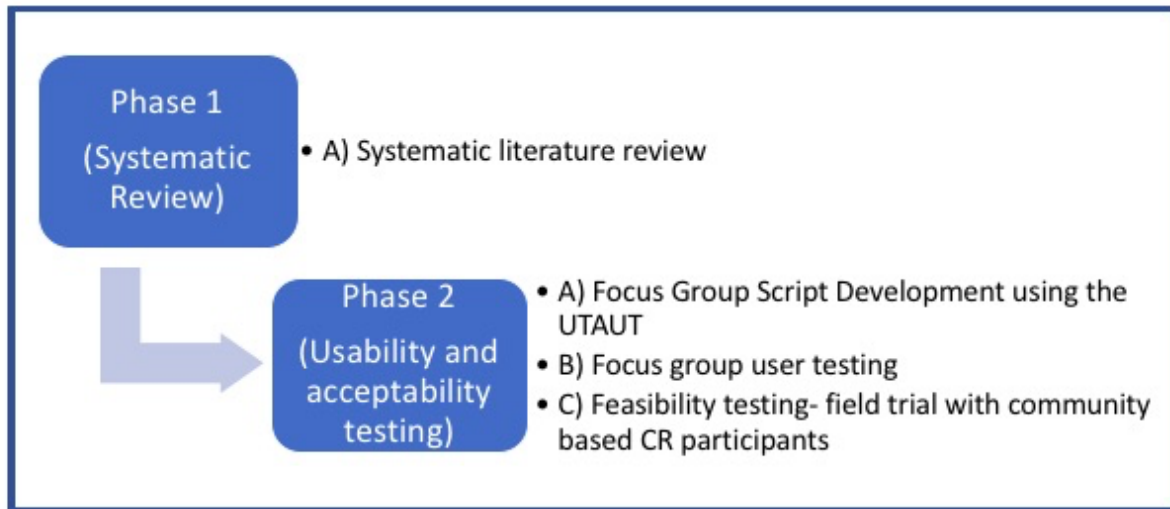
Focus Group Script Development Using the Unified Theory of Acceptance and Use of Technology

To develop a theoretically informed focus group script, the UTAUT model was used [29]. The UTAUT 2 model was employed to ascertain the acceptance and use of mobile phone apps among MedEx Wellness participants. MedEx Wellness is a community-based exercise rehabilitation program for chronic illness located at Dublin City University. It offers supervised exercise classes to individuals with a range of chronic conditions, including CVD, pulmonary disease, diabetes, and cancer. A questionnaire (adapted from a questionnaire developed by Venkatesh et al (2012) [34]) entitled *Acceptability of mobile phone applications among adults with chronic illness* was completed by MedEx participants. A range of participants varying in age, sex, chronic condition, and duration of attendance at MedEx were recruited to the study.

The questionnaire comprised two sections (see [Multimedia Appendix 2](#)). Section 1 asked respondents about tablet computers and smartphones, asking if participants have either and whether they use mobile phone apps. Section 2 sought to obtain opinions regarding the importance of mobile apps using questions based on the UTAUT 2 model relating to participant opinions on factors such as *facilitating conditions*, *effort expectancy*, *social influence*, *performance expectancy*, and finally *hedonic motivation*. Respondents were asked to indicate the extent to which they agreed or disagreed with statements

using a 7-point Likert scale response framework (1=strongly disagree, 2=disagree, 3=somewhat disagree, 4=neutral, 5=somewhat agree, 6=agree, and 7=strongly agree).

Figure 1. MedFit phased development process. UTAUT: unified theory of acceptance and use of technology; CR: cardiac rehabilitation.



The role of the UTAUT2 questionnaire within this study was specifically to develop a theoretically informed focus group script that would pose questions relating to the core constructs identified as impacting on the acceptance and use of apps by participants. The focus group script also focused on the usability of the current prototype app.

Focus Groups User Testing

Participants in the focus groups were recruited from the HeartSmart program in MedEx Wellness that caters to individuals with CVD. In total, 26 HeartSmart participants took part in the focus groups (65% male; mean age=64 years, SD=8.2). There were five focus groups. Each focus group lasted approximately 1.5 to 2 hours in duration with a maximum of 6 people per group. The researcher aimed to balance the groups in terms of gender. The focus group was led by a moderator, who guided the interview, while an assistant moderator took notes on the ensuing discussion. The focus group had two main strands. The first focused on the usability of the MedFit app where the researcher presented the different functions of the app and the participants could follow along using a Samsung Galaxy S5 Neo on which the app was downloaded. Participants were asked to give their feedback and opinions on the prototype app components. The second strand of the focus group concentrated on the acceptability of the app with questions relating to the main constructs identified in the questionnaire that impacted participant's acceptance and use of apps. The data were analyzed using content analysis [35].

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A range of participants varying in age, sex, and duration of attendance at MedEx were recruited to the study (n=20; average age=69.4 years; range: 55-80 years). Three participants were unable to attend focus groups following the feasibility testing; therefore, this focus group is based on analysis of three groups consisting of 17 individuals. All participants were older than 18 years, had clinically manifested CVD, and were stable with

regard to symptoms and pharmacotherapy for more than 4 weeks. Patients were excluded if they had cardiac disease or uncontrolled cardiac arrhythmias that limits exercise tolerance as identified by cardiac rehab staff, cognitive dysfunction that affects the consent process, severe joint pain that limits exercise tolerance, or had any of the American College of Sports Medicine exercise contraindications [36]. Participants then attended one session where they downloaded the app, set up an account, and were shown how to use the app. All patients were then given a user manual and helpline access. The MedFit app was given to each participant for a 2-week period. Following this 2-week period, participants were invited to a semistructured debrief focus group to provide feedback on the app. Full details of the debrief focus group script is available in [Multimedia Appendix 3](#). This details the feedback that was sought from participants ranging from, for example, open-ended questions regarding app usage and experience to specific usability questions on each of the different components of the MedFit app. General feedback, as well as specific feedback on each of the components, was then sent to the technical team to update app further iterations.

Three focus groups were conducted which lasted approximately 1 to 1.5 hours in duration. There was a maximum of 7 per group.

Data Analysis

Focus Group Script Development Using the Unified Theory of Acceptance and Use of Technology

To decipher what constructs played a role in participants use and acceptance of technology, the research team set a criteria whereby factors were rated positively if participants scored ≥ 15 on the 3-item constructs and ≥ 20 on the 4-item constructs on the positive end of the Likert scale; somewhat agree (5) or agree (6) or strongly agree (7).

Focus Groups User Testing

These focus groups were transcribed verbatim, while key notes were made on the usability section. Content analysis was used

to analyze the data. Content analysis has several standard steps that were adhered to throughout the analysis [35]. First, an initial list was generated of ideas about the data and what was interesting about it with an initial set of codes generated for each focus group based on the data. This coding was done manually by going through the content of the entire dataset and linking the information to particular codes. From this step, a dataset was created whereby a full list of preliminary codes was available that emerged from the focus group data. Second, validation of this coding was undertaken whereby two members of the research team independently coded the same piece of transcription and then compared notes. Third, the preliminary codes were sorted into broader themes so that all the codes across each of the five focus groups belonging to a particular theme were grouped together. This stage was performed in Excel (Microsoft) whereby the researcher created a sheet for each focus group. Fourth, following this grouping of codes into potential themes, these themes were given separate columns, which included the relevant codes and illustrative participant quotes. Fifth, as one of the final steps in analysis, these preliminary themes were revised and refined. All the coded data extracts were reviewed to ensure they were appropriately coded to a given theme. The themes were then reviewed to ensure they accurately reflected the dataset and codes. The final sixth step involved defining and further refinement of the themes and subthemes [37].

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These data were analyzed to identify both the general perceptions of the target group and the specific content, format, and navigation-related feedback. These perceptions and feedback were used to modify the relevant components of the intervention.

Results

Results From Focus Group Script Development Using the Unified Theory of Acceptance and Use of Technology

A total of 119 MedEx participants completed the UTAUT 2 questionnaire. Of these, 64.7% (77/119) of the respondents were male, with the average age of the group to be (n=116 [n=3 missing age data]) 65 years (SD 8.86; range=38-84 years). The duration of attendance in MedEx ranged from ≤1 month (15/119, 12.7%), 2 to 5 months (27/119, 22.9%), 6 to 12 months (18/119, 15.3%), 1 to 3 years (33/119, 27.1%), and >3 years (26/119, 21.8%). A total of 74.1% (88/119) of participants had a tablet computer, and 75.2% (90/119) owned a smartphone. A high percentage also revealed that they have used mobile apps on their smartphones (86/119, 72.3%).

Analysis of the UTAUT2 questionnaire revealed that performance expectancy, social influence, hedonic motivation, behavioral intention, effort expectancy, and facilitating conditions all rated highly among a majority of respondents. More than half of the respondents scored a total of 15 or more on performance expectancy, social influence, hedonic

motivation, and behavioral intention (3-item constructs; see [Textbox 1](#)). Greater than half of the respondents scored a total 20 or more on the two 4-item constructs, effort expectancy and facilitating conditions. Almost three-fourths of the respondents from MedEx believed that they had the necessary conditions to facilitate the use of apps in their lives.

Only 22 (22/119, 18.9%) respondents scored ≥15 on the habit construct, indicating that end users did not perceive habit as playing a significant role in the acceptance and use of mobile apps among this cohort. A total of 40.2% (48/119) of respondents scored a total of 15 or more on the price value construct, indicating that perhaps price value does not play as significant a role as some of the other constructs. The results of the questionnaire were used to inform and develop the usability focus group script ([Multimedia Appendix 3](#)).

Results From Focus Groups User Testing

Following in-depth content analysis, four main themes emerged. These were as follows: support, the app as a mentor or guide, translation of activity from gym to home, and technology knowledge gap.

See [Multimedia Appendix 4](#), which provides a list of the feedback from the focus groups based on each app component and the translation of this feedback in app content.

Support

Learning or Familiarization Process

Participants placed huge emphasis on an initial familiarization and setup process. Many participants who weren't familiar with using apps on a regular basis said that it would be very important to have a familiarization period where they would be taught how to use the app either in a one-to-one training session, *one-to-one would be great* (focus group 2), or in *small groups* (focus group 2). It was reiterated across the groups that learning how to use the app would occur over time using a *trial and error* method (focus group 1). However, at the initial introduction to the app, participants would need to be shown how to use the app in a simple step-by-step manner. One participant stated the following:

And it's the lady bird approach. Right from the start, don't assume any knowledge. [Focus group 3]

Participants felt that they would also need written instructions or guide to help them learn how to use the app. This would also be helpful if they forgot how to use the app at home as they would something to look at for guidance:

Well a guide is always good...and that's the only reason so if you don't use something often you can come back to it without having to go miles to find out. [Focus group 5]

These instructions or guide could also come in video format as this format will be familiar to them from CR:

...or even a video. I mean that's what they use in cardiac rehab instead of doctors talking. [Focus group 5]

Textbox 1. Themes from focus groups user testing.

Themes
1. Support <ul style="list-style-type: none"> • Learning or familiarization process • Support from family or friends • Technical support
2. App as a mentor or guide
3. Translation of activity from gym to home
4. Technology knowledge gap

Family or Friends Support

Overall, most participants believed they would get support from family and friends to use the app. This support would come in the form of encouragement to use the app. Most people have families who are interested in their loved ones health and would therefore provide encouragement to use the app if they believed it would benefit their health, as illustrated in the following statement:

Most families, most people are lucky enough to have people interested in them. When you get sick, the first thing they do, if there's anything they can do to help you get better. If it's just to encourage you to exercise, they'd be all too happy to do it. [Focus group 1]

There were differing views in the groups as to whether friends or family could provide technical support to use the app. Some believed their family, particularly their children, would have the knowledge and skills to help them use the app:

There's a lot that we don't understand we ask the kids about, you know, and they show us. [Focus group 1]

One participant thought their family wouldn't take an interest in the app; that they have their own apps and interests to worry about; however, their friends might because they are of a similar age and interest level.

Technical Support

In terms of technical support, most participants agreed that they would need a contact for technical support in case they had an issue that neither they nor their family or friends could solve. The participants provided numerous suggestions as to what format the technical support should come in. Some suggested the use of a comment box where you could leave a message on the app regarding your query either straight to the technical team or to other users of the app:

Probably the comment box is the best. [Focus group 4]

Participants agreed that the best form of technical support would be the availability of contact number that participants would ring during set hours:

Well if you have your contact details there that if you are stuck, eh you can ring in. [Focus group 2]

App as a Mentor or Guide

The theme *app as a mentor or guide* was present in all five focus groups. Participants believed the app would provide instruction and knowledge on how to exercise correctly:

I think it'll be useful in my life because...I'll go to the gym and I have this to do my warm-up...shows me what weights to do, you know...Because when you go sometimes you just haven't a clue and you're kind of doing stuff and you could hurt yourself, you could overdo it, it's perfect, you know exactly what you're doing and...keeps you healthy. [Focus group 1]

Feedback and monitoring on their progress while using the app was seen as important to the participants, as illustrated in the following statement:

It's important to get feedback. [Focus group 5]

Participants liked the idea of *keeping up on things as they're happening* (focus group 4) and expressed an interest in monitoring their progress on the app:

It would be kinda interesting watching what you're putting in and seeing the progress or the opposite. [Focus group 4]

Participants also believed that the app would heighten awareness to exercise and provide motivation to exercise in the form of prompts or cues (eg, push notifications), as illustrated in the following statements:

Because, I mean first of all it would motivate you, and it would also give you correct information and guide you where you're going. [Focus group 5]

I think we sit down a lot more than we realise, we drive a lot more than we realise, you know, I personally speaking and I think it would be sort of a wakeup call to me anyway. To actually see it in black and white. [Focus group 4]

The code *app as a tool* came under the theme *app as a mentor or guide* as participants thought the app has a job or function to do and did not necessarily have to be fun, as illustrated in the following participant quotes:

It's good to have something there to support you but for me, personally it doesn't need to be fun. It just needs to do what it says on the box, as they say. [Focus group 1]

No it's a tool...It's there to do a job. [Focus group 4]

The app would also motivate their family members to exercise having seen their family member use the app. Participants could see the benefit the app would have to the health of their family not just themselves:

I think it would benefit my own family. I have two teenage daughters that do like to sit down a lot when they're at home, so I think if they saw me using the app at home they'd probably, probably slag the hell out of me but they'd probably eventually come out and join in and do something, yano. [Focus group 2]

Yeah. I would say the only thing to do would be to try and include the family, in the programme. [Focus group 4]

Translation of Activity From Gym to Home

Overall, the majority of participants agreed that the app would create an option for people to exercise who are housebound or for those who for one reason or another can't make it to a structured exercise class:

Well I bring Mary from Rush but I have my own business so sometimes I can't come and if I can't come well Mary would have her app on her phone and I'd have it myself where you'd get a few minutes in the day where you can exercise, as I said rather than just saying ah I can't go today I'll sit down and have a rest. [Focus group 2]

I'm living in Skerries, it's not a great job having to get in but if Bridget is gone off in the car well I have to take a bus so eh, well now that makes me think about it again, use that or a bus? I think that would come out first and I would find myself using it. [Focus group 3]

Participants viewed the app as part of building a healthy lifestyle:

Like I'd see this as part of building up a healthy lifestyle. [Focus group 5]

The app would work in conjunction with structured programs, allowing for flexibility and planning, providing no excuse not to exercise, as illustrated in the following statement:

It means I can do it at home and I don't feel like I'm slacking off. [Focus group 1]

With that said, participants thought the app could be used in tandem with the gym or structured exercise classes. For the days that they don't go to the gym, the app could be used instead to build up their activity to meet the guidelines:

Yeah sure you can make the sessions here what happens if you don't make the sessions here but you but you know you've a period in the day where you can exercise...now you know what you can do and even if you go into a gym you're going to go in and do something without damaging yourself. [Focus group 1]

I would use it in tandem with the gym. I'd be more inclined to try and keep up with the gym but where I

couldn't do the gym, I would do it so. I might find that I got to the gym twice and use this once. [Focus group 1]

Technology Knowledge Gap

Participants acknowledged that there is a generation gap when it comes to technology. Participants came from a generation where there were no smartphones and were therefore new to the concept of smartphones and their use of them. In comparison, it was acknowledged that today's youth are familiar with technology and have little difficulty using smartphones:

And I mean that stuff is all so easy to the younger generation, even the seven year old granddaughter can use the bloody phone better than I can. [Focus group 1]

Well I think you see you have a generational problem, here like...You're talking to people who weren't brought up with smartphones and apps. [Focus group 3]

One woman also pointed out that they are not part of the *throw away generation* (focus group 3). She described this as where the older generations are more cautious than young people in trying out new technology in fear that they make break it, whereas younger generations have no fear associated with technology. Older generations came from a time where there was limited use of technology in their working lives and therefore are not up to speed with current smartphone advances.

It was also said that there may be a *fear of the unknown* associated with the use of apps on smartphones, as smartphones weren't available as they grew up, as illustrated in the following participant quotes:

I'm totally illiterate with this stuff, I just...no matter how many times I'm shown I can't do it. [Focus group 1]

No no, well I'm just saying that like, I'm just anxious about it. [Focus group 2]

However it was also acknowledged by a participant that smartphones are part of life and have multiple purposes:

The smartphone is part of my life. I look at football and everything on it. [Focus group 5]

Results From Feasibility Testing—Field Trial With Community-Based Cardiac Rehabilitation Participants

Following this in-depth analysis of each component, it was evident that there were three main usability issues remaining that arose in the second phase of debrief focus groups. These themes mapped directly onto existing themes from previous focus groups but interestingly provided insights into what needed to be further refined in addition to preliminary work done in each area. These themes were as follows: (1) support, (2) technology or knowledge gap, and (3) app as a mentor or guide.

Emerging from the feasibility testing, the feedback for each identified theme was more nuanced. Although the user manual and frequently asked questions (FAQs) were perceived as useful, phone support was cited a crucial aspect of support:

The user manual was great. I would have been lost without it as you are given so much new information at the start. [Focus group 1]

I would always need a phone number to call for help. [Focus group 1]

The *technology or knowledge gap* remained an issue within the feasibility testing, and confidence to use technology was not present across all participants despite familiarization:

I had to call for help 4 times in the fortnight. [Focus group 1]

I am reluctant to try new technology. [Focus group 2]

Many participants felt that they would not be able to download an app themselves and that enhanced support with even more extensive familiarization was needed:

I would not know how to download an app so would need help or instructions to do that. [Focus group 1]

A presentation or video showing all of the functions at the app at the start would be useful. [Focus group 3]

Indeed, many users noted that it was difficult to formulate what the technical issues were making aspects of the FAQ section almost redundant. Participants felt that it was difficult to explain technical issues via phone. A suggestion was that a repository where you could send screenshots of error messages would be useful and cut down on time spent with technical support on the phone:

When I am having problems with the app, I find it hard to put into words what is wrong when I don't really understand it. I would like to be able to send pictures of what is happening. [Focus group 2]

In relation to the app as a mentor guide, most participants did engage with the app and enjoyed the exercise component. However, most participants did not find the healthy lifestyle section useful or engaging.

Many cited that their PA levels were raised as a result of the app use. Checking activity progress was seen as a useful feature to receive accurate feedback on progress:

I found the progress part very useful. I got a reality check when I seen what I was doing and thought I was more active than I am [Focus group 3]

Participants also found that the app made exercise accessible in a more flexible way by the virtue of being able to access the resources at home, which minimized barriers to attendance:

It let me do the exercises at home which cut out the time travelling to the gym. [Focus group 3]

The app also provided variety in the routine, as illustrated in the following statement:

I like having many different exercise options, both the classes and app, which are suitable for my condition. It gives me variety and I feel safe. [Focus group 2]

However, some people were concerned that using the app did not facilitate direct social interaction:

The app is only missing the nice atmosphere in the MedEx classes [community-based exercise] where you can talk to people in a similar situation. [Focus group 2]

Discussion

Principal Findings

To the best of our knowledge, no studies have developed an app using the factors of the UTAUT, as well as health psychology theories (in particular the BCW, which facilitates detailed intervention description), with a CR app and wearable sensors among a typical CVD population. The development of a mobile app for exercise rehabilitation for adults with CVD was carried out in line with the mHealth development evaluation framework [38]. This paper detailing the formative research process, development, and feasibility testing is in line with the Medical Research Council's framework for complex intervention design [39].

The creation of eHealth technologies is often led by a technology-driven approach as opposed to the user-centered approach, which could have been adopted for this project given the multidisciplinary nature of the team. Studies have shown that the full potential of eHealth technology can only be exploited when developed by a multidisciplinary team who apply a human-centered approach codesign approach with the specific context of the technology's use in mind [37,40]. The research team aimed to develop a theoretically informed app with potential cardiac patients at the heart of the design. This design process was undertaken by a multidisciplinary team of health psychologists, PA specialists, and technology specialists. The team used a novel approach to application development whereby health behavior change theory and the UTAUT2 model were used to guide app development, with the patient voice at the heart of the mobile apps development.

This human-centered approach was vital given results indicating severe difficulties emerging from focus groups and field testing in terms of the technology or knowledge gap. Gallagher and colleagues have noted similar issues in a parallel population [22]. They highlight how age is frequently perceived as a critical barrier to technology engagement. People who are currently in the age range of 50 to 70 years tend to have technology but may not have engaged with full features of a smartphone with app capabilities [41]. Meanwhile, people younger than 50 years have a heightened exposure to technology in their everyday lives, thus having the capability to use more complex features. In contrast, people aged 70 years and older generally use devices in a more passive way, such as using a mobile phone for voice calls and receiving texts [42,43]. This can be seen within our MedFit sample. Previous research has shown that older adults tend to rely on younger people in areas where they are less confident, such as for setup and problem solving [43]. The large discrepancies between generations in relation to technology use are likely to dilute within the coming years because of the pervasiveness of technology in our everyday lives [41].

In relation to the mechanisms of behavior change, it is important to use theory to inform intervention design and to specify the BCTs used [44]. It has been well documented that behavior change interventions are poorly described in accurate and sufficient detail for readers to truly understand, evaluate, and replicate the intervention reported [45]. It is also apparent that interventions based on behavior change theory are more effective than those lacking a theoretical basis [46,47]. Therefore, we aimed to describe in detail the active ingredients of our intervention along with each development phase of the app, so that the apps development was easy to understand, track, evaluate, and replicate for future research.

Strengths and Limitations

An important strength of this study is the theoretical underpinning of the MedFit app. Interestingly, it has been recently noted that wearable electronic monitors and mobile apps still lack several important BCTs [21]. In particular, empirically proven techniques such as action planning and problem solving are often absent from such apps [48]. This is an interesting avenue to explore as the MedFit app has built in core BCTs based on a systematic review conducted associated with intervention effectiveness; however, action planning and problem solving are not a part of the MedFit app.

Individuals with CVD were recruited using a convenience sampling method, and the participants in this study were selected from a community-based chronic illness exercise rehabilitation program; this sample may be somewhat different from those that never attend a community-based exercise program. Despite iterative phases of user testing within this study, a long-term testing period is needed. This is planned within the next phase of MedFit development.

This is particularly important given the results that a majority of participants had user difficulties with the MedFit app whereby they were not proficient with mobile apps and felt challenged by the MedFit app format. This is indeed a consideration that needs to be addressed in the future evaluation of the MedFit app. Indeed, it may be necessary in future work to also record level of technology use before participating in the MedFit trial to ascertain where the difficulties are based (ie, technology capability issues vs lack of interest in the MedFit app for CR delivery). Furthermore, it would be useful for future debrief interviews following MedFit app usage to provide parallel quantitative details, as well as qualitative data, to provide a more comprehensive picture of the acceptability of each of the app components.

Directions for Future Research

This study explored the usability and accessibility of the MedFit app. This study has allowed us to gain feedback on patients'

issues using the app and gain feedback on elements that are easy and difficult to use. All relevant information has been shared with the technical team to allow for any feasible and necessary changes. This is important for the development and future implementation of MedFit. In particular, as noted in the introduction, it is important to highlight how uptake and sustained engagement with CR programs is a key issue for this research area. This study has started to explore how using MedFit can eliminate some of the core barriers to uptake and maintenance (ie, elimination of travel time, cost, and social anxiety through access to remote CR via an app); however, it is clear that these potential solutions can only be adequately evaluated and addressed in a full-scale pilot of the MedFit app.

The next step is the pilot of the MedFit app. An updated version of the app will be trialed in a pilot study to assess the app in a hospital-based trial that will involve participants who have recently completed hospital-based CR and are moving into the maintenance of long-term PA within the community. This will involve participants engaging with the app for a minimum of 4 weeks. Assessments will be completed pre and post the using MedFit use, which will include the following measures: cardiorespiratory fitness, PA, accelerometer data and questionnaires investigating PA, smoking, stress, medication adherence, alcohol consumption, and well-being. Additionally, focus groups and process measures will be implemented for the intervention group in their assessment following the intervention to gain an insight into their use of MedFit.

Conclusions

This paper details the development of a mobile intervention for CVD patients. The development work has been carried out in a systematic approach from theory to user testing and technical team design expertise. This paper highlights the importance of transparency when designing mHealth interventions using BCTs and theory, so that interventions are easily understood, evaluated, and reproduced. The researchers have also demonstrated a novel way to examine the usability and acceptability of a mobile app within a focus group setting to ensure long-term technology adoption and use.

MedFit is an example of a person-centered approach combining mHealth and CVD secondary prevention. Mobile technology offers an important opportunity to improve access to secondary prevention and enhance CR programs, particularly for technology-literate participants who may face barriers to attendance of on-site CR [22]. Overall, it is hoped that the MedFit app will encourage the adoption of the mobile app to improve health behaviors, in particular the PA levels of people with CVD.

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Authors' Contributions

OD and SM conducted focus groups. All authors reviewed and provided feedback on the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Intervention development.

[[DOCX File, 17KB - formative_v2i1e8_app1.docx](#)]

Multimedia Appendix 2

Unified Theory of Acceptance and Use of Technology (UTAUT) Questionnaire.

[[PDF File \(Adobe PDF File\), 874KB - formative_v2i1e8_app2.pdf](#)]

Multimedia Appendix 3

Unified Theory of Acceptance and Use of Technology (UTAUT) derived focus group script.

[[PDF File \(Adobe PDF File\), 50KB - formative_v2i1e8_app3.pdf](#)]

Multimedia Appendix 4

Iterative focus group feedback.

[[PDF File \(Adobe PDF File\), 52KB - formative_v2i1e8_app4.pdf](#)]

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Abbreviations

- BCT:** behavior change technique
- BCW:** behavior change wheel
- CR:** cardiac rehabilitation
- CVD:** cardiovascular disease
- eHealth:** electronic health
- FAQ:** frequently asked questions
- mHealth:** mobile health
- PA:** physical activity
- QoL:** quality of life
- UTAUT:** unified theory of acceptance and use of technology

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Original Paper

A Hybrid Web-Based and In-Person Self-Management Intervention Aimed at Preventing Acute to Chronic Pain Transition After Major Lower Extremity Trauma: Feasibility and Acceptability of iPACT-E-Trauma

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Abstract

Background: A transition from acute to chronic pain frequently occurs after major lower extremity trauma. While the risk factors for developing chronic pain in this population have been extensively studied, research findings on interventions aiming to prevent chronic pain in the trauma context are scarce. Therefore, we developed a hybrid, Web-based and in-person, self-management intervention to prevent acute to chronic pain transition after major lower extremity trauma (iPACT-E-Trauma).

Objective: This study aimed to assess the feasibility and acceptability of iPACT-E-Trauma.

Methods: Using a descriptive design, the intervention was initiated at a supra-regional level-1 trauma center. Twenty-eight patients ≥ 18 years old with major lower extremity trauma, presenting with moderate to high pain intensity 24 hours post-injury were recruited. Feasibility assessment was two-fold: 1) whether the intervention components could be provided as planned to $\geq 80\%$ of participants and 2) whether $\geq 80\%$ of participants could complete the intervention. The rates for both these variables were calculated. The E-Health Acceptability Questionnaire and the Treatment Acceptability and Preference Questionnaire were used to assess acceptability. Mean scores were computed to determine the intervention's acceptability.

Results: More than 80% of participants received the session components relevant to their condition. However, the Web pages for session 2, on the analgesics prescribed, were accessed by 71% of participants. Most sessions were delivered according to the established timeline for $\geq 80\%$ of participants. Session 3 and in-person coaching meetings had to be provider earlier for $\geq 35\%$ of participants. Session duration was 30 minutes or less on average, as initially planned. More than 80% of participants attended sessions and $< 20\%$ did not apply self-management behaviors relevant to their condition, with the exception of deep breathing relaxation exercises which was not applied by 40% of them. Web and in-person sessions were assessed as very acceptable (mean scores ≥ 3 on a 0 to 4 descriptive scale) across nearly all acceptability attributes.

Conclusions: Findings showed that the iPACT-E-Trauma intervention is feasible and was perceived as highly acceptable by participants. Further tailoring iPACT-E-Trauma to patient needs, providing more training time for relaxation techniques, and modifying the Web platform to improve its convenience could enhance the feasibility and acceptability of the intervention.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 91987302; <http://www.controlled-trials.com/ISRCTN91987302> (Archived by WebCite at <http://www.webcitation.org/6ynibjPHa>)

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KEYWORDS

Acute pain; chronic pain; wound and injuries; lower extremity; self-care; health promotion; feasibility studies; patient acceptance of health care

Introduction

Background

Most trauma patients suffer from an orthopedic injury [1,2] resulting in a high prevalence of disabling chronic pain affecting up to 86% of patients from several months to years post-trauma [3-5]. Considering the negative impacts of chronic pain on the quality of life of trauma patients [3,5-8] and associated social expenditure [9-13], several studies have focused on risk factors that could trigger acute to chronic pain transition in this population [3-5]. Some risk factors have been consistently identified across studies, including moderate to high acute intensity pain, major lower extremity trauma (ET; ie, patients who usually require hospitalization for surgical and multidisciplinary team acute care management), and psychological variables (eg, anxiety, depression, pain catastrophizing, pain-related fear).

Despite a growing acknowledgment of the issues associated with chronic pain in orthopedic trauma and evidence on identified risk factors, intervention studies aiming to prevent chronic pain in this population are still scarce [14,15]. Indeed, most studies on chronic pain preventive interventions have been conducted in back pain patients [16-27] and, more recently, in the context of nontrauma related major surgery [28]. These preventive interventions were designed according to a cognitive-behavioral approach, where the objective is to promote self-management behaviors, ie, skills to control pain and its effect on physical and psychological functioning [29,30]. Preliminary findings on the efficacy of these interventions showed promising results. These included decreased pain intensity and/or disability [17,18,24-26,28], reduced opioid use [28], as well as improved psychological well-being [17,22,25] or more rapid return to work [16,19-21,27]. Hence, we developed a self-management intervention aimed at preventing acute to chronic pain transition in major lower extremity trauma (iPACT-E-Trauma) patients [31,32], a population at high-risk of developing chronic pain.

The iPACT-E-Trauma was developed according to a systematic approach, to address common factors involved in the transition from acute to chronic pain and meet the needs of patients with major lower ET [31,32]. We used empirical evidence from prior research on chronic pain preventive interventions, the biopsychosocial model of chronic pain [33], and clinical knowledge of the population to determine the main features of iPACT-E-Trauma (ie, what, who, how, where, when and how

much) [34]. Then, acceptability was tested with ten clinicians (ie, nurses, orthopedic surgeons, a psychiatrist, a family physician specialized in pain management, and physiotherapists) from interdisciplinary trauma teams followed by 6 ET patients who received the intervention [32]. Both clinicians and patients found the preliminary features of iPACT-E-Trauma to be acceptable. Nonetheless, refinements were made to the intervention based on the results of an acceptability questionnaire, data gathered during a focus group with clinicians, and individual interviews with patients. Findings from the acceptability questionnaire were presented to clinicians during the focus group with them, which allowed the identification of the refinements needed. The clinicians underscored the need to improve the intervention's suitability for ET patients. To this end, the complexity of proposed activities and session duration were reduced, making the intervention more likely to be adhered to by participants. Also, clinicians proposed to develop web sessions to facilitate the delivery of the intervention by busy health care professionals during patient's hospitalization. The patients' acceptability assessment highlighted the importance of tailoring the activities and timelines according to their pain intensity, pain interference with activities, implementation of self-management behaviors, and recovery pace.

The aims of this study were the following: 1) evaluate the refined version of iPACT-E-Trauma feasibility, and 2) examine its acceptability in patients with major lower ET. Feasibility and acceptability criteria as described by Sidani and Braden [35] were used in this study. Feasibility refers to the practicality of implementing the intervention, focusing on the capability to carry out components and activities as planned and identifying issues in the implementation of the intervention. Variations in implementation can occur at different levels, either with the interventionist or with the clients receiving it and who are expected to carry out recommendations in their day-to-day life [35]. Acceptability is the perceived value or attitude toward the intervention by the client. This is operationalized in different ways. First, the extent to which the intervention is effective and appropriate in addressing the presenting problem, second, whether it is convenient and poses minimal risk, and third, whether participants are willing to adhere to the intervention [35].

Methods

Design

A descriptive design was used. The participants were patients who received the intervention and were randomly assigned to the experimental group of a pilot randomized clinical trial (RCT) [31].

Setting

The intervention was initiated at a 554 beds supra-regional level-1 trauma center in Montreal, Canada. This center admits, on average, 1400 trauma patients annually, 400 of who have a major ET. Patients received intervention sessions during their hospital stay, and, after hospital discharge, in a rehabilitation center, at home, or during their surgical follow-up appointment at the outpatient orthopedic clinic. Ethics approval was obtained from the Centre Intégré Universitaire de Santé et de Services Sociaux du Nord de l'île-de-Montréal, Installation Hôpital du Sacré-Coeur de Montréal (HSCM) Research Ethics Board (REB) (project identification number HSCM-2017-1333) and McGill University REB (project identification A02-M15-16B). Written consent was obtained from each participants included in the study.

Sample Characteristics

Twenty-eight patients received the iPACT-E-Trauma intervention. The inclusion criteria were the following: a) age 18 years or older, b) able to read and speak French, (c) major lower ET, and d) at risk of developing chronic pain. Acute pain intensity has consistently been reported as a risk factor for a transition from acute to chronic pain in the ET population [3-5]. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials has recommended the inclusion of this criterion in chronic pain prevention studies [36]. Consequently, patients were enrolled if they manifested a pain intensity of $\geq 4/10$ upon movement 24 hours post-injury, which corresponds a moderate to severe pain intensity [37], as documented by nurses in medical charts.

The exclusion criteria were the following: a) spinal cord injury, b) amputation, c) other trauma associated with high-intensity pain (>2 fractured ribs [38] or surgical abdominal trauma) or principal site of pain not being lower ET, d) cognitive impairment and language limitation (ie, dementia, moderate-severe traumatic brain injury - Glasgow coma scale score $<13/15$ [39], administration of sedative agents, mechanical ventilation) affecting the capacity to participate in the intervention and to complete questionnaires, and e) needing more than 7 days of hospitalization before being eligible to participate in the study. Patients with pre-injury somatic pain were not excluded unless they were taking analgesics on a daily basis, and neither were patients with pre-injury visceral pain, considering that it is possible to differentiate this type of pain

from musculoskeletal pain. Moreover, although substance abuse, including pre-injury opioid use, may influence pain outcomes, we did not exclude patients with this comorbid factor considering its high incidence in the trauma population [40-43] and the potential threat to the study's external validity.

Intervention

The main features of the intervention have been previously described [31,32]. The topics of the refined version of iPACT-E-Trauma were the bio-psychosocial dimensions of pain, pharmacological (including how to reduce opioids over time) and nonpharmacological strategies for acute pain management, health-promotion strategies, and return to pre-injury activities. Various strategies commonly utilized in interventions based on a cognitive-behavioral approach [44] were used, such as psychoeducation, continued monitoring, provision of feedback, problem-solving, individualized action plan for a progressive increase in activity, and matching of self-management skills with real-life situations.

Regarding structure, the refined iPACT-E-Trauma included seven sessions (five regular and two boosters) lasting between 15 and 30 minutes, provided by a nurse with a master's degree [31,32]. The intervention lasted three months and was initiated within seven days post-injury to allow patients to rapidly develop self-management behaviors and optimally manage their acute pain. Sessions 1 and 2 were expected to be given in the first week post-injury, sessions 3 to 5 on a weekly basis after that, and sessions 6 and 7 at six and twelve weeks post-injury, respectively. A hybrid delivery mode was utilized combining the Web (ie, *Traitement et Assistance Virtuelle Infirmière et Enseignement* platform - Soulage TAVIE Post-Trauma) [45,46] (Figures 1 and 2; Multimedia Appendix 1) and in-person contact with a nurse, over the phone or face-to-face in the outpatient orthopedic clinic. The first three sessions were Web-based, followed by short in-person coaching meetings during hospitalization. Web sessions were delivered with a laptop and headphones in participant room. The last four sessions were designed to be one-on-one, either in a rehabilitation setting, an outpatient orthopedic clinic, a home, or a hospital in case of a lengthy hospital stay. A participant manual was used as a support tool during in-person sessions. Web sessions and the participant manual were designed according to recommended health literacy strategies (Multimedia Appendix 2) [47,48].

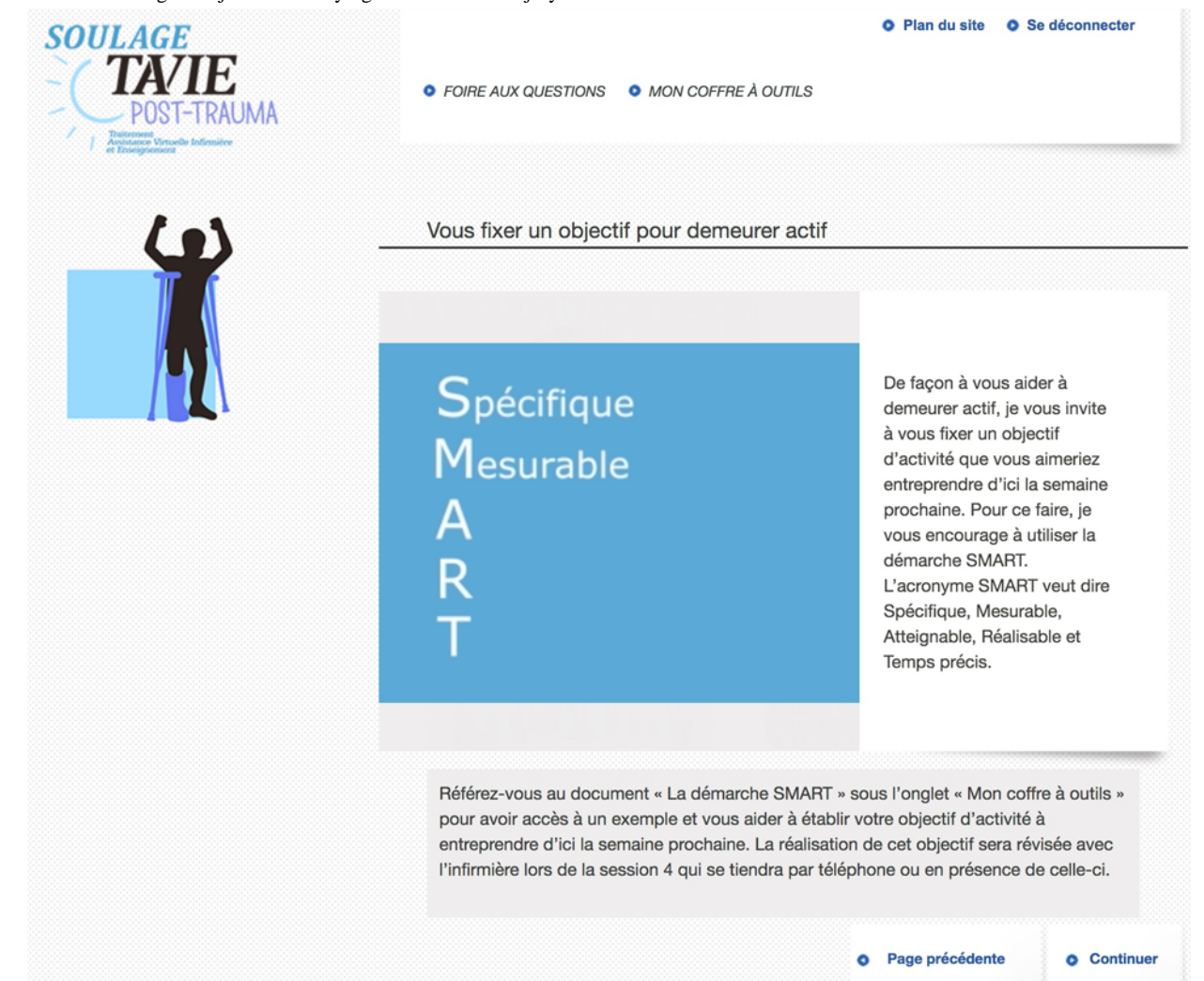
Variables and Measurement Tools

Sociodemographic and clinical data were collected after participants agreed to take part in the study. A clinical profile form was used to gather data related to injuries, treatments received, and pre-injury comorbid factors. Substance abuse was determined according to the toxicology screen as well as the health questionnaire obtained soon after the arrival to the trauma center. The feasibility and acceptability of the intervention were assessed with the following tools.

Figure 1. Introduction page of Soulage TAVIE Post Trauma.



Figure 2. Establishing an objective for staying active after the injury.



Feasibility

Intervention feasibility was assessed according to two criteria: 1) the ability to deliver the intervention as planned (ie, provision of session components to $\geq 80\%$ of participants, length of sessions corresponded to planned duration, and the challenges faced during intervention delivery could be overcome), and 2) the capability of participants to complete the intervention (ie, attendance at sessions as well as application of self-management behaviors after sessions 1 to 6 $\geq 80\%$ of participants) [49]. We used an Intervention Feasibility Evaluation Logbook to document the delivery of session components and a Self-Management Behavior Assessment Checklist to describe participant's capability to complete the intervention.

Acceptability

Web sessions were assessed with an E-Health Acceptability Questionnaire that includes recommended features for internet-based interventions [50], and in-person sessions were assessed with an acceptability questionnaire based on the Treatment Acceptability and Preference (TAP) Questionnaire [51]. The E-Health Acceptability Questionnaire was developed to analyze the TAVIE platform content [50], and includes 21 items rated on a 5-point descriptive scale (eg, 0 = not easy to use, 4 = very much easy to use) divided into nine subscales: ease of use, ease of understanding, credibility, tailoring, relevance, perceived applicability, visual design appreciation, dosage, motivational appeal, and overall satisfaction with the Web-based intervention. Content validation for this questionnaire was established by experts in the field of Web-based health interventions [50]. Participants completed the E-Health Acceptability Questionnaire after session 3. A high-reliability score (Cronbach alpha = 0.87) was obtained for the E-Health Acceptability Questionnaire in this study.

The TAP Questionnaire is a validated and reliable tool for persons receiving self-management interventions [51], that assesses the following intervention acceptability attributes: 1) perceived effectiveness in managing the problem, 2) appropriateness, 3) suitability to individual context, and 4) convenience or willingness to apply and adhere to the intervention. Participants were instructed to rate the intervention's features based on these four attributes, using a 5-point descriptive scale (eg, 0 = not appropriate, 4 = very much appropriate). Open-ended questions were added at the end of each attribute section to gather input on the modifications required to improve intervention acceptability. Participants completed the TAP questionnaire after session 5 to assess the acceptability of sessions 4 and 5, and after session 7 to assess sessions 6 and 7 as well as the intervention overall. Reliability scores for acceptability questionnaires completed after sessions 5 and 7 were high when considering all four attributes (Cronbach alpha > 0.9).

Data Analysis

Feasibility

To determine the ability to deliver iPACT-E-Trauma, uptake of the various components (face-to-face contacts, Web pages, and on-line documents consulted) was described. Rates of

sessions delivered within the established timeline were computed. Mean scores were calculated for the time spent watching Web sessions, consulting Web pages and for the delivery of in-person sessions. Descriptive data about the challenges involved in the delivery of interventions were grouped into categories. Frequencies were calculated for each category. Rates of attendance to sessions and application of self-management behaviors were calculated regarding the capability of participants to complete the intervention.

Acceptability

Descriptive analyses of data for the acceptability questionnaires were performed. Mean scores were calculated for each acceptability attribute. The answers to the open-ended questions on the modifications required to enhance the intervention's acceptability were grouped into categories. However, less than five participants answered the open-ended questions, precluding meaningful data analysis.

Extracts from the data sets and/or analyzed and the material used during the current study are available from the corresponding author.

Results

Sociodemographics

Sociodemographic data are presented in Table 1. More than half the participants were male, and the majority were Caucasian. Mean age was 47 years, ranging from 18 to 79 years. Twenty-two out of 28 participants (78%) had a high school to college education, and 20 participants (72%) had an annual income $< \$ 50,000$. The most common occupation was laborer followed by work as a professional. Six participants (22%) were retired.

Clinical Data

Data on participants' injuries and treatments are presented in Table 2. Almost half of the participants suffered an orthopedic injury secondary to a fall. The most frequent fractures were to the pelvis, the acetabulum, the femur and the tibia. Joint dislocation occurred in 13 out of 22 participants (46%) and soft tissue injury (eg, tissue swelling delaying surgery, deep laceration, crush injury) in more than half of the participants. Almost two-thirds of the participants had at least two fractures, while half had a concomitant injury. The most frequent being a fracture to the upper extremities, followed by a fracture to the spine, and mild TBI. According to the mean Injury Severity Score (ISS) and the Abbreviated Injury Scale (AIS) - Extremity score [52] most participants suffered moderate to serious injury. The dominant comorbidities were substance abuse and mental health issues (eg, history of anxiety or depression) but were present in less than a quarter of participants. Twenty-six participants (93%) had an open reduction and internal fixation surgery for their lower ET and, among these, 11 participants (39%) had a lower limb immobilized by a cast or an orthosis for several weeks after the injury. Weight-bearing limitation on the injured limb was prescribed for 3 to 6 months in almost half the participants.

Table 1. Sociodemographic data for total participants (n=28).

Characteristics	iPACT-E-Trauma group, n (%)
Gender	
Male	15 (54) ^a
Ethnic group	
Caucasian	23 (82)
Haitian	3 (11)
Arabic	2 (7)
Level of education	
< High school diploma	2 (7)
High school diploma	11 (39)
Collegial diploma	11 (39)
Undergraduate studies diploma	3 (11)
Graduate studies diploma	1 (4)
Occupation	
Laborer	6 (22)
Clerical work	2 (7)
Administration	4 (14)
Professional	4 (14)
Student	2 (7)
None	4 (14)
Retired	6 (22)
Annual income	
< \$20,000/year	6 (22)
\$20,000 to \$49,000	14 (50)
\$50,000 to \$69,000	2 (7)
\$70,000 to \$99,000	4 (14)
≥ \$100,000	2 (7)

^aMean age (range)=47 (18 to 79).

Feasibility

The Ability to Deliver the Intervention as Planned

Twenty to 28 out of 28 participants (71% to 100%) accessed all Web pages of sessions 1 to 3 (Table 3). During session 2, six participants (21%) did not access Web pages about the mechanisms of action of opioids and acetaminophen, and 19 participants (67%) did not access Web pages related to pregabalin. Most participants consulted self-management recommendation summaries in the participant's manual, while a few consulted them in the Web platform throughout Web sessions.

Components of the in-person coaching meetings relevant to all participants were provided as planned to most during the first

and the second meetings, and to fewer participants during the third meeting (Table 3). Those that required individualized tailoring were also less frequently delivered. Web sessions were primarily delivered according to the established timeline, except for session 3. The timeline was less frequently followed for the in-person meetings compared to Web sessions. Mean duration for Web sessions combined with in-person coaching meetings were ≤ 30 minutes. The challenges experienced during Web sessions were from various types, but they all occur in seven or less (≤ 26%) of participants: 1) environmental (ie, noise or limited space in participant's room), 2) technical (ie, slow internet connection, difficulty creating password), 3) participant-related (ie, drowsiness, nausea, no glasses), and 4) care-related (ie, interruptions for nursing evaluation and intervention or diagnostic tests).

Table 2. Participants' injuries and treatments received (n=28).

Characteristics	Results, n (%)
Trauma mechanism	
Motor vehicle crash	8 (28)
Pedestrian collision	3 (11)
Fall	13 (46)
Sport	3 (11)
Work	1 (4)
Types of orthopedic injuries^a	
Pelvic fracture	12 (43)
Acetabulum fracture	9 (34)
Femur fracture	8 (28)
Knee joint ligaments sprain	2 (7)
Tibia fracture	8 (29)
Fibula fracture	7 (25)
Ankle fracture	5 (18)
Foot fracture	4 (14)
Open fracture	3 (11)
Joint dislocation	13 (46)
Soft tissue	16 (57)
Number of fractures	
One	10 (36)
Two	11 (39)
≥3	7 (25)
Other injuries	
Participants with at least one concomitant injury	14 (50)
Mild traumatic brain injury	4 (14)
Upper extremities	6 (22)
Thorax	2 (7)
Abdomen	3 (11)
Spine	5 (18)
Injury Severity Score	9.4 (6)
Abbreviated Injury Scale (AIS) – Orthopedic score	
AIS 1 (minor extremity injury)	—
AIS 2 (moderate extremity injury)	15 (54)
AIS 3 (serious extremity injury)	11 (39)
AIS 4 (severe extremity injury, life-threatening)	2 (7)
Comorbidities	
Substance abuse	5 (18)
Somatic or visceral pain before the injury	1 (4)
Mobility issue requiring technical aid	2 (7)
Neurological (eg, epilepsy, previous stroke)	4 (14)
Cardiovascular (eg, previous myocardial infarction, hypertension)	3 (11)
Morbid obesity (Body Weight Index ≥35)	3 (11)

Characteristics	Results, n (%)
Psychological (eg, anxiety, depression)	6 (22)
Treatments^b	
Open reduction and internal fixation surgery	26 (93)
Closed reduction and external fixation surgery	8 (28)
Conservative treatment (no surgery)	2 (7)
Immobilization with a cast or an orthosis	11 (39)
Weight bearing limitation postinjury	
No limitation	1 (4)
6 weeks postinjury	14 (50)
3 months postinjury	10 (36)
6 months postinjury	3 (11)

^aSome participants had more than one type of fractures.

^bSome participants received more than one treatment.

The components of in-person sessions relevant to all participants were provided to a large proportion of participants during sessions 5 to 7 (Table 4), while those requiring individualized tailoring were delivered to fewer participants. In-person sessions were offered according to the established timeline to most of the participants. Their mean duration was also ≤ 30 minutes. Challenges experienced during sessions 4 to 7 were related to participants (ie, lack of motivation, emphasizing other problems than pain), to care (ie, difficulty coordinating sessions with other interventions occurring at the outpatient orthopedic clinic), and to the environment (ie, noise in participant's room). These were present for less than three participants ($< 10\%$).

The Capability of Participants to Complete the Intervention

Attendance at the Intervention Sessions

The Web sessions and in-person coaching meetings were attended by all participants for the first two sessions and by 26 out of 28 participants (93%) for the third session (Table 5). The in-person sessions were attended by all participants for session 4, by 26 (93%) for sessions 5 and 6, and by 25 (89%) for session 7 (Table 5).

Application of Self-Management Behaviors

Overall, less than six over 28 participants ($< 20\%$) did not apply self-management behaviors relevant to their condition (Table 5). Cryotherapy was applied by two-thirds of participants after session 1 and by more than half after session 3 and diminished as the intervention progressed. Cryotherapy was not indicated in several participants after sessions 1 to 4 given they had limb immobilization with a thick elastic bandage, splint cast with an elastic bandage or skin vascularization issues. Following sessions 5 and 6, cryotherapy was not indicated in 18 participants (70%) because pain intensity did not interfere with activities, there was no significant limb swelling, or a splint covered by a thick elastic bandage immobilized the limb. Leg

elevation, a self-management behavior suggested in the first session, was strongly followed from sessions 1 to 3, and as was the case with cryotherapy, its use gradually declined afterward. Leg elevation was not needed in some participants after sessions 1 and 2, considering localized pelvic fractures without associated swelling, and even more after sessions 3 to 7 (reaching up to 20 participants or more than 75% of them) as the gradual decrease in swelling and pain intensity helped participants resume activities.

Appropriate use of co-analgesia was implemented by all but one participant after session 1 and in about two thirds after session 4, after which co-analgesia was not needed in up to 44% of participants, as they were either only taking acetaminophen or no analgesic. Almost half the participants did not use the deep breathing relaxation exercises they were taught in session 2. Relaxation exercises were not indicated anymore for many participants after sessions 4 to 7 because there was no marked pain interference with activities (score $<4/10$) [37]. Problem-solving, when facing a difficult pain experience, was used by 10 participants (36%) after session 3 and three participants (10%) after session 6. However, this self-management behavior did not apply to many participants and was found irrelevant. Moreover, few participants needed to establish sleep hygiene objectives and apply strategies to facilitate sleep over the course of the intervention sessions.

The objective of remaining active without increasing pain intensity and the individualized plans for returning to previous activities were highly achieved by participants. Mobility restrictions prevented some participants from reaching their objectives for staying active. Regarding strategies, several participants used the gradual return to activities, while fewer participants used activity pacing or changing the activity schedule in light of pain intensity variations throughout the day. These two latter strategies were not indicated for several participants since they were not yet active enough.

Table 3. Delivery of web sessions (1 to 3) and related in-person coaching meetings.

Variables	Results
Session 1	
Web (n=28), n (%)	
Participants who accessed all web pages	28 (100)
Summaries accessed in the web platform	4 (14)
Summaries consulted in the participant manual	24 (85)
Session delivered according to the established timeline	28 (100)
Session duration, mean (SD; range)	18 min (6; 13-34)
In-person coaching (n=28)	
Components provided to participants, n (%)	
Answer questions related to the on-line content	27 (96)
Ask participants to report their pain intensity	28 (100)
Ask participants to report their ice and legs elevation utilization	28 (100)
Review how to use ice and legs elevation if needed	12 (46)
Tailor the recommendations on cryotherapy and legs elevation if needed	17 (61)
Meeting delivered according to the established timeline, n (%)	12 (43)
Meeting duration, mean (SD; range)	4 min (2; 2-10)
Session 2	
Web (n=28), n (%)	
Participants who accessed all web pages	20 (71)
Summaries accessed in the web platform	4 (14)
Summaries consulted in the participant manual	24 (86)
Session delivered according to the established timeline	27 (96)
Session duration, mean (SD; range)	20 min (7.4; 11-47)
In-person coaching (n=28)	
Components provided to participants, n (%)	
Answer questions related to the on-line content	27 (96)
Ask participants to report their pain intensity	27 (96)
Ask participant to report their co-analgesia, ice and legs elevation utilization	28 (100)
Review how to use co-analgesia, relaxation exercises ice and legs elevation	16 (57)
Tailor the recommendations on co-analgesia if needed	4 (14)
Tailor the recommendations on cryotherapy and legs elevation if needed	8 (29)
Meeting delivered according to the established timeline, n (%)	16 (57)
Meeting duration, mean (SD; range)	6 min (3; 2-15)
Session 3	
Web (n=26), n (%)	
Participants who accessed all web pages	25 (96)
Summaries accessed in the web platform	2 (8)
Summaries consulted in the participant manual	24 (92)
Session delivered according to the established timeline	17 (65)
Session duration, mean (SD; range)	16 min (4; 8-33)
In-person coaching (n=26)	
Components provided to participants, n (%)	

Variables	Results
Answer questions related to the on-line content	16 (62)
Ask participants to report their pain intensity	13 (50)
Ask participants to report their co-analgesia and relaxation exercises utilization	14 (54)
Review how to use co-analgesia and relaxation exercises if needed	10 (39)
Tailor the recommendations on co-analgesia if needed	5 (19)
Invite participants to discuss the use of problem solving if indicated	9 (35)
Assist participants in the establishment of an activity objective	26 (100)
Meeting delivered according to the established timeline, n (%)	4 (15)
Meeting duration, mean (SD; range)	8 min (6; 2-23)

Acceptability

Web sessions were assessed as very acceptable nearly across all acceptability attributes (Table 6). Visual appeal (ie, colors, pictures, and pages outlook) and applicability (ie, perceived capacity to apply strategies recommended in Web sessions) were rated as acceptable, on average. In-person weekly sessions 4 and 5 were also assessed by participants as very acceptable for almost every attribute (Table 7). Items that were evaluated as acceptable included the perceived effectiveness of

establishing an individualized action plan for returning to pre-injury activities, defining objectives to achieve adequate sleep hygiene, and reviewing previously learned self-management strategies at the beginning of each session. In-person sessions 6 and 7 (ie, booster sessions) were assessed as acceptable to very acceptable (Table 7). Items with the lowest mean scores across acceptability attributes were the following: reviewing the individualized action plan to return to pre-injury activity and establishing a new action plan, as well as the convenience of phone sessions.

Table 4. Delivery of in-person sessions (4 to 7).

Variables	Results
Session 4: in-person (n=28)	
Components provided to participants, n (%)	
Ask participants to report their pain intensity	27 (96)
Ask participants to report their analgesics utilization	28 (100)
Encourage the application of learned self-management behaviors if needed	20 (71)
Provide information on gradual reduction of analgesics if needed	10 (36)
Discuss the use of problem solving if indicated	11 (39)
Provide feedback on the achievement of activity objective	26 (93)
Offer assistance in the establishment of another activity objective	24 (86)
Provide information on sleep hygiene	28 (100)
Provide assistance in the establishment of a sleep hygiene objective if needed	9 (32)
Encourage the use of strategies to optimize sleep if needed	14 (50)
Session delivered according to the established timeline, n (%)	26 (93)
Session duration, mean (SD; range)	19 min (7; 8-38)
Session 5: in-person (n=26)	
Components provided to participants, n (%)	
Ask participants to report their pain intensity	26 (100)
Ask participants to report their analgesics utilization	26 (100)
Encourage the application of learned self-management behaviors if needed	18 (69)
Provide information on gradual reduction of analgesics utilization if needed	8 (31)
Provide feedback on the achievement of sleep hygiene objective	8 (31)
Encourage the continuous use of strategies to optimize sleep if needed	13 (50)
Providing feedback on the achievement of activity objective	23 (89)
Give information on how to return to pre-injury activities if needed	16 (64)
Provide assistance for establishing a plan for returning to pre-injury activities	25 (93)
Session delivered according to the established timeline, n (%)	24 (92)
Session duration, mean (SD; range)	20 min (6; 12-31)
Session 6 (Booster 1): in-person (n=26)	
Components provided to participants, n (%)	
Answer questions related to pain management strategies	13 (50)
Ask participants to report their analgesics utilization	26 (100)
Give information on gradual reduction of analgesics if needed	8 (31)
Provide feedback on action plan achievement	26 (100)
Provide assistance for reviewing the plan for returning to pre-injury activities	26 (100)
Reinforce the importance of using learned self-management behaviors to facilitate the return to pre-injury activities if needed	10 (77)
Session delivered according to the established timeline, n (%)	22 (85)
Session duration, mean (SD; range)	18 min (8; 7-50)
Session 7 (Booster #2): in-person (n=25)	
Components provided to participants, n (%)	
Answer questions related to pain management strategies	14 (56)
Ask participants to report their analgesics utilization	22 (88)

Variables	Results
Give information on gradual reduction of analgesics utilization if indicated	6 (24)
Providing feedback on action plan achievement	25 (100)
Provide assistance for reviewing the plan for returning to activities	24 (96)
Reinforce the importance of using learned self-management behaviors to facilitate the return to pre-injury activities if required	19 (76)
Session delivered according to the established timeline, n (%)	24 (96)
Session duration, mean (SD; range)	15 min (5; 10-30)

Table 5. Intervention completion by participants (N=28).

Variables	Applied, n (%)	Not applied as recommended or not applied, n (%)	Not indicated, n (%)
Session 1 (n=28)			
Behaviors applied between session 1 and 2			
Cryotherapy (every 2h for 20 min)	17 (61)	4 (14)	7 (25)
Legs elevation in straight position while in bed	24 (86)	1 (3)	3 (11)
Session 2 (n=28)			
Behaviors applied between session 2 and 3			
Cryotherapy	18 (64)	3 (11)	7 (25)
Legs elevation in straight position	24 (86)	2 (7)	2 (7)
Co-analgesia	27 (96)	— ^a	1 (4)
Breathing relaxation exercises when experiencing pain interference with activities	11 (39)	11 (39)	6 (21)
Session 3 (n=26)			
Behavior applied between session 3 and 4^b			
Cryotherapy	16 (57)	5 (18)	7 (25)
Legs elevation in straight position	18 (64)	3 (11)	7 (25)
Co-analgesia	22 (79)	2 (7)	4 (14)
Breathing relaxation exercises	8 (29)	12 (43)	8 (29)
Problem solving	10 (36)	5 (18)	13 (46)
Implementation of the activity objective	24 (86)	1 (4)	3 (11)
Gradual return to activities	25 (89)	—	3 (11)
Changing schedule of activities in light of pain	5 (18)	4 (14)	19 (68)
Activity pacing	15 (57)	1 (3)	11 (39)
Session 4 (n=28)			
Behavior applied between session 4 and 5^c			
Co-analgesia (with reduction of opioids)	17 (65)	1 (4)	8 (31)
Problem solving	10 (39)	1 (4)	15 (58)
Implementation of the activity objective	20 (77)	5 (19)	1 (4)
Gradual return to activities	21 (81)	1 (4)	4 (15)
Changing schedule of activities in light of pain	3 (12)	1 (4)	22 (85)
Activity pacing	18 (69)	—	8 (31)
Implementation of sleep hygiene objective	8 (31)	2 (8)	16 (62)
Strategies to facilitate sleep	10 (39)	—	16 (62)
Other pain management strategies			
Breathing relaxation exercises	4 (15)	6 (23)	16 (62)
Cryotherapy	12 (46)	1 (4)	13 (50)
Legs elevation	13 (50)	—	13 (50)
Session 5 (n=26)			
Behaviors applied between session 5 and 6			
Co-analgesia (with reduction of opioids)	17 (65)	1 (4)	8 (31)
Implementation of the action plan	24 (92)	2 (8)	—
Gradual return to activities	18 (69)	3 (12)	5 (19)

Variables	Applied, n (%)	Not applied as recommended or not applied, n (%)	Not indicated, n (%)
Changing schedule of activities in light of pain	3 (12)	21 (81)	2 (8)
Activity pacing	17 (65)	1 (4)	8 (31)
Other pain management strategies			
Breathing exercises	1 (4)	5 (19)	20 (77)
Cryotherapy	8 (31)	—	18 (69)
Legs elevation	5 (19)	1 (4)	20 (77)
Strategies to facilitate sleep	3 (12)	—	23 (89)
Problem solving	7 (27)	2 (8)	17 (65)
Session 6 (n=26)			
Behavior applied between session 6 and 7^d			
Adequate use of analgesics (with no or minimal use of opioids)	14 (56)	—	11 (44)
Implementation of the action plan	25 (96)	1 (4)	—
Gradual return to activities	21 (84)	1 (4)	3 (12)
Changing schedule of activity in light of pain	3 (12)	2 (8)	20 (80)
Activity pacing	18 (72)	6 (24)	1 (4)
Other pain management strategies			
Breathing relaxation exercises	1 (4)	4 (17)	19 (79)
Cryotherapy	4 (16)	3 (12)	18 (72)
Legs elevation	5 (20)	3 (12)	17 (68)
Strategies to facilitate sleep	3 (12)	—	22 (88)
Problem solving	3 (12)	1 (4)	21 (84)

^aThe category does not apply to any participant.

^bPercentage was calculated from 28 participants since the application of self-management behaviors was verified at the beginning of session 4.

^cPercentage was calculated from 26 participants since the application of self-management behaviors was verified at the beginning of session 5.

^dPercentage was calculated from 25 participants since the application of self-management behaviors was verified at the beginning of session 7.

Table 6. Web-based sessions (1 to 3) acceptability.

Web session components	Results, mean ^a (SD), (n=28)
Navigation	
Directives and instructions	3.4 (1.0)
Web pages navigation	3.5 (1.0)
Understanding	
Language and vocabulary used by the nurse	3.8 (0.5)
Content	3.7 (0.7)
Credibility	
Content and documents	3.4 (0.8)
Virtual nurse and information tailoring	
Appreciation of nurses' videos	3.8 (0.5)
Interactions with the virtual nurse	3.8 (0.4)
Perception to have received a tailored consultation	3.4 (1.0)
Personalization of messages	3.1 (1.1)
Individual relevance	
Content and documents	3.4 (0.6)
Appropriateness for the management of pain and for returning to activities	3.4 (0.7)
Recommendations corresponding to participant's needs	3.6 (0.6)
Usefulness	3.3 (0.6)
Applicability	
Capacity to implement strategies recommended in web sessions	2.9 (1.1)
Visual appealing	
Videos	3.3 (0.7)
Colors, pictures and pages outlook	2.8 (1.0)
Dosage	
Sessions duration	3.1 (1.1)
Interval of time between each session	3.1 (1.1)
Number of sessions	3.3 (0.8)
Motivational appealing	
The participant would recommend web sessions to patients with ET	3.7 (0.6)
In-person coaching session	
Relevance of follow-up made by the nurse between sessions	3.6 (0.6)
Usefulness of follow-up made by the nurse between sessions	3.5 (0.7)
General	
Global satisfaction	3.4 (0.9)

^aRange (0-4)

Table 7. In-person sessions (4 to 7) acceptability.

Intervention Components and Features	Effectiveness, mean ^a (SD)	Appropriateness, mean (SD)	Suitability, mean (SD)	Convenience, mean (SD)
Sessions 4 and 5 (n=25)^b				
Feedback and encouragements on the utilization of recommended pain management strategies at the beginning of each session	3.1 (0.8)	3.2 (0.8)	3.2 (0.7)	3.2 (0.8)
Review of previously learned self-management strategies at the beginning of each session according to participant's needs ^c	2.9 (0.8)	3.0 (0.8)	3.2 (0.8)	—
Education on sleep hygiene strategies	3.0 (1.0)	3.2 (0.9)	3.1 (1.0)	3.5 (0.8)
Establishment of an objective to attain adequate sleep hygiene	2.7 (0.9)	3.0 (0.9)	3.0 (0.9)	3.2 (0.7)
Guidance on the gradual reduction of analgesics utilization	3.1 (0.9)	3.1 (0.9)	3.2 (1.0)	3.2 (1.2)
Establishment of objectives to stay active	3.0 (0.8)	3.2 (0.8)	3.1 (0.8)	3.0 (1.0)
Discussion on problem-solving utilization	3.2 (0.9)	3.2 (0.8)	3.2 (0.8)	3.0 (0.8)
Establishment of an action plan for returning to pre-injury activities	2.5 (1.2)	3.1 (1.0)	3.0 (1.0)	3.4 (0.7)
The number of weeks between each session (one week) ^c	—	—	3.2 (0.8)	—
Sessions duration ^c	—	—	3.4 (0.7)	—
Sessions 6 and 7 (boosters; n=23)^b				
Review of previously learned self-management strategies at the beginning of each session according to participant's needs ^c	3.0 (0.8)	3.1 (0.8)	2.9 (0.9)	—
Guidance on gradual reduction of analgesics utilization	3.0 (0.8)	3.5 (0.6)	3.2 (0.7)	3.1 (0.8)
Review of the action plan for returning to pre-injury activities	2.7 (0.9)	2.9 (0.9)	2.9 (1.0)	3.0 (1.0)
Establishment of a new action plan for returning to pre-injury activities	2.7 (1.0)	2.9 (0.9)	3.0 (1.0)	3.0 (0.9)
Having received sessions over the phone ^c	—	—	3.0 (0.9)	2.8 (1.1)
Having received sessions in-person ^c	—	—	3.5 (0.6)	3.1 (0.9)
The number of week between each session ^c	—	—	3.1 (0.9)	—
Sessions duration ^c	—	—	3.1 (0.8)	—
The sequence of the topics covered during the intervention	—	—	3.3 (0.6)	—
Intervention duration (3 months)^c				
The total number of sessions included in the intervention (7 sessions)	—	—	3.0 (0.7)	3.0 (1.0)

^aRange (0-4).

^bA total of 25 participants completed the acceptability questionnaire related to sessions 4 and 5. A total of 23 participants completed the acceptability questionnaire related to sessions 6 and 7

^cOnly relevant acceptability items were assessed

Discussion

Principal Findings

This study aimed to determine the feasibility and acceptability of iPACT-E-Trauma. Findings were positive for feasibility criteria, with components for Web sessions and in-person sessions provided to $\geq 80\%$ of participants, except components covered in Web session 2, in-person coaching meeting 3, and those that required individualized tailoring. Sessions were delivered according to the established timeline for $\geq 80\%$ of participants, excluding session 3 and in-person coaching meetings for sessions 1 to 3. Average session duration was ≤ 30

minutes, as expected. Moreover, except for one participant, all the challenges faced during intervention delivery were overcome, either by assisting participants with internet use or rescheduling sessions. Regarding participants' adherence to the intervention, $\geq 80\%$ were able to attend planned sessions. Likewise, most participants applied self-management behaviors relevant to their condition, except deep breathing relaxation exercises. Overall, session features were evaluated as very acceptable and no feature was considered as not acceptable.

Findings from this study highlighted ways to improve the feasibility and acceptability of iPACT-E-Trauma in preparation for a larger scale study. Additional tailoring of iPACT-E-Trauma

by adjusting its content, dosage, and timing of session delivery is required to improve the ability to deliver the intervention and the capability of patients to apply self-management behaviors (ie, feasibility). Another change would be to enhance the perceived applicability of some recommended pain management strategies (ie, acceptability). Tailored interventions are based on characteristics that are unique to the person receiving it, using a combination of information or changing strategies to achieve the outcomes of interest [53,54]. The procedures to tailor self-management interventions involve increasing relevance or meaning of the content by including personally identifiable information and explaining how information is relevant to a person's condition (ie, personalization). This also includes making recommendations related to the targeted behaviors (ie, feedback), and adapting the intervention (ie, content, dose, delivery timing) according to individual data such as determinants of the targeted behaviors [53-55]. In this study, iPACT-E-Trauma was personalized by suggesting pain management strategies relevant for patients with lower ET and by specifying in which context such strategies were applicable. Questioning patients on pain intensity, pain interference with activities, and application of self-management behaviors at each intervention session also promoted individualized feedback and content matching, according to participants' needs.

Recent research showed that tailored Web-based and non Web-based health interventions are slightly more effective than nontailored interventions [56-59]. One of the main causes of this result is that features of tested interventions were not enough matched to the participants' profile [55-59]. Thus, in iPACT-E-Trauma, self-management recommendations to participants should be based on behaviors they can implement considering their condition, personal attributes, and recovery pace. For example, information on how to take pregabalin should only be provided to those that use this analgesic. Problem-solving in the presence of a difficult pain experience should be exclusively reinforced in participants who experience problems regulating their negative thoughts and emotions in the presence of pain. Moreover, promoting strategies for staying active and returning to previous activities should consider the participant's capacity to ambulate.

Concerning the dosage of iPACT-E-Trauma, the number of sessions (ie, less or more than 7 sessions) offered to participants should be tailored according to pain intensity, pain interference with activities, and abilities in pain self-management. For example, a greater number of sessions should be provided to participants who still experience significant pain interference with activities (ie, score $\geq 4/10$) 3 months after their injury and who still need support from a health care professional for the implementation of self-management behaviors. Fewer than 7 sessions could also be offered to participants with pain intensity $< 4/10$ and who have restarted to ambulate on their injured limb(s).

Furthermore, the timing of in-person coaching meetings, Web session 3 and booster sessions should be revised. In-person coaching meetings were integrated between each Web-based session, since clinicians and patients emphasized the importance of keeping in direct contact with health care professionals providing the intervention during the development phase of

iPACT-E-Trauma. More frequent interactions with health care professionals have also been identified as an important strategy to increase adherence to Web-based health interventions [60,61]. In-person coaching was planned 24 hours after each Web session, to give participants enough time to implement self-management behaviors. However, this study found that in-person coaching should be offered right after Web sessions to answer questions on the content covered and tailor self-management recommendations when required.

Web session 3 had to be delivered earlier than planned or was not delivered to some participants because of early hospital discharge. Also, components of the third in-person coaching meeting were not provided to each participant due to the time constraints associated with their hospital discharge. Hence, the timing of session delivery should be more flexible, to adjust to participant's hospital length of stay. Another option would be to deliver session 3 in-person for those who do not have internet access after hospital discharge. Moreover, patients may experience less pain to their injured extremity when no weight is put on it. Hence, booster sessions, which focus on reviewing learned self-management behaviors and establishing an individualized plan for returning to previous activities, should be scheduled after participants are allowed to fully weight bear on their injured extremity. Doing so will allow participants to re-engage in self-management behaviors required to prevent pain relapse while returning to their normal activities of daily living [62]. Likewise, considering that participants preferred to receive sessions face-to-face, the timing of session delivery should be coordinated, as much as possible, with the orthopedic surgeon appointment at the outpatient clinic.

The steps necessary to further tailor iPACT-E-Trauma could be achieved through a Sequential Multiple Assignment Randomized Trial (SMART). This type of design allows the development of adaptive interventions in which the components and the dosage of the intervention are personalized, on the basis of patient characteristics or clinical presentation. They are then repeatedly adjusted over time to individual progress [63]. Adaptive interventions include a multistage process, operationalized via a sequence of decision rules that recommend when and how the intervention should be modified, in order to maximize the effects on outcomes [63]. In a SMART, participants move through multiple stages and are randomly assigned to one of several intervention options at each stage, allowing for a comparison of their efficacy [64].

Findings related to the application of self-management behaviors also indicated that the integration of relaxation therapies to iPACT-E-Trauma must be reexamined. Relaxation therapies include a number of techniques, such as progressive muscle relaxation, guided imagery, hypnosis and deep breathing exercises [65]. In this study, only deep breathing exercises were taught. Ease of implementation in the acute care context, while also providing participants with a strategy to decrease their anxiety and its effect on pain intensity, at rest and during mobilization, made this technique relevant [66]. Nevertheless, a large proportion of participants did not practice deep breathing exercises, which could be explained by the fact that relaxation techniques require training [46,67,68]. Indeed, in a recent study conducted in patients with acute orthopedic trauma, with positive

disability and pain outcomes, relaxation techniques (ie, deep breathing and progressive muscle relaxation) were taught during a 60-minute session, and patients were instructed to practice daily, guided by videos [14]. Therefore, more training time should be scheduled for participants in future applications of iPACT-E-Trauma, to optimize their use of relaxation therapies. Other techniques, such as progressive muscle relaxation, could also be offered to participants, particularly for those experiencing considerable pain interference with activities.

Another improvement to iPACT-E-Trauma relates to the feasibility of using the Web platform. Some participants needed assistance to create and enter a password at the beginning of Web sessions or did not consult actionable content (eg, Web pages on the analgesics prescribed) requiring interactions from participants with the platform to access programmed information, while most participants did not consult self-management recommendation summaries integrated in a toolbox. As many as 50% of adults have limited literacy skills [69], which may affect how they find, understand, and use information on the Web. Moreover, even users with high literacy skills may find reading and using the Web more difficult when they are sick and stressed [70]. To help developers designing digital health information tools for users with limited literacy, the Office of Disease Prevention and Health Promotion of the US Department of Health and Human Services [69] has recently developed an evidence-based guide on health literacy online. Several strategies presented in this guide could be used to overcome issues faced during Web session delivery. One of these is avoiding asking users to enter too much information. Therefore, only the participant's name could be used to access the Web sessions in iPACT-E-Trauma, since no confidential information is shared on the platform. Also, clickable elements to consult actionable content should be made more recognizable. For example, large and bright clickable buttons in a contrasting color from the surrounding text and background, and obviously clickable (eg, rectangular shape and rounded corners) could be created. Such strategies could also improve the visual appeal of the Web application, and therefore its acceptability. The summaries on self-management recommendations presented

throughout Web sessions could be removed to avoid links to pages with redundant content and provided in a paper format to participants as needed.

Study Strengths and Limitations

This study is the first to assess the feasibility and acceptability of a hybrid, Web-based and in-person, intervention for the prevention of chronic pain, to be initiated in acute care settings. Nonetheless, there are some limitations that must be addressed. First, the implementation of self-management behaviors was self-reported by participants, which could have introduced a social desirability bias in the study. To avoid this, participants were invited to discuss how they applied self-management behaviors with the interventionist at each session, instead of using a formal questionnaire, which also provided the opportunity for feedback and to determine the content that needed to be reviewed. Second, it is not possible with this study to draw any conclusions on the effect of iPACT-E-Trauma. Findings from both this study and a pilot RCT [31] in which the feasibility of the research methods will also be assessed will serve for the development of a full-scale RCT. This type of study will make it possible to determine if iPACT-E-Trauma can prevent chronic pain after a major lower ET.

Conclusions

This study showed that iPACT-E-Trauma is feasible and perceived as highly acceptable by patients. Further tailoring the intervention, better support when learning deep breathing relaxation exercises, and modifying the Web platform to increase its convenience could improve both the delivery of iPACT-E-Trauma and patient satisfaction. Several studies have focused on the evaluation of self-management interventions when the pain has already become chronic. However, there is a pressing need for an intervention that can prevent disabling and costly chronic pain problems that often ensue after a major injury. The development of iPACT-E-Trauma is a milestone in the research efforts aimed at developing a relevant chronic pain preventive intervention that could be easily applied in the acute and rehabilitation continuums of care.

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Authors' Contributions

MB conducted data collection and analysis in the context of her doctoral studies and drafted the manuscript. CG closely supervised data analysis and was involved in manuscript drafting. NF, GM, JC, GYL, DR, and MC provided clinical advice on data analysis and critically revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of Soulage TAVIE Post Trauma.

[[PDF File \(Adobe PDF File\), 3MB - formative_v2i1e10323_app1.pdf](#)]

Multimedia Appendix 2

Design of the intervention material (web sessions and participant manual) according to health literacy strategies.

[[DOCX File, 26KB - formative_v2i1e10323_app2.docx](#)]

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Abbreviations

AIS: Abbreviated Injury Scale

iPACT-E-Trauma: Intervention to prevent acute to chronic pain after major lower extremity trauma

ET: extremity trauma

ISS: Injury Severity Score

TAP: Treatment and acceptability preference

TAVIE: Traitement et Assistance Virtuelle Infirmière et Enseignement

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Original Paper

Developing a Self-Administered Decision Aid for Fecal Immunochemical Test–Based Colorectal Cancer Screening Tailored to Citizens With Lower Educational Attainment: Qualitative Study

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Abstract

Background: Citizens with lower educational attainments (EA) take up colorectal cancer screening to a lesser degree, and more seldom read and understand conventional screening information than citizens with average EAs. The information needs of citizens with lower EA are diverse, however, with preferences ranging from wanting clear recommendations to seeking detailed information about screening. Decision aids have been developed to support citizens with lower EA in making informed decisions about colorectal cancer screening participation, but none embrace diverse information needs.

Objective: The aim of this study was to develop a self-administered decision aid for participation in fecal immunochemical test–based colorectal cancer screening. The decision aid should be tailored to citizens with lower EA and should embrace diverse information needs.

Methods: The Web-based decision aid was developed according to an international development framework, with specific steps for designing, alpha testing, peer reviewing, and beta testing the decision aid. In the design phase, a prototype of the decision aid was developed based on previous studies about the information needs of lower EA citizens and the International Patient Decision Aid Standards guidelines. Alpha testing was conducted using focus group interviews and email correspondence. Peer review was conducted using email correspondence. Both tests included both lower EA citizens and health care professionals. The beta testing was conducted using telephone interviews with citizens with lower EA. Data were analyzed using thematic analysis.

Results: The developed decision aid presented information in steps, allowing citizens to read as much or as little as wanted. Values clarification questions were included after each section of information, and answers were summarized in a “choice-indicator” on the last page, guiding the citizens toward a decision about screening participation. Statistics were presented in both natural frequencies, absolute risk formats and graphically. The citizens easily and intuitively navigated around the final version of the decision aid and stated that they felt encouraged to think about the benefits and harms of colorectal cancer screening without being overloaded with information. They found the decision aid easy to understand and the text of suitable length. The health care professionals agreed with the citizens on most parts; however, concerns were raised about the length and readability of the text.

Conclusions: We have developed a self-administered decision aid presenting information in steps. We involved both citizens and health care professionals to target the decision aid for citizens with lower EA. This decision aid represents a new way of

communicating detailed information and may be able to enhance informed choices about colorectal cancer screening participation among citizens with lower EA.

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KEYWORDS

colorectal neoplasms; mass screening; decision support techniques; socioeconomic factors; qualitative research

Introduction

Colorectal cancer (CRC) has particularly high mortality among disadvantaged groups, including those with low educational attainment (EA) [1,2]. A US study observed that the mortality rate of those primarily with higher EA decreased between the years 1993 and 2001, whereas it increased for those with lower EA [3].

Screening using the guaiac fecal occult blood test (gFOBT) may reduce both CRC incidence and mortality by removing precancerous adenomas and detecting the earlier stage CRC [4]. Recent studies have determined that the fecal immunochemical test (FIT) is superior to gFOBT in detecting CRC [5-7], and hence, FIT has been implemented in an increasing amount of screening programs worldwide [8-10]. In addition to screening benefits, screening harms, such as risk of overdiagnosis and risk associated with invasive procedures, also exist, thereby making participation in screening beneficial for some individuals and more or less harmful for others [4]. Hence, the decision to take up CRC screening is a preference-sensitive choice, that is, a choice that should be based on adequate knowledge about screening and reflect personal values [11,12].

Deprived populations tend to participate less in CRC screening than others [13], and this may reflect a lack of screening knowledge as well as social barriers [14]. Health authorities in countries offering CRC screening provide citizens with information on CRC screening, but a Dutch study has shown that conventional information material, although of high quality and with few unique content words per paragraph, might be overwhelming for citizens with low health literacy and lower EA [15]. The study showed that citizens with lower EA tend to read only headings and look at pictures [15].

Decision aids (DAs) are evidence based and aim to support citizens in making specific choices about health-related issues. In general, they improve knowledge, decrease decisional conflict, and increase the proportion of citizens being active in the decision-making process [16]. Several DAs have been developed for CRC screening [17-21]. These DAs must be self-administered, as the citizens receive the screening-kit by mail, obtain the sample at home, and mail it directly to the laboratory for analysis. In general, these DAs increase citizens' knowledge of CRC and CRC screening, enhance informed decision-making, and decrease decisional conflict [17,18,20,21]. However, the effect of the DAs on the participation rate is not conclusive [17-19,21].

An increasing amount of information from health authorities occurs via eHealth and mHealth (electronic- or mobile-based health) solutions. Email, text messages, and various Web

services are used to provide information and to communicate scheduled appointments, reminders, test results, etc. EHealth has the same effect on health care appointment attendance, screening uptake, and general well-being as the traditional conventional mailing system and telephone calls, but it is cheaper and faster [22,23].

Few DAs are also available in eHealth formats (Web pages, apps, etc) [24]. Web-based DAs have advantages in easy accessibility and the potential for broadened reach and regular updates. However, regardless of the format, the DA must be developed according to the targeted citizens' information needs [25]. Citizens with lower EA have diverse information needs [26], but few DAs have been specifically tailored to citizens with lower EA [17,27-29] and none have been developed, embracing diverse information needs in CRC screening.

The aim of this study was to develop and field test a Web-based, self-administered DA for FIT-based CRC screening, embracing diverse information needs tailored to 50- to 74-year-old citizens with lower EA.

Methods

The Danish Setting

The implementation of population-based CRC screening in the Danish health care system began in 2014, and it was fully implemented in 2018 from when eligible 50-74-year-old Danish citizens will be invited biennially to CRC screening using FIT. The invitation contains a screening kit for obtaining a fecal sample to be submitted directly to the laboratory for analysis. If a sample is not submitted within 6 weeks, a digital reminder is sent.

In Denmark, secure digital communication with authorities is mandatory [30], although disabled citizens can be exempt and continue to receive conventional mail [30]. In July 2017, 8.7% of the Danish population aged 45-74 years was exempt from digital communication [31]. Thus, CRC screening communication occurs mainly via secure digital mails, except for invitation letters containing a screening kit, and positive screening results that include an invitation to follow up colonoscopy and medication for bowel preparation.

Planning the Development

In the context of mandatory digital communication in Denmark, we chose to develop a digital DA, using the validated and internationally accepted framework proposed by Coulter et al [32], on the basis of the International Patient Decision Aid Standards (IPDAS) [33]. This framework describes the development process in 5 steps: (1) the scoping of the DA, (2) the formation of the steering group (preferably multidisciplinary), (3) the design phase, (4) alpha testing (user

testing), and (5) beta testing (field testing). This method also corresponds to previously proposed frameworks for the development of eHealth solutions of high reliability, usefulness, and quality [34].

Figure 1 depicts the development process for the DA (adapted from Coulter et al [32]). Steps 1 and 2 were carried out according to the framework. In the design phase (Step 3), a prototype of the DA was drafted, based on the citizens' information needs and preferred format, as described in a previous study, ranging from preferences to receive a clear recommendation with a minimum of information to desires for a detailed information and the opportunity to make a highly informed decision [26]. In that study, most participants agreed that information about CRC symptoms, benefits and harms of screening, and instructions to perform the FIT test were relevant information, and information should be presented in bullet points or as flowcharts, using absolute numbers. The DA should be accessible via the Internet. Information about colonoscopy, however, was requested only by those wanting detailed information [26]. In this study, the specification of the DA prototype adhered to the IPDAS instrument and checklist. It was based on the 4 domains of content: (1) providing information, (2) presenting probabilities, (3) including methods for values clarification and expression, and (4) recommending support [25,35]. Furthermore, as developed by Clerehan et al [36] and validated by Hirsh et al [37], the content was evaluated by using the 9 items of the evaluative linguistic framework: (1) generic structure, (2) rhetorical elements, (3) meta-discourse, (4) headings, (5) factual content, (6) technicality, (7) lexical density (average number of content words per clause), (8) writer and reader relationship, and (9) format. Throughout the development phase, texts were kept as short as possible while taking the information needs into account. The lexical density was assessed for the final DA, as described in the evaluative linguistic framework [36]. We chose to develop a Web-based DA, presenting information in steps, and thereby embracing diverse information preferences. The DA was an interactive Web page with no specific outcome or product.

Participants

Citizens with lower EA were residents of the Central Denmark Region aged 50-74 years. They were recruited for Steps 4-6 via an external professional recruitment company [38]. Lower EA is defined according to the United Nations Educational, Scientific, and Cultural Organization classification of basic education (ISCED 2011) Levels 1-2 [39], which is equivalent to less than 10 years of education in Denmark, corresponding to 24% of the population in the targeted age group [40]. The recruitment company recruited citizens from an existing panel of citizens who voluntarily signed up to receive regular Internet-based surveys on various health and nonhealth topics. The Internet skills of the participants were not measured, but skills at or above average were assumed, due to regular Internet-based survey activity. At recruitment, the citizens agreed to take part in either a focus group interview or in a telephone interview. The citizens who accepted to take part in the focus group or the review (Step 5) were told that they would

receive a gift (of value US\$ 80) as a token of the appreciation for their time. Furthermore, the travel expenses would be covered. Health care professionals were recruited via the professional network surrounding the Danish National CRC screening program in the Central Denmark Region. Both general practitioners (GPs) and colonoscopists with responsibilities for CRC screening were recruited.

Alpha and Beta Testing

For the first alpha testing (Step 4a), we conducted focus group interviews with citizens to evaluate the design and usability of the prototype DA. According to Coulter et al [32], this step should also evaluate comprehensibility; however, as the citizens' information needs and their preferred figure and chart representations were already described [26], we deferred this evaluation to Step 5. For the second alpha testing (Step 4b), we conducted email correspondence with citizens and health care professionals, exploring usability, acceptability, and design.

The review (Step 5), particularly focusing on content and readability, involved email correspondences with citizens and health care professionals not previously involved in the development process. Thus, we included more health care professionals and citizens in the development process than would have been the case with only the steering group conducting the review, as proposed by Coulter et al [32].

The beta testing (Step 6), including semistructured telephone interviews with citizens, examined feasibility, comprehensibility, and usability. No clinicians were involved in this step as the decision to take up CRC screening is usually made by citizens alone, without contacting health care professionals.

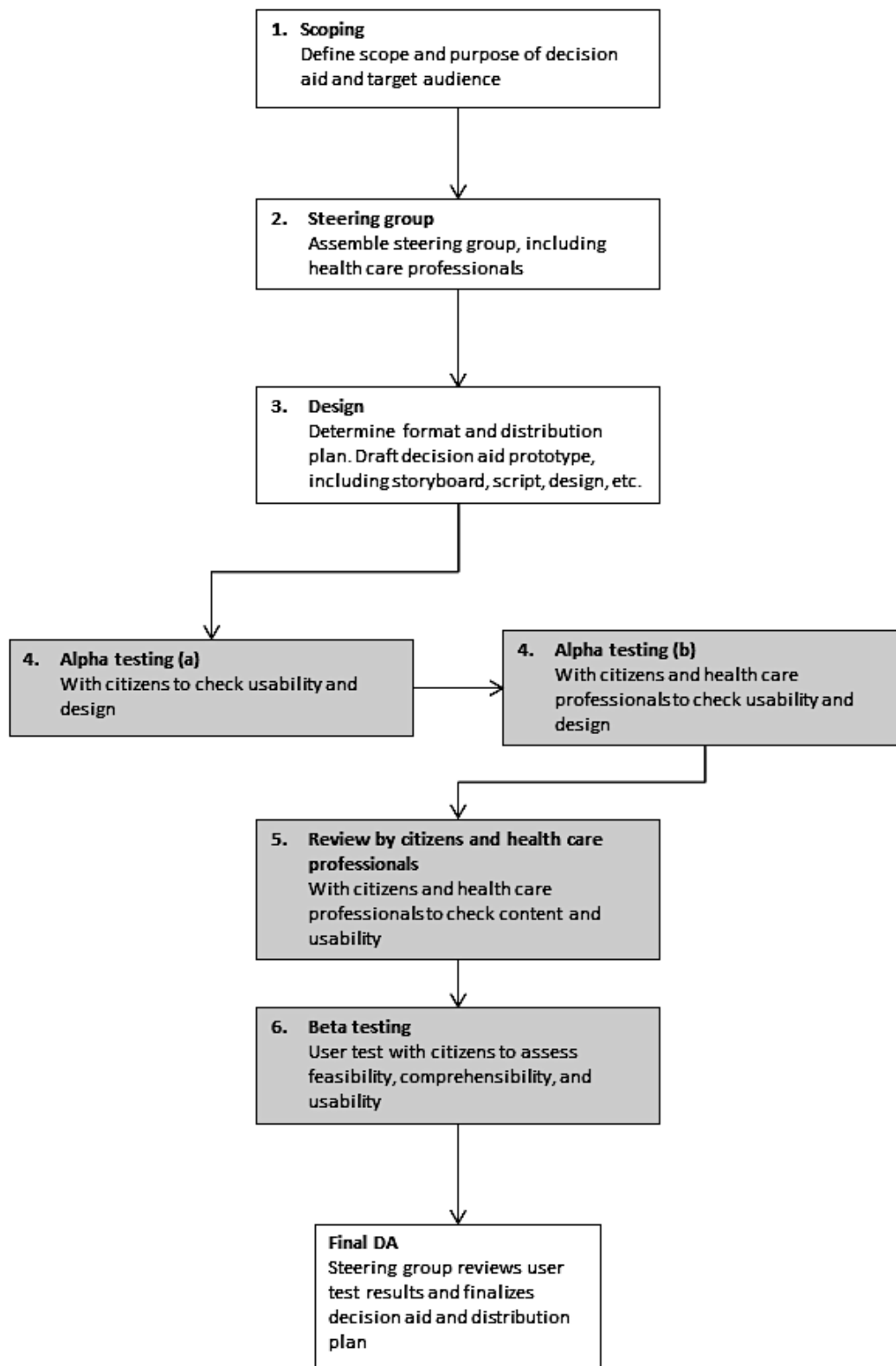
Data Collection

On the basis of the themes for the specific development steps, semistructured interview guides were developed ([Multimedia Appendices 1-4](#)). During the focus group interview (Step 4a), the citizens read the DA without any introduction. They were asked to think aloud about any immediate impressions of the DA. After this session, the semistructured interview guide ([Multimedia Appendix 1](#)) was used for a discussion of the DA. The first author (PG) and a coauthor (PK) were present, and both observed and made notes, which were later compared. In email correspondences (Steps 4b and 5), questions guiding the respondents to the focus of the evaluation were sent to the citizens and health care professionals ([Multimedia Appendices 2 and 3](#)). The telephone interviews (Step 6) were based on a semistructured interview guide as well. Both open-ended and categorical questions were asked in the telephone interviews ([Multimedia Appendix 4](#)).

Analysis

All data from meetings, email correspondences, and interviews were divided into specific datasets corresponding to each step of the development process. A thematic analysis was conducted for each dataset focusing on readability, usability, comprehensibility, and feasibility [41]. Data coding was done by the first author (PG) and subsequently discussed with the coauthors.

Figure 1. Framework for the decision aid development. Adapted from Coulter et al [32]. Gray boxes indicate involvement of a citizen or health care professional. DA: decision aid.



Results

Prototype (Step 3)

The development of the prototype was based on the IPDAS guideline and checklist as well as the evaluative linguistic

framework [25,35,36]. A simple and appealingly designed DA with only 3 different colors was developed by an external Web agency [42]. The texts were kept as short as possible with the font size 12. The information was presented in a plain language, with a minimum of medical terms used. A site map was provided in the left-side margin, and help options and contact information

were provided in the right-side margin. At the bottom of each page, a status bar showed a user's progress through the DA content (7 steps). There were 16 pages in total. On the first page, the purpose of the DA was explicitly stated, thereby also emphasizing the sender's role as informant and the reader's role as an active decision maker.

Each page consisted of a heading, a figure, and a values clarification question (Figure 2). A pop-up with additional information was accessible via a link in the figure. Furthermore, most pop-ups had a *read-more* option with detailed information. In this way, information was presented in steps, allowing the reader to read as much or as little as desired. The relevant subjects were presented in an intuitive order, and the function of each clause was underpinned as informative by writing in general terms, or as instructive by speaking directly to the reader (using singular personal pronouns).

Information in the DA was selected according to the IPDAS instrument dimensions (information, probabilities, values, decision guidance, development, evidence, disclosure, plain language, evaluation, and test), addressing all content dimensions. Development and evaluation are addressed in this paper [25]. Information was derived from both the Danish Colorectal Cancer Screening Database [43] (participation rates, positive FIT, etc), Statistics Denmark [44] (Central Denmark Region population of 50- to 74-year-old citizens), a systematic review [45] (general effect of CRC screening), and NORDCAN (CRC prevalence, incidence, and mortality) [46]. Two versions were developed, 1 for men and 1 for women, as incidence and mortality rates differ according to sex [46].

All estimates were presented in both natural frequencies and absolute risk formats, sometimes also in pictograms and charts (Figure 3). The DA encouraged reflection on facts by providing interactive pictograms, in which the proportions were to be guessed, immediately followed by a presentation of the correct proportion (Figure 4). The values clarification questions encouraged reflection at each step on personal values. On the last page, the DA provided a *choice indicator* with an arrow pointing toward "Want to participate", "Don't want to participate", or somewhere in between. Along with the indicator, a printable list was provided, presenting the answers given to the values clarification questions. The DA encouraged users to think about participation in screening and to talk to a doctor or relatives about the decision, if necessary.

Alpha Testing With Citizens (Step 4a)

A total 5 out of 6 citizens accepted to participate in the planned focus group, of whom 3 did not attend the meeting in November 2016 and the remaining 2 citizens evaluated the DA.

In general, the citizens appreciated the initiative:

Finally someone talks to us as citizens, instead of just talking to each other as experts. [Female citizen: 66 years]

They easily navigated around the pages and intuitively knew how to do this:

It's easy to press read more and to exit by clicking the X in the corner. [Female citizen: 66 years]

They found the DA useful and would recommend it to friends and family if it were available.

The design was accepted as appropriate:

I like the set-up, the design and the colors. Not too clinical, but not too frisky either – it's official looking, and appealing. [Male citizen: 71 years]

The interactive pictograms were, however, difficult to understand, and "Factual knowledge instead of guesswork" (female citizen: 66 years) was preferred.

These findings from Step 4a were discussed in the steering group and the pictograms were amended to be static and no longer interactive.

Alpha Testing With Health Care Professionals and Citizens (Step 4b)

In December 2016, the revised DA was sent to 2 health care professionals (a GP and a colonoscopist) and the 2 citizens from the citizen alpha testing (Step 4a). Usability and design were evaluated via emails.

In general, both citizens and health care professionals found the DA "extremely relevant" (colonoscopist). The citizens found the information "of suitable length...without it being too much" (male citizen: 71 years), whereas the health care professionals found that "the amount of text in the *read more* pop-ups seems large and could be difficult to understand for non-professionals" (colonoscopist).

Both citizens and health care professionals found the links that provided the pop-ups a little difficult to use, as the text stated to:

...click on the text...when in fact, it is the blue arrow you have to click on. [GP]

Following this feedback, the texts in the pop-ups were redrafted to a plainer language, preserving the content. Furthermore, both text and arrows were activated as links for the pop-ups.

Peer Review (Step 5)

For the peer review, 2 health care professionals (a GP—different from the one in Step 4b—and a nurse conducting colonoscopies related to screening) and 3 citizens were recruited. In December 2016, these 5 reviewers received an email containing a link to the DA, followed by telephone interviews.

Due to some technical difficulties, 1 citizen and 1 health care professional (nurse) could not review the DA.

The GP and the 2 remaining citizens approved the content. It is "good information material that is easy to understand" (female citizen: 66 years) and with "an appropriate amount of information" written in "a good readability index" (male citizen: 59 years). However, at some points, the text was felt to be on a "professional and technical level," and contained "a lot of numbers and estimates" (GP).

The citizens found the DA "intuitive to use" (female citizen: 66 years). They would "definitely use it" (male citizen: 59 years) and "recommend it to others" (female citizen: 66 years).

Figure 2. Page from the final decision aid.

Bowel cancer

Get information on bowel cancer by clicking on the text by the arrow

Answer the question below:
How do you feel about taking up screening, when you consider how many women will develop colorectal cancer?

I want to take up screening

I don't know if I want to take up screening

I don't want to take up screening

← Previous Next →

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

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Figure 3. Pop-up from the final decision aid.

Bowel cancer

X
Read more →

How many people are affected?

Bowel cancer is the third most common type of cancer in Denmark. Only lung cancer and breast cancer are more frequent.

The frequency of bowel cancer can be described in different ways.

About 230 women aged 50-74 years develop bowel cancer each year in the Central Denmark Region. This means that one in thirty women or 3 % will develop bowel cancer before they are 75 years old.

Each year about 80 women aged 50-74 years die from bowel cancer in the Central Denmark Region. This means that one in 100 women or 1 % will die from bowel cancer before they are 75 years old.

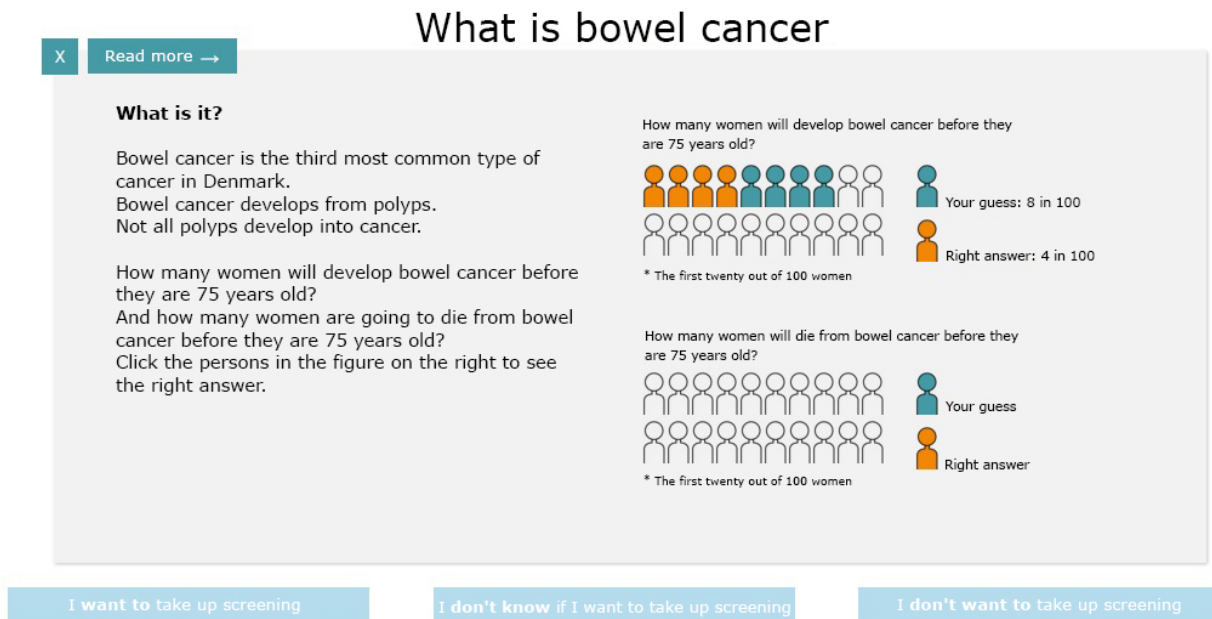
Three in 100 women will develop bowel cancer before they are 75 years old

One in 100 women will die from bowel cancer before they are 75 years old

← Previous Next →

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

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Figure 4. Interactive pictograms in prototype of decision aid.

Following this review, some passages in the pop-up texts were further revised to plain language and compatibility problems were resolved.

Beta Testing (Step 6)

For beta testing, 21 citizens were recruited, of whom 20 participated. This was followed by a telephone interview, examining feasibility, usability, and comprehensibility. The included citizens represented both citizens with lower EA opposed to screening and those who were proscreening. Furthermore, both citizens with limited computer skills and citizens with average or excellent computer skills, and higher and lower incomes, were represented. Different occupational status was also represented: full time occupation, citizens who were retired, including some with early retirements. Most citizens stated this information during the telephone interview (Multimedia Appendix 4). However, data were not systematically collected.

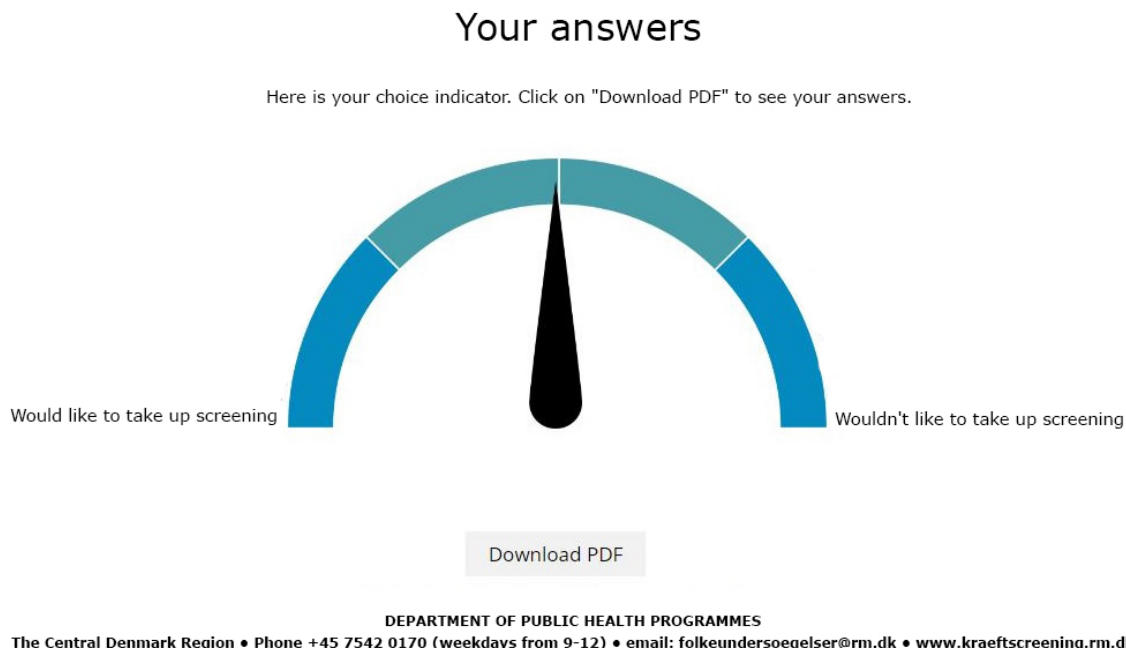
In general, the citizens appreciated the design; they found it appropriate with “light pages and nice and simple figures, manageable and formal” (female citizen: 58 years). The content was also appreciated, and they found the DA “easy to read and comprehend” (female citizen: 66 years). A few expressed that there was a “tendency for too much information, it can be confusing” (female citizen: 58 years), and “I’m afraid many people will skip great parts of this” (male citizen: 64 years).

Most citizens spent less than 15 min going through the DA, and agreed that a link in an email would be a feasible way to access the DA. The values clarification questions were regarded as useful: “They are fine, they make you think” (female: 57 years) and “they are easy to comprehend” (female: 60 years). Most people felt encouraged to think about benefits and harms while reading the DA. On the basis of this user testing, minor revisions were made, primarily proof reading of text and setting up the online domain and hosting for the DA.

Final Decision Aid

The final DA was an interactive Web page. It consisted of 7 steps (15 pages in total). Each page contained a values clarification question and a figure or chart with links to pop-up text (Figure 2). The lexical density is generally 1.5 to 2 in the spoken language and 3 to 6 in the written language [36]. For the pop-ups in the original (Danish) DA, the lexical density was 3.3 (ie, the lower end of the written language). Most pop-ups (Figure 3) had a *read more* function, with a lexical density of 4.2, which is medium for the written language. On the last page, citizens were presented with the choice indicator (Figure 5) and the opportunity to print out their answers to the values clarification questions. The DA is available (in Danish) by contacting the authors. (Figures 2-5 are English translations of the original versions.)

Figure 5. Choice indicator from the last page of the final decision aid.



Discussion

Principal Findings

We developed a self-administered DA for FIT-based CRC screening, embracing diverse information needs among citizens with lower EA. The initial prototype contained interactive elements (Figure 4), but these features were dismissed and removed in the final version. The remaining parts of the DA underwent minor revisions throughout the process, and citizens and health professionals accepted the design of the final DA as appropriate, official, and appealing. They appreciated the simplicity of the figures and the light colors. The content was considered relevant, and the citizens found it of suitable length without information overload. The health professionals, on the other hand, assessed it to be rather long and potentially difficult to understand for laypersons. The presentation of both absolute risks and natural frequency formats and the plain language were found comprehensible. Most citizens stated that they read only selected paragraphs of the DA. Most of them said that they would use the DA and recommend it to others.

Strengths and Limitations

We followed a predefined framework for the development as proposed by Coulter et al [32]. However, as the developed DA is a self-administered DA not intended to be used by health care professionals, no (beta) user testing was done with health care professionals. The diverse information needs in citizens with lower EA as described by Kirkegaard et al [26] prompted the presentation of information in steps. Furthermore, the stepwise development of the DA made it possible to include a wide range of citizens and health care professionals and to use different ways of communication. Email correspondences and telephone interviews were convenient for the citizens to comment on the DA. Email correspondence was chosen to provide as much liberty as possible for the responses of health care professionals and citizens. According to a previous research, asynchronous

email interviewing is an acceptable alternative to telephone interviews [47,48], also among citizens older than 65 years [49]. Email interviewing is cost-saving because less time is spent in participant transportation and data transcription. Furthermore, the email responses are often more deliberate and reflective in fewer words due to the respondents' opportunity to edit before pressing send. The anonymity adds to the strengths of email interviewing because personal or complex subjects are more easily discussed. However, email interviewing requires more explicit questions, and caution is required because no facial expressions or personal interactions are observed in these interviews [47,49]. The face-to-face meeting provided an opportunity to observe the citizens going through the DA, and the citizens supplemented each other in the subsequent conversation about the DA. The use of a framework and previous findings have ensured a DA truly aimed at the targeted population, containing the most relevant and accessible information.

The citizens in this study were recruited from an existing citizen panel. Hence, they are likely more accustomed to using the Internet and more engaged in surveys than the rest of the population. This should be taken into consideration when transferring the results of this study to the general lower EA population because the most disadvantaged citizens may be the ones who experience most difficulties using the DA. However, some citizens who stated that they did not think of themselves as Internet knowledgeable and citizens who stated that they had less favorable attitudes toward CRC screening were recruited. Hence, we feel that the diversity of the population was represented to some degree in the study population.

The fact that only 2 citizens took part in Step 4a (the face-to-face meeting, planned as a focus group interview) might have compromised the generalizability of the feedback given during the meeting [50]. However, we consider that this is balanced

by the comprehensive data collection opportunities in the following steps.

Technical problems were experienced during the alpha testing, and the citizens needed to start again with the DA several times. Both citizens in the face-to-face interview stated that they felt they had to hurry and would have spent longer reading it if they had been at home. Even though the content evaluation in this step might have been compromised somewhat, the technical problems helped us make technical adjustments, making the DA accessible from almost all types of electronic devices and Internet browsers.

Interpretation of Results

Health care professionals generally expected the citizens to find the DA long and more difficult to understand than was reported by the citizens. This may be due to several factors. First, previous studies have shown that doctors are poor judges of their patients' health beliefs [51] and priorities [52] when it comes to trade-offs over different treatment options. Second, the treatments doctors recommend for patients are often different from those they would choose if they were a patient, indicating that the counseling role is different from the patient role [53].

Citizens with lower EA often have lower levels of health literacy [54], and hence, they might experience difficulties reading and understanding health care information [15]. The length of the DA may, therefore, be at odds with its intended target audience of citizens with lower EA. The stepwise presentation of data in our DA may, however, have contributed to its readability and could explain why citizens in our study did not report information overload.

According to the IPDAS guidelines, DAs should have a values clarification exercise in some form [33]. In general, values clarification methods increase citizens' attention to benefits and harms, and they are considered useful [55]. However, in this Danish setting, the paper format of the values clarification exercise was considered inapplicable [26]. In this study, the citizens liked the exercises, indicating that the format of the exercises might influence the acceptance and usability of the values clarification methods.

The DA was distributed via email because most citizens are expected to use eHealth solutions, as digital communication is mandatory [30]. However, eHealth solutions are less commonly used by citizens with lower EA [56,57]. According to Norman et al [58], eHealth literacy is an important skill to use eHealth solutions; eHealth literacy is defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving

a health problem" [58]. EHealth literacy decreases with increasing age and with lower EA [59]. We sought to avoid exacerbating social inequality by using lay language and unique, easy to use Internet features in this newly developed DA.

A DA aims to give citizens enough information to make them feel they can make an informed choice about screening participation. This is important as CRC screening participation is a preference-sensitive choice [60]. Seeking to provide citizens with sufficient information, conventional information material contains detailed information about CRC and CRC screening. This might increase the existing social gradient in CRC screening because citizens with lower levels of health literacy are likely to read and understand these conventional information materials to a lesser degree [54]. For those citizens with lower EA who prefer a clear recommendation about screening rather than detailed information [26], there are questions about whether detailed information material is the best way of informing these citizens about CRC screening. However, citizens with preferences for detailed information should be able to access this. By providing information in a stepwise manner, we have sought to tailor the information to the needs of the individual citizen in the population, thereby potentially decreasing the social gradient in utilization of CRC screening information.

Implications for Practice

The development of this self-administered DA may prove to be a new method of communicating detailed information about CRC screening to citizens with lower EA, with built-in flexibility to avoid information overload. The effect of the DA on knowledge and screening attitudes in the population with lower EA remains to be investigated in a future effectiveness study, the LEAD trial (P Gabel, MD, unpublished data, April 2018). The DA will be provided to citizens as a link in a digital mail sent by a conventional mail to citizens who are exempt from digital communication. Hence, all eligible citizens will receive the link, regardless of their Internet accessibility or skills. Subject to such evaluation, this DA might guide decisions when developing information material for citizens with lower EA in other screening programs.

Conclusions

The development of this DA identified the needs and preferences of citizens with lower EA regarding the level and amount of content in an eHealth solution for decision making about participation in CRC screening. The DA appeared acceptable and accessible for citizens with lower EA, enabling citizens to reflect on the benefits and harms of CRC screening to decide about screening participation.

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Authors' Contributions

All authors contributed to the designing of the study. PG and PK led the focus group interview, and PG conducted all telephone interviews and email correspondences. PG managed the thematic analyses, supervised by PK and AE. PG wrote the first draft of the manuscript, and all authors have contributed to this subsequently. The final manuscript has been approved by all authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Step 4a interview guide.

[[PDF File \(Adobe PDF File\), 40KB - formative_v2i1e9_app1.pdf](#)]

Multimedia Appendix 2

Step 4b interview guide.

[[PDF File \(Adobe PDF File\), 27KB - formative_v2i1e9_app2.pdf](#)]

Multimedia Appendix 3

Step 5 interview guide.

[[PDF File \(Adobe PDF File\), 33KB - formative_v2i1e9_app3.pdf](#)]

Multimedia Appendix 4

Step 6 interview guide.

[[PDF File \(Adobe PDF File\), 39KB - formative_v2i1e9_app4.pdf](#)]

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Abbreviations

CRC: colorectal cancer

DA: decision aid

EA: educational attainment

FIT: fecal immunochemical test

gFOBT: guaiac fecal occult blood test

GP: general practitioner

IPDAS: International Patient Decision Aid Standard

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Original Paper

A Multimedia Support Skills Intervention for Female Partners of Male Smokeless Tobacco Users: Use and Perceived Acceptability

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Abstract

Background: UCare is a new multimedia (website+booklet) intervention for women who want their male partner to quit their use of smokeless tobacco. The intervention is based on research showing that perceived partner responsiveness to social support is highest when the supporter conveys respect, understanding, and caring in their actions. The website included both didactic and interactive features, with optional video components, and special activities to help women develop empathy for nicotine addiction. The booklet reinforced the website content, encouraged women to use the website, and served both as a physical reminder of the intervention and a convenient way to share the information with her partner.

Objective: The objective of this study was to describe the utilization and acceptability of a multimedia intervention among women seeking to support their partner in quitting smokeless tobacco. Lessons learned with respect to design considerations for online interventions are also summarized.

Methods: We present the evaluation of the intervention components' use and usefulness in a randomized trial.

Results: In the randomized clinical trial, more than 250,000 visits were made to the website in a 2-year period, with the vast majority from mobile devices. Of the 552 women randomized to receive the intervention, 96.9% (535/552) visited the website at least once, and 30.8% (170/552) completed the core website component, "The Basics." About half of the women (287/552) used the interactive "Take Notes" feature, and 37% (204/552) used the checklists. Few women used the post-Basics features. At 6 weeks, 40.7% (116/285) reported reading the printed and mailed booklet. Website and booklet use were uncorrelated. User ratings for the website and booklet were positive overall.

Conclusions: Intervention website designers should consider that many users will access the program only once or twice, and many will not complete it. It is also important to distinguish between core and supplemental features and to consider whether the primary purpose is training or support. Furthermore, printed materials still have value.

Trial Registration: ClinicalTrials.gov NCT01885221; <https://clinicaltrials.gov/ct2/show/NCT01885221> (Archived by WebCite at <http://www.webcitation.org/6zdIgGGtx>)

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KEYWORDS

tobacco cessation; social support; multimedia; website design; website development; website use assessment; usability testing

Introduction

Background

Approximately 8.2 million Americans regularly use smokeless tobacco (ST), which increases their risk of head and neck

cancers [1], as well as cardiovascular and cerebrovascular mortality [2,3]. The vast majority of ST users are males; 4.8% of males and 0.3% of females use ST "every day" or "some days" [4]. ST use is highly addictive [1], and few resources exist to help users quit. As a novel approach toward facilitating ST

users' cessation, we developed an intervention targeting male ST users' wives and female domestic partners to help motivate their partners to quit and support them during quit attempts. We found in our previous research [5-9] that that women were enthusiastic about the prospect of helping their partners quit their use of ST.

With support from the National Institute on Drug Abuse (NIDA, grant 1R01DA033422), we developed an intervention for women based on a framework of perceived partner responsiveness [10], indicating that support is best received when it conveys respect, understanding, and caring. We named the intervention with an acronym for these themes: UCare. We then conducted a randomized clinical trial (RCT), enrolling 1145 women in 15 months using Facebook advertising [11], randomizing 552 women to the intervention condition and the rest to Delayed Treatment Control. We administered online assessments at baseline and at 6 weeks and 7.5 months postenrollment.

In this paper, we present data on the use and perceived acceptability of the intervention features. We then discuss the lessons learned from this process and their applicability to future eHealth intervention design.

Intervention Content: UCare Website and Booklet

The UCare intervention is a multimedia program, featuring both an interactive, mobile-optimized website and a printed booklet. The multimedia approach has several benefits: 1) the intervention fits a variety of preferences for accessing information (audio, text, etc); 2) the mobile-optimized website is easily accessible from anywhere at any time; 3) the booklet provides the women with material she can easily show her partner to reassure him that the program is not focused on trying to "make him" quit; and 4) the public health approach is cost-effective and sustainable over time. The website also offers the opportunity to track intervention use, whereas data on use of the booklet relies on the users' self-report.

Intervention Structure

The UCare website provided a concise instructional program ("The Basics"), with options for personal tailoring and printable lists of decisions and chosen activities ("My Notebook"), supplemented with ST cessation resources ("Quitting Resources"), social support forums, and email reminders to remain engaged with the program. Figure 1 provides an overview of the intervention.

Website Content

The Basics

The core of the intervention was a four-module linear website component that we called "The Basics." We designed the first three modules to teach users about the three main stages of quitting (planning, quitting, and maintenance), and the fourth module helped the user create a plan for how to approach her partner about quitting. Within each section, we presented information sequentially, starting first with how to convey respect at that stage, followed by how to convey understanding, followed by how to convey caring (see Figure 2). Progress through "The Basics" was linear ("tunnel" architecture, such that each page could be accessed only after completing the previous page), but once a page had been visited, it could be accessed directly from the menu thereafter (random access). The website software system tracked each user's progress through "The Basics" so that she would automatically return to the furthest page she'd reached when she next logged in. Each Basics section was color-coded, with each color indicating the respective responsiveness theme (respect, care, and understanding), to allow for easy discrimination between sections. A fourth theme was self-care, including stress reduction for the caregiver, as stress management and patience have been found to be key to providing support to others in many contexts [12-14].

Figure 1. UCare intervention schematic.

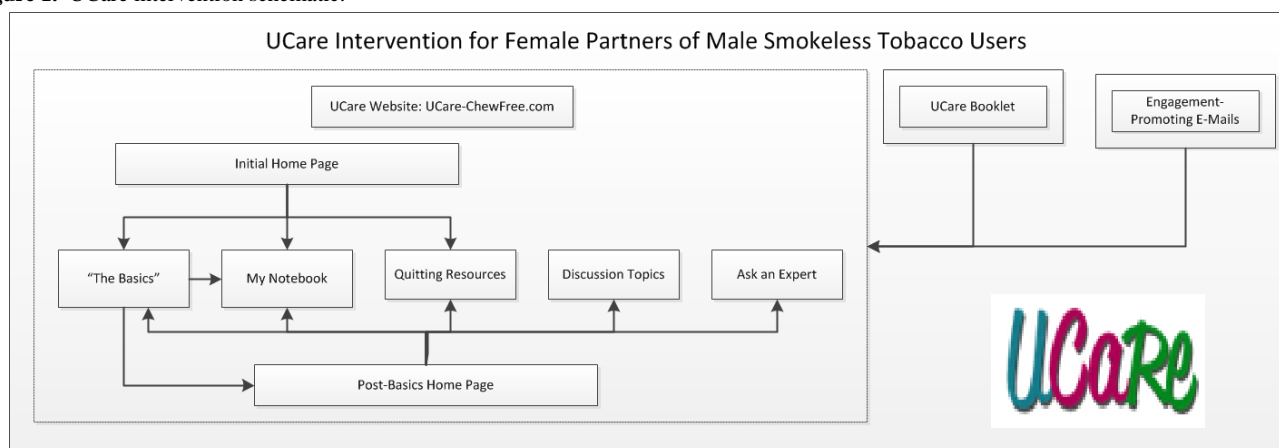
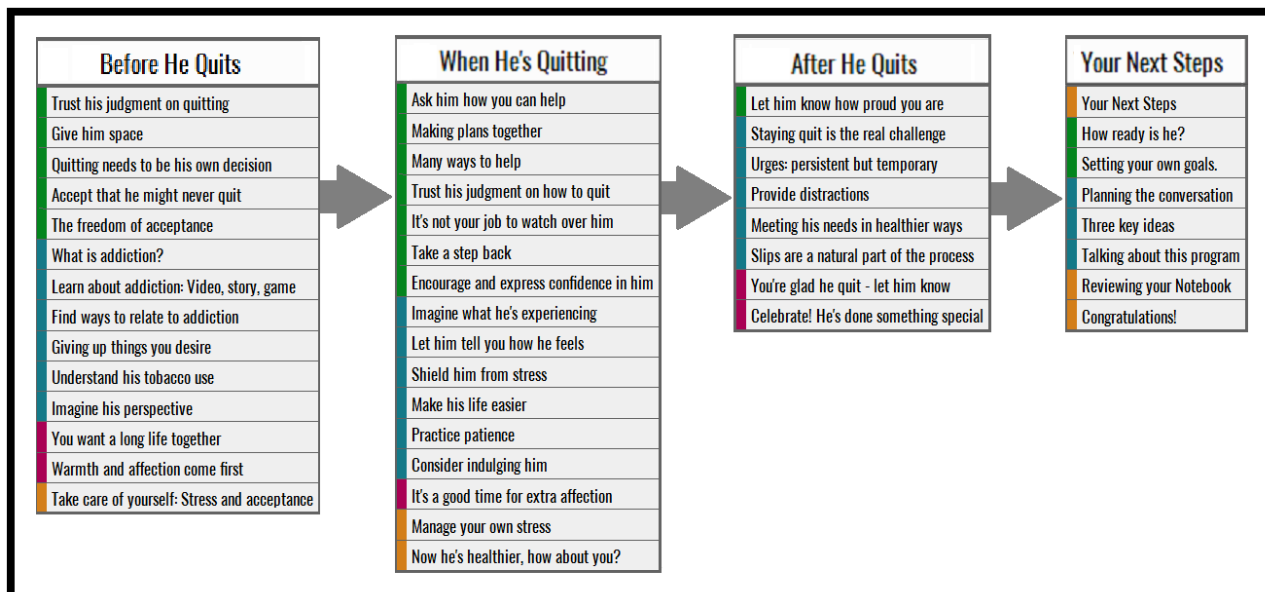


Figure 2. Structure of the UCare “Basics.”



Most of the 46 pages in “The Basics” were either text plus a stock image (31 pages) or testimonials (10 pages); see Figure 3. Each testimonial page included 3 quotes from women, each associated with a photograph of a woman, with the text crafted from formative interviews (see Multimedia Appendix 1, Figure A-1). Users could click an audio link to hear the quote in the woman’s voice. Video clips were not used because they would require more bandwidth and be less compatible with mobile phone use of the program.

“Learn About Addiction” Features

Previous formative work [15] suggested that women often experience difficulty in understanding addiction. We used three approaches to teach women what addiction is and what it is like: a didactic approach (presenting scientific information), a narrative immersion approach, and an experiential approach. One Basics page provided links to three special features using these approaches. A “Nicotine in the Brain” video featured a 41-second animation, with accompanying text matching the animation audio, as a didactic approach to explaining addiction (Multimedia Appendix 1, Figure A-2). The video was inspired by a short video developed by the Mayo Clinic. “Megan’s Morning” (Multimedia Appendix 1, Figure A-3) was a 1200-word fictional story in text and audio formats about the experiences of a woman trying to quit smoking (third grade reading level). This story, written for the website by award-winning author Nina Kiriki Hoffman, provided a narrative immersion approach to help the reader or listener empathize with the quitting process. To provide an experiential approach to conveying the challenge of addiction, “The CONCENTRATE Game” (Multimedia Appendix 1, Figure A-4) illustrated the disruptions to concentration that nicotine cravings can cause and the effect of tobacco on alleviating the cravings while reinforcing addiction. Playing a game involving perspective-taking has been shown to build empathy in other contexts [16]. The project team extensively tested the special features for their functionality across a wide variety of platforms.

My Notebook

Retention and use of intervention information has been shown to be greatest when the user can personalize their experience and create their own plan for using the information [17,18]. Furthermore, meta-analyses have found that goal-setting and action planning via internet interventions are associated with behavior change [19]. The “My Notebook” feature, accessible from the Main Menu, was an interactive tool allowing the user to create and print her own supporter plan, organized into 2 pages, “Things to Remember” and “Things to Do.” “Things to Remember” was populated by choices made throughout “The Basics,” as most pages (both text and testimonials) included a “Take Notes” feature allowing her to save key points from the program (her choice of presupplied notes and her own text entries). “Things to Do” was created from 4 interactive checklists in “The Basics” (see Multimedia Appendix 1, Figures A-5 and A-6), with ideas for managing stress, setting goals the participant could achieve without the ST user’s participation, and working with her partner to plan how she could best support him if he decided to try to quit (see Multimedia Appendix 1, Figure A-2)

Quitting Resources

We provided a main menu link to 16 pages of quitting information for women who wanted more information about addiction and the quitting process. Pages in this section describe smokeless tobacco and its contents, explain how nicotine addiction works, describe the quitting process, present information on how to access quitlines and the ChewFree.com ST cessation program, and describe quitting aids for ST users.

Discussion Topics

Based on our experiences with ST users, we anticipated that long-term engagement with the intervention would be desirable and helpful for this population, and we wanted to give the women the opportunity to develop a mutually supportive community. This type of asynchronous mediated peer-to-peer communication has been associated with relatively more

effective eHealth interventions [20]. We also wanted to be able to add new content to the website if users identified needs we had not anticipated. For these reasons, we created a section of Discussion Topics, which included text explaining a topic (eg, how to quit tobacco with your partner, how to talk to your children about their father's quit attempt, how to broach the topic of quitting with your partner), and then a threaded comments section (see [Multimedia Appendix 1](#), Figure A-7). New Topics were added with an email announcement and a direct link to that page. A "Suggest a Topic" button allowed users to propose ideas for new "Discussion Topics."

"Ask an Expert" Forum

This feature provided users with the opportunity to ask questions of our staff, either about providing support or quitting ST.

Marketing Page and Enrollment Process

We created the study homepage with two functions: marketing information explaining the study to new visitors and a login option for registered users (see [Figure 4](#)). Women who registered

with the study and were randomized to intervention began their use of the UCare website with an animated tour of the main menu and website functions which invited them to begin "The Basics." They received up to 8 reminders to finish "The Basics" and notices of new "Discussion Topics."

Booklet Content

We adapted our existing supporter booklet, developed in a previous pilot study (National Cancer Institute; NCI 1R21CA131461), to better match the themes, content, and graphics of the website. Three goals for the booklet were to summarize the essence of the intervention content (focusing on realistic goal-setting depending on her partner's readiness to quit and providing quick lists of support do's and don'ts); to provide a means for the women to show their partner what the UCare program is about and to allay any concern on his part that the intervention might be coercive; and to encourage the women to use the website. The booklet gives an overview of the three responsiveness themes and numerous examples of how to use them in conversations.

Figure 3. UCare Basics sample text page.

RESPECT UNDERSTANDING CARE

UCare

HELPING YOU SUPPORT YOUR PARTNER WHEN HE'S READY TO QUIT SNUFF OR CHEW

Home Basics Discussions Notebook Quitting Resources Ask an Expert

Before He Quits

SHOW RESPECT

Trust his judgment about what's best for him.

From your perspective, your husband/partner's use of smokeless is not a good thing. You're probably concerned about his health, and you may not like the snuff or dip itself. Maybe your partner agrees with you, and he's ready to quit. Maybe he just loves the stuff and wants to keep using it forever. Or maybe he's somewhere in between.

Whichever of these is true for you, **the most important thing is to respect and trust him** on this issue. Quitting smokeless can be difficult unless it's something he really wants to do.

Take Notes

Mark the points that seem useful to save in your Notebook, and add your own.

- Your partner may already want to quit, or he may never want to quit.
- Most people can't quit tobacco unless it's something they really want to do.
-

Next >


Did You Know?

Two-thirds of women whose partners have quit smokeless report that quitting was his decision, and half of these women say they had to stop nagging him about quitting.

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Figure 4. UCare home and marketing page.



HELPING YOU SUPPORT YOUR PARTNER WHEN HE'S READY TO QUIT SNUFF OR CHEW

Welcome to UCare

He chews. You wish he'd quit.

Maybe you've already told him how you feel, and you're frustrated that he doesn't want to quit. Or maybe he's tried to quit, but it was too hard.

Email:

Password:

Forgot your password? [Log In](#)

The UCare research study is for women like you!

...women married to (or living with) a man who uses smokeless tobacco. **The UCare program can help you talk to your husband about his smokeless use and become a more effective supporter** if he decides to quit.

If you sign up with UCare, you'll get access to a proven quitting program for smokeless tobacco users. You'll also learn

- how to find out if your husband is ready to quit
- what to do if he isn't ready
- the best ways to quit smokeless
- why quitting smokeless is so difficult
- things you can do to make quitting easier
- ways to reduce your frustration and improve your relationship, whether or not he quits tobacco

Sign up now!


You don't need your husband's permission to sign up, and he doesn't have to be interested in quitting. **This program is for you.**

We'll ask you to complete some surveys later, so we can learn how well the program worked for you. That's it.

Our research team has many years of experience in helping people quit smokeless tobacco. Join the hundreds of women who have already helped their partners!

Sign Up Today

I love that this is available to help women now!



"I think you have done a fantastic job providing the necessary information and resources to help people support their partners in the process of quitting the addiction of tobacco."

"I like the fact that you reinforce that it is the partner/spouse's choice to quit. I fought with mine for so long, and we could have avoided a lot of tension if I'd had this information sooner. I love that this is available to help women now!"

The UCare study is a project of the Oregon Research Institute (ORI) and sponsored by the National Institute on Drug Abuse (NIDA).

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Formative Testing and Refinement

Throughout the formative testing, participants were primarily drawn from a pool of female partners of ST users who had participated in our previous research. For the overall pool,

demographics were similar to the target population: the women were 94.5% (493/522) white, with 85.3% (436/522) attending some college or greater and 34.4% (180/522) having earned at least a bachelor's degree, and with a mean age of 43.9 years (SD 7.4 years). First, 49 women reviewed initial webpage

designs, then 17 women provided feedback on the “Learn About Addiction” features; based on their feedback we added an audio track for the story.

We then conducted in-person usability testing with a new sample of 12 women from the local area who had been in a long-term relationship with a male ST user. Each individual testing session involved the user sitting with a research assistant and using each of the website features, while “thinking out loud” as they made their choices. We made minor text changes and a few tweaks to the graphics based on their feedback.

Finally, 70 women signed up to beta test the website, and within 2 weeks, 46 of the women completed the 2- to 3-hour beta testing process. This involved going through the UCare enrollment process and creating an account, reading all of “The Basics” and any other website content of interest, making at least 1 post each on a “Discussion Topic” and in the “Ask an Expert” forum (seeding these features in an attempt to create a norm for their use among RCT participants), reading the printed booklet (which we mailed to them), and completing an online follow-up survey giving their reactions to each of the intervention components.

To assess the beta testers’ experiences with the website and booklet, we administered a user satisfaction measure with items adapted from Brooke’s [21] widely used and validated System Usability Scale [22]. Items in the measure were generally in 5-point Likert-scale format. The measure asked users to rate the website overall (eg, ease of use, helpfulness, desire to keep using, willingness to recommend to others), specific website components, and the acceptability and ease of use of the booklet. It also included open-ended questions about potential improvements to the website and booklet, especially to streamline the enrollment process and to include the website URL in the booklet.

Randomized Trial: Assessment of Program Use and Acceptability

Enrollment for the RCT took place between July 2015 and December 2016. Inclusion criteria for the RCT were (a) being the wife or female domestic partner (living together) of a male currently using ST; (b) being interested in having him quit; (c) willing to provide a phone number, mailing address, and email address; (d) and willing to give informed consent. Additionally, the woman and ST user were (e) both US or Canadian residents aged 18 years or older, (f) both able to read English, and (g) both able to access a computer.

The women’s mean age was 43.2 years (SD 9.5) and the sample was 95.3% white (1081/1145), 96.3% non-Hispanic (1100/1142), and 87.8% (1001/1140) having completed some college; 25.6% (293/1145) of the women had ever used tobacco; the mean length of the relationship between the participant and the ST user (her husband or domestic partner) was 15.6 years (SD 10.3). The female participants were racially and ethnically similar to ST users but likely better educated (Cheng and colleagues [23] report 53.1% of ST users with some college education).

During the RCT, we unobtrusively tracked participants’ use of the website, recording all page hits and all choices made within

the website, using standard methods that created a time-stamped archive of each user’s activities. An “admin site” with a user-friendly interface allowed the research staff to find contact information, assessment tracking information, and site use details for each participant. Information such as how many pages the user had visited was available both through the admin site and in a downloadable Excel spreadsheet.

Participants were asked to complete follow-up assessments at 6 weeks and 7.5 months postenrollment. We assessed perceived acceptability of the program components (and self-reported use of the booklet) at 6-week follow-up, using the measure that had been used with the beta testers. Women randomized to Delayed Treatment received access to the intervention after completing the 7.5-month follow-up.

Results

Website Use

Upon enrolling, women randomized to the intervention were immediately given access to the website, and almost all of the women eventually visited the website at least once (96.9%). Over the course of the 2-year RCT, more than 250,000 visits were made to the website, and 74.9% (190,968/254,915) of visits were from smartphones, 9.7% (24,728/254,915) from phone-tablets, or “phablets,” 8.5% (21,739/254,915) from tablets, and only 1.9% from desktops (4895/254,915), with 4.8% (112,297/254,915) from unidentifiable devices.

Table 1 shows the rate of intervention component use. Basics completion patterns were associated with the weekly reminder email—almost one-third of women (31.5%) who completed “The Basics” after their enrollment day did so on a day when they had received such an email, and the email with the “UCare final reminder” header (at 8 weeks after the last website visit) was especially effective at getting women to complete “The Basics.”

By the 6-week follow-up, 45.8% of the women used the “Take Notes” feature to populate “My Notebook” with “Things to Remember,” and 30.8% used the checklists within “The Basics” to choose “Things to Do.” These rates increased to 52.0% and 37.0% by the 7.5-month follow-up.

The three “Learn About Addiction” features each required the user’s choice to access them. The CONCENTRATE game was the most popular of these features; 24.3% of the women used it by 6-week follow-up. The game functions differently depending on whether the user clicks the “take a dip” feature or does not, and women were encouraged to try it both ways; 38.8% of those who tried it did so. By 6-week follow-up, 16.7% of the women watched the video, and 12.5% of the women accessed the “Megan’s Morning” story; for those accessing the story, 81% (111/137) chose to listen (the default), 12% (17/137) chose to read, and 7% (9/137) chose to listen while reading. Use of the three Learn About Addiction features was highly correlated (viewing the video and reading the story, $r=.72$; viewing the video and playing the game, $r=.54$, and reading the story and playing the game, $r=.50$).

Table 1. Use of UCare intervention components (N=552) and usability ratings (1-5).

Intervention component	Component usage, n (%)		P value ^a	Usability rating at 6-week follow-up, mean (SD)	Usability rating, n (%)
	By 6-week follow-up	By 7.5-month follow-up			
UCare website (any use)	529 (95.8)	535 (96.9)	N/A ^b	3.79 (.89)	259 (46.9)
The Basics (any use)	346 (62.7)	387 (70.1)	<.001	3.98 (.78)	217 (39.3)
The Basics (completion; 46 pages)	105 (19.0)	170 (30.8)	<.001	4.28 (.61)	94 (17.0)
Notebook entries (Take Notes)	253 (45.8)	287 (52.0)	<.001	3.58 (.86) ^c	170 (30.8)
Notebook entries (Checklist Choices)	170 (30.8)	204 (37.0)	<.001	3.58 (.86) ^c	170 (30.8)
"Nicotine in the Brain" video	92 (16.7)	98 (17.8)	.01	3.85 (.87) ^c	62 (11.2)
"Megan's Morning" fictional story	64 (12.5)	68 (13.2)	.045	3.49 (1.12) ^c	49 (8.9)
CONCENTRATE Game	134 (24.3)	146 (26.4)	.001	3.46 (1.18)	97 (17.6)
Basics testimonial audio (default printed text)	60 (10.9)	69 (12.5)	.003	N/A	N/A
Quitting Resources	56 (10.1)	96 (17.4)	<.001	4.06 (.08)	49 (8.9)
Post-Basics Discussion Topics	36 (6.5)	80 (14.5)	<.001	3.87 (.92)	31 (5.6)
Post-Basics Ask an Expert	5 (0.9)	17 (3.1)	.001	4.20 (.84)	5 (0.9)
UCare printed booklet (self-report at 6-week follow-up)	116 (40.7)	N/A	N/A	3.89 (.78)	252 (45.7)

^aPairwise *t* tests between 6 weeks vs 7.5 months.

^bN/A: not applicable.

^cRatings for the three Learn About Addiction features are the mean of two items: how much did the feature help you understand addiction and how much did it help you understand how hard it is to quit.

Table 2. Co-use of website "Basics" and printed booklet by 6-week follow-up.

Basics use	Self-Reported booklet use				Total
	"None"	"Some" or "Most"	"All" or "More Than Once"	Unknown ^a	
None (0-1 pages)	10	37	33	160	240
Some (2-45 pages)	14	63	37	96	210
Basics (all 46 pages)	9	36	46	11	102
Total	33	136	116	267	552

^aCombines participants randomized to the intervention who did not complete the 6-week follow-up assessment and those who skipped that item while completing that assessment.

Completing "The Basics" typically takes 20-40 minutes, and for many women, this was all they did with the website. Very few read all of the Quitting Resources pages. Although 60.2% (332/552) of women returned to the UCare website after completing "The Basics," use of the post-Basics features was very low. Only 1 woman made a comment on the Discussion Topics, none suggested new topics, and none made posts to Ask an Expert.

In the 6-week follow-up survey, 40.7% (116/285) of respondents reported that they had read all of the UCare booklet at least once. Booklet use was not asked about in the 7.5-month survey. [Table 2](#) compares self-reported use of the booklet with automatically tracked use of "The Basics."

Chi-squares and paired *t* tests indicated that use of every website component was significantly greater by 7.5-month follow-up than by 6-week follow-up. This finding applied both to whether

the component had been used (yes or no) and how many times it had been used (eg, pages of a section read, notebook entries made, times video viewed, times game played).

Understanding Use of Intervention Features

For the purpose of understanding use of the various aspects of the intervention, we used factor analysis to reduce 12 website use variables to a more manageable number. Using principal components analysis with varimax rotation, we identified three factors. Variables which loaded >.34 on the relevant factor were considered indicators of that factor. The factors were: Interactive Engagement (overall website engagement and use of the interactive features; 6 items), Audio Preference (use of the optional audio features; 3 items), and Thoroughness (use of the Quitting Resources and post-Basics features; 3 items—see [Table 3](#)). We created scales through standardizing the variables that loaded on each factor and summing them.

Table 3. Factor loadings of website exposure variables by 6-week follow-up (principal components analysis). Factor loadings >.340 are indicated in italics.

Website exposure variable	Factor 1: Interactive Engagement	Factor 2: Audio Preference	Factor 3: Thoroughness
Number of Notebook entries	<i>.907</i>	.121	.121
Number of Checklist Choices	.885	.023	.084
Basics pages completed	.829	.170	.321
Total minutes engaged in website	<i>.663</i>	<i>.406</i>	.311
Total visits	<i>.519</i>	.220	<i>.507</i>
Times played CONCENTRATE Game	<i>.426</i>	<i>.348</i>	-.382
Times viewed brain video	.136	<i>.818</i>	.088
Times listened to/read "Megan's Morning"	.141	<i>.804</i>	-.038
Number of testimonial audio feature uses	.048	<i>.536</i>	.006
Quitting Resources visited	.013	.270	.728
Discussion Topics read	<i>.379</i>	-.085	<i>.521</i>
Expert forum threads read	.137	-.095	<i>.387</i>

The scale measuring Interactive Engagement was moderately correlated with Audio Preference ($r=.304$, $P<.001$) and with Thoroughness ($r=.372$, $P<.001$). The correlation between Audio Preference and Thoroughness ($r=.061$) was not significant, and none of the website exposure scales was correlated with the use of the printed booklet.

We then predicted each of the three scales along with booklet use from baseline variables for the RCT participants. "Interactive Engagement" was more common for the women with younger partners (standardized $\beta=-.142$, $P=.02$). "Thoroughness" was more common for women who were white (standardized $\beta=.132$, $P=.03$) and for women whose partner was not White (standardized $\beta=-.208$, $P=.001$). "Audio Preference" and use of the printed booklet were not correlated with baseline variables.

Program Perceived Acceptability

At 6 weeks, 297 (53.8%) of women randomized to the intervention completed a follow-up assessment that included measures of consumer satisfaction with intervention components. For the website components, the calculations of mean satisfaction ratings, shown in Table 1, were limited to those women whose use of the rated components was verified by website tracking. For the booklet, the mean satisfaction rating was limited to the women who had reported at least some use of the booklet by 6-week follow-up. All components were rated as "somewhat helpful" or better, and the website and booklet were rated as "helpful" overall.

Discussion

Principal Findings

The UCare intervention is a multimedia program for women who want their male partner to quit his use of smokeless tobacco. Both online and print components had value. Some women used both, and others used the medium they preferred. The program accommodated different personal preferences for text vs audio; it also accommodated bandwidth limitations by

using text-plus-audio rather than video to present interview content. Website and booklet use were uncorrelated (but note that only a third of the women randomized to the intervention provided booklet usage data). Participants generally rated all of the intervention components favorably.

Our experiences in developing the program yielded several findings that may benefit others who are developing eHealth interventions. First, changing trends in how people access websites must be taken into account. More than 90% of visits to our website were made via mobile devices; optimizing websites for mobile device use is vital.

Second, it is important to take into account that many users will access the intervention only once or twice and will not complete the intervention as it is intended. On average, our participants spent only 16 minutes on the website within 6 weeks of enrollment, whereas our core program takes 20-40 minutes to complete. If it is likely or plausible that many users will engage with the intervention only once, the most important information and key takeaway message should be presented early in the program. Throughout our website, booklet, and follow-up emails, we emphasized the value of completing "The Basics," but only some 30% (170/552) of participants randomized to intervention did so.

Further, many women were not ready to use the intervention when they signed up for the study, and many women continued to access the intervention well after the initial 6-week period. Use of all intervention components was significantly higher at 7.5-month follow-up than at 6-week follow-up. This finding is relevant for at least two reasons: prompts designed to increase engagement (eg, emails) should continue past the initial use period, and assessments of exposure-related outcomes should be timed accordingly.

It is also critical to distinguish the core program from "extra" features, and to maximize users' exposure to the core message. Intervention designers should consider using "tunnel" architecture to force users through the core program in its intended order, but make the pages directly accessible after their

initial viewing for ease of use. The core program can then be supplemented as needed. For example, although our “Learn About Addiction” features were embedded in the core part of the program, they were optional and many skipped them. Likewise, few used the “Quitting Resources,” but the information could be readily accessed later, and many returned to read them.

Because our program consisted of many different components and activities, we were unable to discern which parts of the intervention contributed to program efficacy. Future studies could address this problem by using the Multiphase Optimization Strategy (MOST) developed by Collins et al [24-26] to refine potential intervention components in a preliminary trial prior to inclusion in the final program. Members of our team have used this approach successfully in other studies [27,28]. Strecher et al used this approach in developing a Web-based smoking cessation program for smokers ready to quit at two health maintenance organizations (HMOs) [29], and McClure and colleagues used MOST to explore components for new websites at the same HMOs, for smokers at any stage of readiness [30-32]. These studies tested specific program components for preliminary efficacy with their intended population prior to conducting a randomized efficacy trial of the overall program.

At the outset, intervention designers should consider whether their primary purpose is to provide training or support. If the former, users should be expected to visit only once or twice, and a core training module may be all that is needed. However, for lifestyle changes, ongoing engagement with the intervention may be desirable to produce a dose-response relationship [33]. In this case, the intervention information may be supplemented by creating a community for peer support and an opportunity to ask questions of experts. These features were popular in our ChewFree.com cessation program for ST users [34], but the UCare participants didn’t find them helpful and generally ignored them. Not only were these features apparently unwanted by the users, but they also represented a potential ongoing cost to our staff in terms of monitoring, maintenance, and crafting “expert” responses. It may have been easier for these women to find the peer support they needed among their friends and on social media than it had been for the ChewFree.com users, or they may have felt that the information in “The Basics” was

all they needed. For this population, we could have omitted the “Discussion Topics” and “Ask an Expert” features. Other options would have included incorporating the information from the “Discussion Topics” into “The Basics.” Conversely, if we believed that adding new information throughout the study was important, we could have allowed users to access the post-Basics content (and potential community) from the beginning. We recommend that others weigh these features carefully when designing their own interventions.

Finally, eHealth intervention designers should consider whether the need they are addressing is an urgent one, such that participants will immediately make use of the program, or whether participants are more likely to wait for a convenient time. When an intervention is delivered soon after enrollment (eg, in-person or through phone counseling for tobacco cessation), effects are expected to follow soon thereafter, and traditional short-term and long-term follow-up assessments should be able to capture behavior change and assess whether it is being sustained. For an intervention like UCare, however, many study participants were not ready to access or complete the intervention until after the 6-week assessment. It is important to keep reminding participants that the intervention is available (we sent up to 8 reminder emails plus the assessment prompts), and measure use and its mediated effects accordingly.

Limitations

User feedback on the usability of intervention components was collected only at 6 weeks, as we anticipated that retrospective recall at 7.5 months would be inaccurate. However, many women first used the website features after the 6-week assessment. Furthermore, it should be noted that the sample was self-selected, with women choosing to use the components they were rating. Usage data for the booklet were necessarily self-reported. Further analyses are necessary to connect the use of the intervention components to clinically meaningful outcomes.

Conclusions

Today’s technology offers many opportunities for eHealth intervention. Researchers designing such interventions should take into account the behavior of users to ensure that key content is delivered most effectively.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

UCare Development Appendix of Figures.

[[PDF File \(Adobe PDF File\), 970KB - formative_v2i1e10_app1.pdf](#)]

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Abbreviations

HMO: health maintenance organization
MOST: multiphase optimization strategy
NCI: National Cancer Institute
NIDA: National Institute on Drug Abuse
RCT: randomized clinical trial
ST: smokeless tobacco

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Short Paper

Feasibility of a Proactive Text Messaging Intervention for Smokers in Community Health Centers: Pilot Study

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Abstract

Background: Few smokers receive evidence-based cessation services during primary care visits.

Objective: We aimed to assess the feasibility of a proactive text messaging program for primary care patients who smoke.

Methods: We used electronic health records to identify smokers who had a mobile phone number listed from two community health centers in Massachusetts. Between March 2014 and June 2015, patients were screened by their primary care physician and then sent a proactive text message inviting them to enroll by texting back. Patients who opted in were asked about their readiness to quit. The text message program included messages from the QuitNowTXT library and novel content for smokers who were not ready to quit.

Results: Among 949 eligible smokers, 88 (9.3%) enrolled after receiving a single proactive text message. Compared with those who did not enroll, enrollees were more often female (54/88, 61% vs 413/861, 48.0%, $P=.02$), but otherwise did not differ in age, race, insurance status, or comorbidities. In all, 28% (19/67) of enrollees reported they were not ready to quit in the next 30 days, 61% (41/67) were ready to quit, and 11% (7/67) already quit. The median time in the program was 9 days (interquartile range 2-32 days). Of current smokers, 25% (15/60) sent one or more keyword requests to the server. These did not differ by readiness to quit.

Conclusions: A proactively delivered text messaging program targeting primary care patients who smoke was feasible and engaged both smokers ready to quit and those not ready to quit. This method shows promise as part of a population health model for addressing tobacco use outside of the primary care office.

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KEYWORDS

smoking cessation; primary health care; text messaging

Introduction

Among US smokers, less than one-third use any assistance—pharmacologic or behavioral—when they try to quit smoking [1]. Text messaging shows promise as a way to assist smokers to quit by delivering behavioral advice. Prior studies indicate that text messaging interventions for smokers increase tobacco abstinence rates by 36% to 70% [2-13].

However, most prior text messaging studies recruited motivated smokers through public advertisements, the Internet, or school-based recruitment. The few text messaging studies that recruited smokers from health care settings targeted motivated smokers [14], those already in tobacco treatment programs [15], pregnant smokers [16], or patients with coronary disease [17]. The feasibility of delivering tobacco cessation assistance by

text message for the broader population of smokers in primary care is unknown.

Primary care practices are well positioned to promote smoking cessation because 70% of smokers visit a physician each year [18]. However, although physicians often recommend quitting during visits, competing priorities and time constraints prevent them from offering further assistance [19]. Thus, new proactive models of care delivery are being developed for smokers [20-26]. These programs reach out to patients who are listed as smokers in electronic health records (EHRs) between visits to offer them help [27]. Prior models using mailings and telephone calls to engage smokers produced increases in treatment use and tobacco abstinence [20-26]. Text messaging interventions may be a less costly way to increase the reach and engagement of smokers in these proactive models [28].

Proactive models allow health systems to reach out to all smokers, not just those seeking treatment. In the United States, 80% of smokers are not ready to quit in the next 30 days [29]. However, smokers who are not ready to quit report substantial interest in mobile health interventions [30]. A low-intensity intervention such as text messaging may be a better fit with the treatment preferences of smokers who are not ready to quit compared to more intensive or intrusive treatments. Furthermore, even moderately efficacious interventions that target the large proportion of smokers who are not ready to quit may have a large public health impact [31]. The objective of this study was to assess the feasibility of delivering a proactive text messaging intervention for smokers in primary care in terms of proportion of patients reached, their interaction, and duration of time spent with the program.

Methods

Participants

We recruited smokers receiving primary care at Massachusetts General Hospital-affiliated community health centers in Charlestown and Revere, Massachusetts. We identified patients receiving primary care using a validated algorithm used by the Massachusetts General Hospital Practice-Based Research Network [32]. Other eligibility criteria based on EHR data included a primary language of English, age 18 years and older, current smoker, and with a mobile telephone number.

Intervention

We developed the GetReady2Quit (R2Q) text messaging program with content for smokers ready to quit in the next 30 days and content for smokers not ready to quit (Table 1). For smokers who were ready to quit in the next 30 days, we used the downloadable QuitNowTXT library [33]. QuitNowTXT includes 118 messages delivered over 6 weeks tailored to a user-entered quit date. These messages include behavioral advice and motivational and educational messages about the harms of tobacco and the benefits of quitting. The program has limited two-way communication including keywords to request help by texting "CRAVE," "MOOD," or "SLIP." There were also weekly smoking status assessment messages that invited a user response. Unlike other text messaging programs [34], if a user did not respond to an assessment, no further messages were sent. Maximum message volume was 25 messages per week with the highest volume in the 2 weeks before and after the quit date. For smokers who were not ready to quit in the next 30 days, 31 novel messages were developed by an expert team of primary care physicians (PCPs), a tobacco cessation counselor, a mobile health manager, and a behavioral scientist.

Table 1. Sample messages from GetReady2Quit (R2Q).

Type	Example	Reference
Opt in	Reply "yes" to participate in the R2Q Text Connect program offered to you by your doctor.	—
Campaign for smokers ready to quit in the next 30 days		
Behavioral advice	Next time you have the urge to smoke, try and resist for 5 minutes. Or skip the cigarette entirely. Think of it as practice for quit day!	[33]
Motivational messages	Need motivation? Make a list of your reasons for quitting. Put it someplace you can see every day. Keep thinking about why you want to quit.	[33]
Educational messages	Lung capacity increases by 30% after a few weeks without cigarettes! Ride your bike or take a walk. Put your healthy lungs to good use!	[33]
Smoking status	Are you still smokefree? Reply: YES or NO.	[33]
Keywords	Text your supporters and remind them of the big day. Make sure they are there for you. Text back CRAVE, MOOD, or SLIP for more support anytime.	[33]
Campaign for smokers not ready to quit in the next 30 days		
Motivational messages	Write down your reasons to quit. Put your reasons someplace where you will see them when you smoke, like in your car, your kitchen, or at your computer.	[35]
Practice quit attempt	A practice quit attempt is a few hours or days when you don't smoke to learn how you will feel when quit for real. Try it this week!	[36]
Readiness to quit	Are you ready to quit for good? If yes, reply with the date you would like to quit on, in this format: MMDD, for ex: 0513 for May 13. If not, reply WAIT.	—

Content included 16 motivational messages to encourage individuals to identify personal reasons for change and internal motivations to quit [35,37]. Fifteen messages encouraged smokers to try a practice quit attempt explained as an attempt to not smoke for hours or days without a commitment to stop for good [36]. Practice quit attempts can increase motivation and self-efficacy [36,38]. Smokers not ready to quit were sent three to five messages per week. At the end of this message campaign, users were asked again if they were ready to quit in the next 30 days. Those that were ready were sent the QuitNowTXT messages. Those that were not ready were sent a final recommendation to contact their doctor or the state quitline.

Procedures

Between March 2014 and June 2015, PCPs were asked to screen potentially eligible patients. The PCP-approved patients were sent an opt-out letter (Multimedia Appendix 1), informing them about the purpose of the feasibility study, content of the R2Q text messaging program, and that they would be sent a text message in the next week unless they called to opt out. Patients who did not opt out were sent a single text message inviting them to opt in to the R2Q program (Table 1). Opting in implied consent. Participants were sent four text message queries assessing nicotine dependence, readiness to quit, and quit date. Ethical approval was obtained from the Partners Healthcare, Inc Institutional Review Board.

Statistical Analysis

We compared R2Q enrollees, those who opted in following the proactive text message, with patients who were eligible and invited but who did not enroll in terms of demographics, primary insurance, and comorbidities. We used portions of the Reach

Effectiveness Adoption Implementation Maintenance (RE-AIM) methodology [31] to measure program reach, engagement, and adoption. Reach was the proportion of users sent a proactive text invitation who opted in. Engagement was measured as sending one or more keywords to the server. Adoption was defined as days in the text messaging program before the participant texted "STOP" or failed to respond to an assessment message. We compared engagement and adoption by readiness to quit using unadjusted *t* tests, Wilcoxon rank sum tests, and chi-square tests.

Results

We identified 1279 adults who met our inclusion criteria. Of these, 949 patients were reviewed and approved by their PCP for recruitment and 88 patients enrolled by opting in to the program after a single recruitment text for a reach of 9.3% (Figure 1).

Enrollees were more likely to be female and were less likely to have cardiovascular disease, but did not otherwise differ from eligible patients who were sent the opt-in text but who did not enroll (Table 2). Of the 88 enrollees, 67 (76%) completed all query messages about readiness to quit and nicotine dependence. Seven enrollees (11%) had already quit, 19 (28%) were not ready to quit, and 41 (61%) were ready to quit in the next 30 days. Of the 60 current smokers, median time in the program was 9 days (interquartile range [IQR] 2-32 days). Fifteen of 60 (25%) current smokers engaged with the program by texting keyword messages (eg, CRAVE, MOOD, or SLIP). Program time and engagement did not differ by readiness to quit (Table 3). However, compared to smokers not ready to quit, those ready to quit received more messages (median 18, IQR 14-40 vs median 12, IQR 7-44, $P=.04$).

Figure 1. GetReady2Quit patient enrollment flow. Eligible patients were adults (>18 years) listed as current smoker in their electronic health record (EHR) with English listed as primary language. PCP: primary care physician.

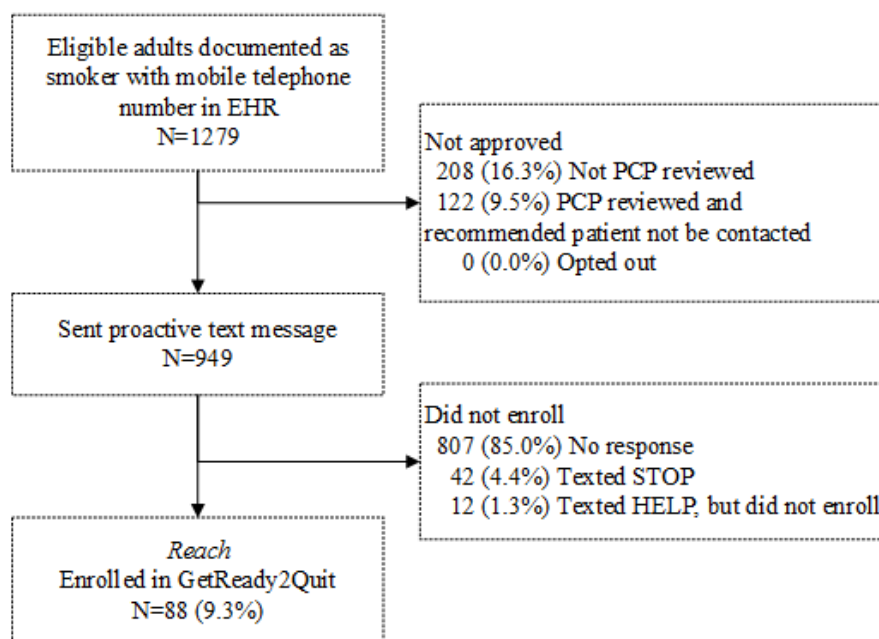


Table 2. Characteristics of eligible participants by GetReady2Quit enrollment status.

Characteristics	Enrolled (N=88)	Did not enroll (N=861)	χ^2 (df)	t_{944}	P
Demographics					
Gender (female), n (%)	54 (61.4)	413 (48.0)	5.7 (1)	–	.02
Race (white), n (%)	78 (89.7)	754 (87.8)	0.3 (1)	–	.61
Age (years), mean (SD)	47 (12)	48 (14)	–	0.7	.50
Primary insurance, n (%)					
Commercial insurance	52 (59.8)	458 (53.3)	–	–	–
Medicaid	18 (20.7)	233 (27.1)	–	–	–
Medicare	15 (17.2)	149 (17.4)	–	–	–
Self-pay	2 (2.3)	19 (2.2)	–	–	–
Comorbidities, n (%)					
Cardiovascular disease	3 (3.4)	87 (10.1)	4.2 (1)	–	.04
Diabetes mellitus	11 (12.5)	88 (10.2)	0.4 (1)	–	.51
Hypertension	22 (25.0)	255 (29.6)	0.8 (1)	–	.36
Chronic kidney disease	1 (1.1)	13 (1.5)	0.1 (1)	–	.78
Depression	2 (2.3)	25 (2.9)	0.1 (1)	–	.74

Table 3. Characteristics of enrolled smokers by readiness to quit.

Characteristics	Ready to quit (n=41)	Not ready to quit (n=19)	χ^2_1	t_{48}	z	P
Cigarettes per day, mean (SD)	15 (7)	15 (5)	–	–0.1	–	.92
Time to first cigarette (<30 minutes), n (%)	32 (80)	10 (77)	0.1	–	–	.81
Messages received, median (IQR ^a)	18 (14-40)	12 (7-44)	–	–	–2.0	.04
Engagement (program days), median (IQR)	16 (3-31)	4 (1-35)	–	–	–0.8	.40
Adoption (texted a keyword), n (%)	13 (32)	2 (11)	3.1	–	–	.08

^aIQR: interquartile range.

Discussion

Comparison With Prior Work

This study evaluated a proactive tobacco cessation intervention that reached out to patients by text message. It shows promise as a low-cost, scalable intervention for primary care populations. Program reach at 9.3% was comparable to other proactive care models for smokers that used more intensive outreach methods, including up to 15 outreach telephone calls [24]. Similar to telephone outreach programs, both smokers ready to quit and those not ready to quit enrolled [27]. These results support the feasibility of future work to design and test a proactive text messaging intervention targeting primary care patients.

Text messaging programs originating from the physicians' office may leverage the influence physicians have on smokers [18]. Individuals most often look to their own health care systems for online health information [39]; therefore, trust in their health care providers may make health-promoting advice more potent if it is coming from their physicians' office. This trust may also encourage even unmotivated smokers to engage in health-promoting activities sent to them by their physicians' office.

Our single message enrollment process was simpler than recruitment used by other proactive care models [20-26]. The low intensity may have been appealing to both smokers not ready to quit and those busy managing other chronic diseases, who may not have time or interest in more complex interventions. Indeed, except for cardiovascular disease, patients with comorbid chronic diseases were no less likely to opt in. Integrating the program with other optional cessation services, such as pharmacotherapy, may increase the program's appeal and improve reach and effectiveness. Future work will need to explore ways for text messaging to be integrated with other cessation services available to primary care patients who smoke.

Limitations

In this pilot study, we did not have enough resources to assess smoking outcomes or receipt of text messages. Therefore, we could not account for invalid telephone numbers or failed message delivery. If these are considered, the uptake of the program following receipt of the proactive text may have been even higher.

Conclusions

A proactively delivered text messaging program targeting primary care patients who smoke reached as many smokers with a single text as more intense and costly telephone call- or

mailed-based proactive outreach methods. This method engaged both smokers ready to quit and those not ready to quit and shows promise as part of a proactive care model for addressing smoking in primary care populations.

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Conflicts of Interest

GK has interests in two mobile health companies, including a family financial interest in Dimagi, Inc, and is a paid consultant for Click Therapeutics. NAR has a research grant from and served as an unpaid consultant on tobacco cessation treatment to Pfizer and receives royalties from tobacco topics in UpToDate.

Multimedia Appendix 1

Opt-out patient letter.

[[PDF File \(Adobe PDF File\), 394KB - formative_v2i1e11_app1.pdf](#)]

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Abbreviations

EHR: electronic health record
IQR: interquartile range
PCP: primary care physicians
R2Q: GetReady2Quit

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Original Paper

Developing Technology to Mobilize Personal Strengths in People with Chronic Illness: Positive Codesign Approach

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Abstract

Background: Emerging research from psychology and the bio-behavioral sciences recognizes the importance of supporting patients to mobilize their personal strengths to live well with chronic illness. Positive technology and positive computing could be used as underlying design approaches to guide design and development of new technology-based interventions for this user group that support mobilizing their personal strengths.

Objective: A codesigning workshop was organized with the aim to explore user requirements and ideas for how technology can be used to help people with chronic illness activate their personal strengths in managing their everyday challenges.

Methods: Thirty-five participants from diverse backgrounds (patients, health care providers, designers, software developers, and researchers) participated. The workshop combined principles of (1) participatory and service design to enable meaningful participation and collaboration of different stakeholders and (2) an appreciative inquiry methodology to shift participants' attention to positive traits, values, and aspects that are meaningful and life-giving and stimulate participants' creativity, engagement, and collaboration. Utilizing these principles, participants were engaged in group activities to develop ideas for strengths-supportive tools. Each group consisted of 3-8 participants with different backgrounds. All group work was analysed using thematic analyses.

Results: Participants were highly engaged in all activities and reported a wide variety of requirements and ideas, including more than 150 personal strength examples, more than 100 everyday challenges that could be addressed by using personal strengths, and a wide range of functionality requirements (eg, social support, strength awareness and reflection, and coping strategies). 6 concepts for strength-supportive tools were created. These included the following: a mobile app to support a person to store, reflect on, and mobilize one's strengths (Strengths treasure chest app); "empathy glasses" enabling a person to see a situation from another person's perspective (Empathy Simulator); and a mobile app allowing a person to receive supportive messages from close people in a safe user-controlled environment (Cheering squad app). Suggested design elements for making the tools engaging included: metaphors (eg, trees, treasure island), visualization techniques (eg, dashboards, color coding), and multimedia (eg, graphics). Maintaining a positive focus throughout the tool was an important requirement, especially for feedback and framing of content.

Conclusions: Combining participatory, service design, and appreciative inquiry methods were highly useful to engage participants in creating innovative ideas. Building on peoples' core values and positive experiences empowered the participants to expand their horizons from addressing problems and symptoms, which is a very common approach in health care today, to focusing on their capacities and that which is possible, despite their chronic illness. The ideas and user requirements, combined with insights

from relevant theories (eg, positive technology, self-management) and evidence from the related literature, are critical to guide the development of future more personalized and strengths-focused self-management tools.

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KEYWORDS

patient personal strengths; participatory design; codesign; appreciative inquiry; service design; positive computing; positive technology; chronic disease; eHealth; mHealth; patient requirements; patient participation

Introduction

The Importance of Personal Strengths for Illness Self-Management

Living with chronic illness is highly demanding. It often requires a person to simultaneously manage multiple symptoms, disability, complex medical regimens, difficult lifestyle adjustments, and emotional consequences (eg, depression, fear, and anxiety) [1,2]. Learning how to manage these illness-related challenges is a crucial part of self-management. Self-management is defined as “the tasks that individuals must undertake to live well with one or more chronic conditions” [3]. To support patients in performing these tasks, a range of technology-based self-management programs and interventions exist, which focus primarily on supporting patients in learning, developing, and practicing new skills and knowledge required to manage their symptoms and problems as well as live healthy and satisfying lives [4,5]. However, so far, technology-assisted self-management interventions are usually designed to support problem-solving approaches to self-management, for example, monitoring and providing information on how to manage symptoms and biological outcomes.

Increasing evidence from psychology and the bio-behavioral sciences suggests that the focus on pathology and health deficits that has considerably dominated the health care discourse may not be optimal to help patients reach their best health potential. For example, sustained attention on symptoms and problems can create a downward spiral of sensitization with negative emotional and moral implications (eg, fear, anger, and injustice) as well as serve as a constant reminder of negative aspects of the persons' illness [6,7]. On the other hand, shifting the focus to personal strengths and resources may counteract these processes as it creates a horizon of possibilities accompanied by a sense of control and mastery, which inspire mobilization and positive action [8]. While a focus on strengths does not ignore the patients' problems, it shifts the attention from peoples' deficits to addressing their health issues in light of their individual capacities, talents, competencies, possibilities, and values [9]. Surprisingly, the crucial role of patients' personal strengths has not been directly addressed in the self-management literature and very few interventions have been designed that specifically support patients in identifying and mobilizing their personal strengths in the self-management of their illness.

Positive Psychology and Personal Strengths

A concept of character strengths originated in positive psychology and has been defined as “the characteristics people use to achieve well-being and to flourish, and include attributes such as hope, gratitude, love of learning, honesty, and humor”

[10]. In addition to its emphasis on utilizing personal strengths, positive psychology is used as a more general term for the study of positive emotions, positive character traits, and institutions that enable a person to flourish (eg, families and communities) [11]. In relation to health and chronic illness management, the term “patient strengths” (sometimes also referred as health assets) is very often used as a much wider concept that covers internal strengths (eg, optimism, sense of meaning in life, acceptance, and positive emotions), external strength qualities (eg, supportive family, neighborhood and institutions, and stable socioeconomic status), and mastering and coping strategies (eg, meaningful priorities, changing perspective, and being vigilant) that patients use to meet their day-to-day health-related challenges [12-14].

Using strengths have been found to broaden people's thought-action repertoires, to encourage them to discover novel lines of thinking and behavior, and to increase intellectual, social, and psychological resources [15,16]. Some studies have shown the potential of strengths-based interventions to positively influence healthier lifestyle practices [17], increase mood and happiness [11], promote the efficacy of health management activities [14], and improve general health and well-being [18]. Additionally, the literature reports numerous studies that use technology to deliver positive psychology interventions to wider user groups, both to help them identify and raise awareness and build on, and use more of, their personal strengths in everyday life [11,19,20]. Strengths-based interventions are more commonly evaluated and used in the fields of positive psychology [10], social work [21], community development [22], and business [23]; however, such interventions have been largely unexplored in the field of health care and more specifically, for people with chronic illness.

Positive Technology and Positive Computing

Positive technology and positive computing approaches to the design of technology introduce underlying design principles and guidelines that are highly relevant for developing strength-supportive interventions. Sander's term, positive computing, was introduced as “the study and development of information and communication technology that is consciously designed to support people's psychological flourishing in a way that honors individuals' and communities' different ideas about the good life” [24]. Positive computing refers to the design of technology that helps people to be “who they want to be” and supports them to better address negative situations and challenges in life [24]. This concept has been further expanded by Calvo and Peters, who in their recent book explore the potential of technology to positively influence different areas of peoples' lives, such as human positive functioning, positive

emotions, motivation, engagement and flow, mindfulness, and empathy [25].

The positive computing concepts were further explored by Riva and colleagues with a specific focus on improving the quality of peoples' personal experiences [26,27]. They introduced the term positive technology, a scientific and applied approach to "use technology to enhance the features of our personal experiences with the goal of increasing wellness, and generating strengths and resilience in individuals, organizations and society" [26]. Positive technology is classified based on its effects on a specific feature of our personal experience: (1) hedonic: technologies used to induce positive and pleasant experiences, (2) eudemonic: technologies used to support individuals in engaging and self-actualizing experiences, and (3) social or interpersonal: technologies used to support and improve the connection between individuals, groups, and organizations. The authors argue that by positively influencing the positive and self-actualizing experiences and improving interpersonal connections, the positive technologies have the potential to increase people's engagement in self-management activities and their role in the partnership with health care providers [26]. While research has explored the role of positive technology and computing approaches in the general population (eg, [28-30]), the potential of applying positive technology principles in chronic illness management is still in early stages and needs to be further explored.

Successful development of electronic interventions that build on the principles of positive computing and positive technology require multidisciplinary partnerships that explore the design and shape of digital experiences to support human flourishing [25]. This goes beyond mere user acceptance of the system and requires the technology to also be enjoyable, exciting, engaging, and suitable for users' needs [24,31,32]. The potentials of technology can only be fully exploited when end users and other stakeholders are involved in the design process and their needs and the specifics of the context (both organizational and that of the individual user) in which the technology will be used are taken into consideration. Therefore, close collaboration between different stakeholders, multidisciplinary research teams, and system designers and developers from the early stage of development is a main requirement in the development of successful system design and implementation processes [31].

The study presented in this article is a part of a larger project funded by the Research Council of Norway titled "The Power of Personal Strengths – using gamification to support patients in chronic illness management". The goal of the project is to build on the concepts and principles of positive computing and positive technology design to develop and evaluate a gamified application that helps people with chronic illnesses identify and mobilize their personal strengths in illness self-management. In this paper, we describe the applied methods and results of a whole-day codesign workshop with a range of stakeholders (patients, health care providers, designers, software developers, and researchers) organized as part of the project. The main goal of the workshop was to identify and collaboratively explore stakeholders' requirements and cocreate ideas for a technology-supported self-management tool that integrates and builds on patients' strengths.

Methods

Design Approach

The overall design approach in the whole research project combines participatory design and service design methodologies. Participatory design is a design methodology that promotes close collaboration, common understanding, and mutual learning between designers and users in designing a product [33]. Service design also relies heavily on collaboration but further focuses on developing entire services that support value cocreation between customers and service organizations [34]. As such, it typically includes a wider group of stakeholders that are relevant to and involved with the service, not only end users and designers. Therefore, the goal of applying this integrated design approach for our research project was to promote involvement of wide group of stakeholders throughout the development process, and also to give them an important and meaningful role in the design and decision-making processes.

The codesign workshop described in this study was organized in a similar way to what is often termed a Future Workshop within participatory design methodology [35]. Such workshops are often used for developing new and innovative ideas and contain three phases: (1) The critique phase where one openly discusses and presents issues surrounding the topic; (2) The fantasy phase where one creates and suggests possible or impossible solutions or ideas about solutions for the issue(s), and finally (3) The concretization phase where one tries to shape the proposed ideas into something concrete and realizable [35]. However, in our approach, instead of critiquing current systems and focusing on problem-solving, we applied basic concepts of appreciative inquiry methodology to guide the organization of workshop tasks and frame the questions in all three phases with a positive stance [36]. An appreciative inquiry methodology approach aims to focus peoples' attention on positive traits and values, and discovery of "what gives life" to a system when it is most effective and most constructively capable, and how this state can be extended and improved [36]. Through this process, the goal is not only to explore the system's capacity to apprehend, anticipate, and heighten positive potential but also to evoke positive emotions with participants during this process. Previous research has shown that when people experience positive emotions, their attention span lengthens, they are curious, and they simultaneously hold multiple perspectives [37]. Facilitating the participants' curiosity and positivity in this manner can encourage them to be more open to viewing things from different perspectives, and this is more likely to trigger insights and inspire innovation and, as a result, open up new possibilities for action [36]. The philosophy of appreciative inquiry further argues that inquiry and change are deeply interconnected. The type and form of the questions will not only guide the conversation and cooperation between participants but also, at the same time, it will shape what people discover and pursue and instill certain images and expectations of their future, which will further attract energy and mobilize intention and action. Thus, the rationale for using the appreciative inquiry approach was twofold: (1) to engage users in more positively oriented, creative cocreation activities and facilitate a richness of creative ideas; and (2) to engage and empower users to reflect

on their situation from new perspectives and look for new possibilities for capacity building and flourishing that is beyond the problem-focused thinking that is predominant in health care today.

Often in the literature, methods for involving stakeholders are only superficially described, leaving other researchers without the necessary detail to reapply the methods. As we applied a novel way to design a codesign workshop, the methods are purposely described in more detail in the following section.

Participants

In total, 35 participants (13 male, 22 female) from diverse backgrounds took part in the workshop (Table 1). Recruitment was done through patient organizations such as the Norwegian competence center for self-help and the youth council of a local hospital (8/35, 23%), center for family and professional carers (2/35, 6%), the professional network of the project team (20/35, 57%), and by inviting participants from earlier strengths-related studies (5/35, 14%). The study was approved by the Privacy Protection Committee at Oslo University Hospital and all participants signed an informed consent.

Workshop Procedure

Introduction

The workshop started with a short welcome and introduction of the project, after which the workshops' goals and rules were presented. The rules were formulated to promote joint work and collaboration between participants (eg, listen actively to others, build on each other's ideas, show curiosity about others in the group and their ideas). To set the stage and energize the participants, a patient representative, also a participant from one of our previous research studies, shared his personal story about how he uses his own strengths to manage daily challenges when living with chronic illness, or chronic pain in this specific case. This was followed by a group exercise where participants were asked to characterize and reflect on the personal strengths of other people—in our case we used the patient representative who had shared his story and another fictional character from a movie. The purpose of this exercise was to engage the participants in a shared emotional experience, help them think

about personal strengths, and prepare them for noticing the strengths of others or themselves in the future [38]. Additionally, this also served as a powerful example they could draw upon later during other activities.

Working in Small Groups

The participants were then divided into 6 smaller groups, aiming to distribute participants with different backgrounds evenly within the groups. Each group consisted of 3-8 participants. Table 1 shows the distribution of participants across groups.

Each group had one facilitator and one observer. The main role of the facilitator was to facilitate the activities and support the participants during this process, while the observer was in charge of taking notes and provided additional support for the facilitator when needed. All facilitators were researchers (4/6, 67%) or research assistants (2/6, 33%) from the project. Observers were other researchers (2/6, 33%) or part of the staff (4/6, 67%) from the research center. Both facilitators and observers gained detailed group training and guidance about the activities, tasks, and their role during the workshop.

Activity 1

The purpose of the first activity was to prompt participants to build positive, anticipatory images of themselves. In appreciative inquiry, this process is called establishing the "positive core", and it plays a key role in changing people's focus and collective attention to what is valuable, life giving, and vibrant in their life [36]. Therefore, in this task, each participant was asked to do a strengths assessment and reflection exercise. To support this process, each participant was provided a short premade text guide that showed examples of strengths that people with chronic illness from earlier studies had reported [13,39], and it visualized strength items as branches in a tree metaphor (Figure 1, top left). Participants were asked to select existing "strength branches" that describe their own strengths and/or use empty tree branches to write down new strengths items and describe one example from their life where they had used their strengths successfully. The goal of this exercise was to help participants articulate key strengths that they may wish to build upon in the future and to promote reflection of earlier situations in which they accomplished something positive by using these.

Table 1. Distribution of participants' backgrounds across small groups.

Background	Group number					
	1	2	3	4	5	6
Patient (n=12)	1	1	1	3	4	2
Patient organization representative (n=3)	0	0	0	1	2	0
Health care provider (n=10)	2	3	1	1	1	2
Relative (n=2)	0	2	0	0	0	0
Information technology developer (n=4)	1	1	0	0	1	1
Designer (graphic designer, industrial designer; n=2)	0	0	1	1	0	0
Researcher (external, not part of the project team; n=2)	1	0	0	0	0	1

Figure 1. Poster templates: (top left) the strengths assessment and reflection exercise guide; (top right) the strengths interview guide and poster; (bottom left) poster for working and presenting challenge-reason-strengths connections; and (bottom right) poster for conceptualizing and presenting final group ideas.

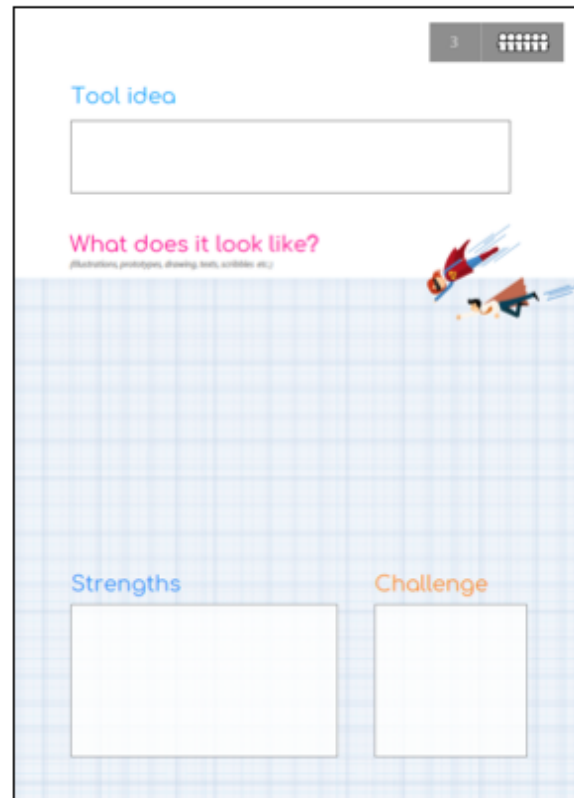


Table 2. Overview of data types gathered during the workshop.

Type of data	Description	Use
Audio Recordings	20:20 hours of plenary and group sessions	Primary data
Observation Logs	Reflection notes of facilitators and observers	Contextualizing
Photos	Photos of activities, ideas, scribbles, etc	Contextualizing
Written products	Sticky-notes, posters, note-papers, etc	Contextualizing

In the second part of the activity, the participants were asked to interview each other in pairs by following guidelines and fill-in fields of the premade poster template (Figure 1, top right). The poster was then presented by an interviewer to their small group. In addition to letting the participants become acquainted with each other, the purpose of these interviews was also to engage the participants to openly share stories about using their personal strengths and to inspire and energize the whole group with these positive stories.

Activity 2

In the second activity, all participants were asked to think about and report challenges and problems they perceived to be interfering with their overall well-being, as well as the reason why they were difficult to manage. While focusing on negative issues is a deviation from strict appreciative inquiry principles, recognizing challenges was an important part of making participants feel heard and acknowledged, especially patients who often faced substantial challenges in their everyday life. Therefore, we formulated this activity not so much as an activity that focused on the negative aspects, but rather as a first step in the process of changing the perspective and seeing the same challenges in a different light, which is also the main philosophy of a strengths-based approach.

After presenting the challenges and their underlying reasons on sticky-notes gathered on a wall, all participants voted for one that they would like to continue working on as a group. They were then asked to reflect and write down personal strengths that they themselves could use to overcome the chosen challenge. The reported strengths were used in a plenary discussion to expand the challenge-reason dyads into the challenge-reason-strengths connections (poster template presented on Figure 1, bottom left). The main reason for this step of the workshop was that strengths are often reported as highly context-sensitive [40,41], so enabling participants to report and see their strengths and challenges in an interconnected manner was considered an important part of the process. Additionally, this last step was designed to turn participants' attention back to the "positive core" and in this manner, to set the stage for thinking about and developing new ideas for a future system that builds upon this concept.

Activity 3

For activity 3, the overall goal was to develop and conceptualize ideas for tools that could be used to support its users in identifying and using their strengths to address the selected challenges. The activity was organized based on standard guidelines for setting up codesigning activities and exercises and collaborative prototyping [35,42]. The participants were encouraged to brainstorm and create new and "crazy" ideas

about possible tools. They were instructed not to think just about a technical tool but any kind of tool (eg, magical or fantasy solutions). The important part of this task was to describe how and why the tool could be useful and helpful. The last part of this activity was used to concretize the idea and describe the main features of the proposed concept by filling in a templated poster presenting their idea (Figure 1, bottom right).

Activity 4

Finally, each group presented their final ideas in a plenary session. After this presentation, all participants voted on the best idea and each group was rewarded with a prize in various categories. In addition to the idea with the most participants votes (peoples' favorite), prizes were also awarded for most creative idea, best strengths collector, most inspiring idea, best idea for bridging people, and most magical idea. At the end, each participant was handed a diploma and a symbolic prize of a chocolate gold-medal.

Data and Analysis

The workshop yielded multiple types of data, which are presented Table 2.

Two of the authors (JM, TK) made detailed summaries of all group discussions based on audio recordings and using observation logs, photos, and written products for contextualizing and gaining more details about the process. In addition, sections of audio recording relevant to overall workshop theme and specific activities' topics were transcribed. The summaries and transcribed data were imported into NVIVO 11 (QSR International, London, United Kingdom) [43] for analysis. The data was categorized corresponding to the different topics that were addressed during the workshop (personal strengths, health challenges, creative ideas, and functionality and design requirements) and analysis was performed for each topic separately. Data were analyzed in several rounds by JM and TK according to the conventions of thematic analysis [44]. All results were discussed and inconsistencies, such as in understanding of design ideas, were jointly discussed until consensus was reached.

Results

Strengths

The participants reported a wide range of strength items during the first two activities of the workshop. In total, the participants contributed over 150 strength items. The reported strength items were sorted into six main categories or themes. The overview of the categories and example of strength items are presented in Table 3. The first four categories—my characteristics, coping strategies, resources in my environment, and behavior promoting

health and positive emotions—relate to more general and personal strengths in people with chronic illness. In addition, we separated those strengths identified by health care providers and relatives that particularly pertained to their specific role.

Challenges

In total, the participants reported over 100 challenges, which are summarized in the categories and examples shown in [Table 4](#). Some of the challenges were related to performing general illness-related self-management tasks, such as understanding and managing illness and symptoms, communication with health care professionals, and gaining knowledge about the illness. However, a number of challenges were also related to living well, for example, managing and balancing everyday activities, establishing and preserving social relations, challenges at work and school, working on self-improvement, and gaining and preserving healthy lifestyle.

The challenges selected within each of the six groups are presented in [Table 5](#), together with examples of strengths items participants proposed for addressing the selected challenges.

Table 3. Categories of strengths and examples of strengths items reported by participants in the study.

Categories	Examples of strengths
My characteristics (<i>I am</i>)	<ul style="list-style-type: none"> • Solution oriented • Goal oriented • Like to learn new things • Open for new possibilities • Have a sense of humor • Empathic • Brave • Able to show vulnerability
Coping strategies (<i>What I do/use</i>)	<ul style="list-style-type: none"> • Set up clear goals • Knowing my goals • Being able to think and be positive • Making plans • Being aware of negative thoughts • Knowing and setting my own limits • Visualize things • Stress management strategies • Thinking long-term
Resources in my environment (<i>What I have</i>)	<ul style="list-style-type: none"> • Support from family/friends • A good health care system • Support from health care professionals • Support from peers
Behavior promoting health and positive emotions	<ul style="list-style-type: none"> • Eating healthy • Being physically active • Finding and doing activities that give me positive energy
Specific for health care professionals	<ul style="list-style-type: none"> • Good in communicating with people • Focus on patient security • Share information on different communication channels
Specific for relatives	<ul style="list-style-type: none"> • Having knowledge about my rights as a relative • Are involved in care processes at the hospital

Ideas

With the selected challenges as a point of departure, all groups managed to create ideas for tools or services that could help them to master the selected challenges while keeping a positive and constructive approach and promoting the utilization and mobilization of a person's personal strengths during this process. To support the participants in out-of-the-box thinking, we, as mentioned above, gave no restriction for the scope of their ideas and proposals. The final groups' ideas are described in [Table 6](#).

Functionality Requirements

During the group work, various functionality requirements were raised and discussed among participants. Main themes and examples of user requirements related to functionalities of strengths-based self-management tools are summarized in [Table 7](#).

Table 4. Categories and examples of challenges reported by participants in the study.

Main category of challenges	Example of challenges
Balancing everyday life and activities	<ul style="list-style-type: none"> • Prioritizing important things • Finding enough time for doing what you like • Finding balance • Managing time • Finishing projects
Finding new ways to live with illness (mastering strategies)	<ul style="list-style-type: none"> • Managing symptoms • Spending time with family and friends • Managing things as before illness • Building better understanding of illness • Learning how to adjust to environmental factors • Accepting your situation
Challenges for being social	<ul style="list-style-type: none"> • Socializing with other people • Meeting new people • Building relationships with other people
Work and school	<ul style="list-style-type: none"> • Being at work or school • Finishing school in time • Limiting work load • Keep motivation at work
Self-improvement	<ul style="list-style-type: none"> • Being yourself • Control thoughts and feelings • Speak up when things become difficult
Relationship with health care providers	<ul style="list-style-type: none"> • Communication between patient and health care provider • Communication between relative and health care provider • Access to knowledgeable people • Health care provider does not see the whole picture
Getting new knowledge	<ul style="list-style-type: none"> • Getting access to updated new knowledge • Understanding complicated language
Healthy lifestyle	<ul style="list-style-type: none"> • Doing physical activity • Eating healthy • Get enough sleep and rest • Lose weight

Table 5. Challenges chosen by groups and strengths participants reported that can be used to address those challenges.

Chosen challenge	Examples of related strength items
Prioritizing important things	<ul style="list-style-type: none"> • Willpower • Able to ask for help and support • Focused • Prioritize my needs • Solution oriented • Optimistic • Able to set and adjust my goals
Difficult to be a young adult in a hospital	<ul style="list-style-type: none"> • Support from peers • Independent • Good communication skills • Being able to think and be positive • Well-functioning health care system open for improvements • Have clear goals • Will to learn new things
Finishing projects	<ul style="list-style-type: none"> • Set up clear goals • Taking small steps toward goal • Enthusiastic • Persevering • Systematic • Flexible to adjusting goals
Communication among relatives and the health care system	<ul style="list-style-type: none"> • Having knowledge about my rights as a relative • Brave, not afraid to say what I mean • Creative • Good and clear communication with health care providers • Empathic • Good network
Finding balance in life	<ul style="list-style-type: none"> • Able to set my own limits • Acceptance • Knowledge about illness • Prioritize things that are important to me • Able to set and adjust my goals • Good network • Being able to think and be positive
Mastering various aspects of life	<ul style="list-style-type: none"> • Grateful • Goal oriented • Plan the day ahead • Stubborn • Prioritize my needs • Support from family/friends • Being able to think and be positive

Table 6. Ideas developed during the group work and their short description.

App idea	Challenge	Short description of idea
Strengths treasure chest	Finding balance in life	A treasure chest app where a person can store his/her strengths, both those written by himself/herself and strengths added by others (eg, friends and family). The strengths can also be linked to different areas in life, and the app helps a person to plan how to use them, provides reminders about his/her strengths, and enables sharing information about his/her strengths with others.
Cheering squad app	Mastering various aspects of life	An app where a person can invite people to join his/her own cheering squad. People in the cheering squad can provide their personal support to the user by sending positive and encouraging messages through the app. The user has full control and can decide who he/she wants to invite and sets his/her own rules for communication (eg, no asking "how are you doing" questions, no need to respond and send answers to cheers).
User-controlled personalized hospital	Difficult to be young adult in a hospital	An app for a person transitioning from a pediatric ward to a unit for adults in a hospital. It provides support for establishing better and more clear communication with different people in person's surroundings (eg, family, doctors, nurses). Some features include: always available and open communication channel with all parties, option for defining and sharing with everybody personal requirements and preferences, and link to a patient journal and information bank.
Empathy Simulator	Communication among relatives and the health care system	Virtual Reality 4D glasses that simulate experiences from different parties present in a consultation setting (eg, patient, caregiver, or a family member). The goal is to help a person experience the same situation from another person's perspective. The glasses simulate what the person hears and sees and also what is felt and sensed.
Prioritizing app	Prioritizing important things	An app to help a person to make choices based on previous knowledge and experiences. The app supports a user during the process of making a choice—making a pro and con list for each option, help and tips on the strengths and resources one can use when making specific choice (based on previous experiences), and registering your satisfaction and experience with the selected choices afterwards.
Task-completer app	Finishing projects	A personalized app that helps a person identify his/her strengths and use them to complete challenges and tasks in everyday life. For example, it integrates sensors to understand when a person is stressed, and then prompts him/her with some of his/her strengths to help and motivate him/her to finish started tasks.

Table 7. Functionality requirements participants reported for strengths-based self-management tools.

Theme	Example of functionality requirements
Social support	Receiving support from others over, for example, online chat, calls, or messaging system Supporting others by for example sharing your knowledge and experience Connecting to other people (eg, peers, role models)
Support for patient-health care providers collaboration	Support for sharing information (symptoms, strengths, resources, and values) Supporting communication and collaboration
Awareness and reflection	Adding information about you, what is important to you, and current situation in different areas of life Overview of previous actions, goals, choices, and progress Identifying and providing overview of your current and previous strengths Registration and overview of how you use your strengths
Support for coping strategies	Support for prioritizing and making choices Exercises for identifying your strengths Exercises for mobilizing and building upon your strengths Goals (defining goals, defining and making small steps towards goals, support for achieving goal)

The most prevalent requirement across the groups was that technology should be designed to provide social support and connectedness with others. To accomplish this, features such as messaging, chat, or call were proposed as modes through

which others (eg, friends, family, and peers) can provide support. For example, others could provide help during the process of identifying and reflecting on user's personal strengths, or friends and peers can recognize user's efforts, cheer him/her up, and

support him/her for using and mobilizing his/her strengths in everyday life by sending positive and encouraging messages. In addition, the important part was also enabling the user to provide support to others, for example, by sharing knowledge and experiences in the common online space.

The other requirement often raised was supporting consultation with health care providers. In this context, participants proposed that technology could be used both in preparation for and during clinical consultation to facilitate sharing information between different parties (eg, patient, health care provider, or relative). Here, the main goal of the technology would be to facilitate a better understanding of each other's needs, priorities, and limitations, and promote collaboration and cooperation supporting a person to see the situation from the different perspectives.

Other proposed functionalities centered on helping people to gain and further develop skills for raising awareness and reflection about themselves and their current situation. For example, this included implementing features for increasing awareness and reflection about personal characteristics and values (including strengths that one has), as well as monitoring progress and changes in different areas of life. The main goal of these features was to support the user in a process of reflection and learning about himself/herself and his/her current situation, goals, choices, and priorities, and make this knowledge available and capable of being reused in future similar situations.

Additionally, it was suggested that the technology should support people in transitioning from raising awareness to making concrete actions and plans, and developing coping strategies that could help them master everyday challenges. This could be done, for example, by helping them in prioritizing and making new choices and in defining the goals and small steps to reach these goals. An important requirement involved enabling and helping users to integrate their personal strengths, values, preferences, previous knowledge, and experience in this process, and to provide personally tailored guidance and support. Finally, adding support for exercises to help build and nourish personal strengths was seen as an important feature. Some proposed exercises were: registering good and positive experiences during the day, reflecting on positive experiences afterwards, and relaxation and mediation exercises.

Design Requirements

In addition to functionality requirements, participants outlined various design requirements. Maintaining a positive focus was identified as an important requirement, especially in relation to giving positive and encouraging feedback to the user or framing the content in a positive way. Examples of how to make the design more engaging included using metaphors such as glasses, weight scale, tree, treasure chest, islands in the sea, and different worlds, or to use different visualization techniques such as dashboards, color coding of areas of life, smiley faces for registering daily mood, or the use of multimedia such as graphics and videos. Personal customization and adaptation to one's own preferences and values were also raised as very important requirement both in relation to the user interface and features of the tools. Other user requirements included items such as

giving the user full control, providing timely feedback, and making sure the tool was always available and accessible.

Discussion

Design Process: Combining Appreciative Inquiry, Participatory Design, and Service Design

In this study, we applied a new approach for involving stakeholders in the design process that builds on the core principles of participatory design and service design that emphasize enabling meaningful participation and collaboration with different stakeholders. Additionally, these principles were expanded with appreciative inquiry methodology that focus on integrating participants' core values and on promoting positivity and creativity in the design process. This approach was also in line with the main principles of positive computing and positive technology, arguing that the design and development of technology should support psychological wellbeing and human potential, and foster a positive user experience. Combining principles from these different design approaches enabled us to create a positive and open environment that engaged and supported the participants to explore and propose new overall ideas, specific features, and contexts for the implementation of tools that expand users' personal strengths and resources in a valuable and meaningful manner. For instance, the workshop started with an activity where the participants interviewed each other about their strengths, allowing them to both gain a better understanding of the concept of strengths by recognizing strengths in themselves and in others and to reflect and share positive personal experiences that they experienced while using them. Even though the literature reports that the concept of strengths can sometimes be both vague and difficult to grasp (especially when it is used in context of person's health [45,46]), all participants in the study were able to identify and report their own strengths and integrate them into their groups' work and ideas. Identifying and sharing their positive potentials also set the stage for a better common understanding, for collaboration in further group work, and for exploring the wider range of innovative ideas that build on these concepts.

Concluding the workshop, we gained overwhelming positive feedback from the participants, stating that the overall positive focus helped to keep them interested and engaged during the whole day workshop. This was also reflected through the amount and variety of participants' feedback, as well as the themes and topics they discussed and the ideas that they proposed during the workshop. Thus, we can conclude that combining principles from participatory design, service design, and appreciative inquiry methodologies was an effective approach to enhance overall participant engagement, reflections, and creativity during the workshop with multiple stakeholders. This approach engaged them to think about new ideas and possibilities for technology that go beyond problem solving and addressing peoples' deficits.

During the workshop, the varied backgrounds of participants contributed to producing innovative ideas that we, as researchers and designers, would not have considered alone without their insights. However, while stakeholders' input about their challenges, preferences, needs, and values are crucial, creating successful new tools and systems also requires the specific

knowledge and expertise of experts (eg, designers and researchers) to make sure the functional purpose, existing evidence, and the standards of good design are followed and addressed [42]. As presented in this study, a thorough analysis of the results of the workshop moved beyond the surface and concrete ideas. The inputs from the participants were also classified according to the types of functionality and requirements reported and the types of values and challenges these functionalities should promote and address. With this as a point of departure, the next step for researchers and designers is to integrate these inputs in the design of new and innovative tools and solutions that integrate user input and requirements and also build on theoretical and evidence-based frameworks and findings, such as the self-management models or the principles of positive computing or positive technology.

Design of Self-Management Interventions

Concept of Personal Strengths

Assisted by the exercises and examples, the participants reported a large repertoire of strengths during the workshop, which ranged from personal qualities and characteristics (aligned with the character strengths within the field of positive psychology) to self-management and coping strategies (activities that promote positive emotions and healthy behavior) and supportive people and networks in their environment. This confirms previous research that shows that people perceive the concept of personal strengths in different ways and, when asked about their strengths, they report not just their internal personal characteristics but also external resources (eg, people from their environment) and positive and energizing behaviors that promote wellbeing and a healthy lifestyle (eg, knowing and working on the goals and healthy eating) [12,13,39].

This ambiguity of the term personal strengths reported by participants also influenced the idea-generating part of the workshop. While some of the groups stayed focused on a tool that could help people build awareness and mobilization of their personal strengths (*Strengths treasure chest* idea), other groups focused more on developing a tool that supported self-management activities (*Task-completer* idea) or social relatedness (*Cheering squad* app), where a component focusing more specifically on personal character traits was only a part of the app and not the main component. Having the groups initially either converging or diverging from the main concept of personal character strengths enabled further widening of the design space that afforded us rich insights into the variety of user needs and innovative ideas on how to use technology to facilitate integration of different types of strengths into self-management process.

Integrating Personal Strengths Into Self-Management Models and Interventions

Even though the concept of strengths was the main theme for this workshop, identifying participants' challenges in daily life was also an important part of the process, both in relation to the design of the technology tools and its features. Such challenges constitute the larger context that tools for people with chronic illness should address. The diversity of challenges reported

ranged from illness-specific challenges to more general everyday life challenges and are in line with previous literature [2,47].

Self-management programs and interventions (both online and offline) available today build on existing self-management models and are designed to address these known challenges. For instance, taking action is one of the main self-management skills defined in the self-management model by Lorig and Holman [3,48]. This includes developing mastering and coping mechanisms that support people in the process of changing their behavior (eg, making short-term action plans and performing them [49]). Other self-management skills are forming and keeping a well-functioning patient-provider partnership (defined in the same model by Lorig and Holman [3,48]) or building and utilizing better social support from family and peers [50]. However, as stated earlier, these strategies are most often implemented by emphasizing a person's deficits and by focusing their attention mainly on a person's problems and symptoms. Some examples of features implemented in technology-based self-management programs include: monitoring symptoms in an online symptom diary [51,52], teaching coping strategies to manage and lessen symptom burden [53,54], or providing training for improved collaboration between patient and care provider by facilitating joint discussions about symptoms and their management [55,56]. In line with a person-centered care approach, patients' resources and strengths are starting to receive more attention in the field of self-management [57,58]. However, few technology-based tools that support patients in mobilizing their strengths are available today [39,59]. Therefore, the results of the present study provide valuable insights from stakeholders regarding the potential use of technology to integrate patients' strengths as part of existing self-management programs, and to promote the process of creating better designed tools that also promote a person's potentials, values and resources. Ideas from the present study such as the *Task completer* and *Prioritizing app* presents two concrete examples of how patients' strengths could be integrated as part of self-management strategies for supporting patients to develop skills and take action. The app *Task completer* is not only helping the person to finish their tasks but also providing reminders to the user of his/her strengths to help him/her to remain motivated and to continue progress even in stressful situations. In the *Prioritizing app*, the system supports the user when making important choices and plans for the future by reminding him/her about his/her strengths, resources, and previous experience.

One other example proposed by the participants was how the patient-provider partnership and collaboration could be enhanced by integrating the topic of people's strengths and resources in the conversation. In this context, it was proposed that technology could be used as a facilitator to support patients, relatives, and/or caregivers in consultation settings to identify, share, and jointly reflect on their strengths, resources, and values and how they could be used for planning more successful self-management activities and action plans (*Empathy Simulator* system). In this manner, the consultation could be enhanced beyond discussions revolving around symptoms and problems and provide support for more holistic person-centered care.

The findings from this study also support the importance of cultivating social relations, which in previous literature were identified as highly relevant ingredients of self-management programs [60,61]. Participants in this study recognized and reported the importance of people from their environment as a strength and proposed different approaches for how technology could further deepen relationships. All of the six tool ideas from the workshop contain at least some form of support for social interaction, including a shared platform for communication with different people from patient's network, such as family, friends, doctors, and nurses (*User-controlled personalized hospital* idea), or creating a tool that promotes empathy and a common understanding between different parties (*Empathy Simulator* idea). Another example was the *Cheering squad* idea that included a one-way communication channel to the user, allowing others from the user's network to cheer him/her on by sending supporting messages but not requiring the user to send feedback or a response. For chronic patients this is a very important feature since, due to their illness and severe symptom burden, this group often experiences a lack of energy and this is one of the main reasons that directly influences the erosion of contacts and network participation [62,63]. In this manner, designing social interactions can keep some of the motivational and engaging outcomes typical of social features [64] while also creating a safe and controlled space that does not require extra work from the user.

The described examples present just some examples and overall concepts that should be further explored and developed to accommodate the potential contexts where they will be used, integrate in more detail the stakeholders' requirements and preferences, and build on knowledge from existing self-management models and interventions. The results of this study could be seen as an important initial step to guide the development of future research regarding the integration of personal strengths and resources in more advanced person-centered self-management programs and interventions.

Designing for Quality of User Experience and for Promoting Human Potential and Wellbeing

The design of technology to promote a positive user experience and engagement is one of the main principles of positive technology (*hedonic level*) [26,27]. Previous related research proposed that this could be accomplished by: using virtual reality for fostering and manipulating joy and relaxation [65,66], using videogames and serious games for inducing positive emotional states [30], providing positive and encouraging feedback [67], and using engaging design principles (such as personalization, tailoring to ambient information, and applying metaphors in visual design) to provide a better user experience and to make the technology more appealing, engaging, and fun [31]. Positive user experiences and engagement were also raised as important requirements in this study. Participants proposed interaction- and interface-specific features, such as providing positive and encouraging messages and feedback to the user, framing the content in a positive way, and using engaging design features, such as metaphors or visualization techniques.

In addition to promoting a positive user experience, supporting self-actualizing and meaningful experiences that promote

psychological wellbeing and human potential is one of the main principles of positive computing and an important pillar of positive technology (*eudemonic level*) [25-27]. Some previous research describing designing for meaningful and self-actualizing experiences include applying participatory design methods to explore how design could support autonomy, competence, and relatedness for young people living with asthma [68] or developing a mobile wellness-training app for people suffering from stress built upon the principles of acceptance and commitment therapy [69]. As the main theme of this study and the whole project was in line with this principle of supporting people in experiences that help them build on their potential, most of the ideas that participants proposed contributed to this overall goal. For example, the *Strengths treasure chest* idea that enabled users to easily add their personal strengths and receive reminders about them was suggested to provide boosts of positive emotions when the users were feeling down or under stress. Additionally, building upon and nourishing one's own personal strengths and resources as part of self-management coping strategies (supported by the ideas behind the *Prioritizing app* and the *Task Completer* idea) can be seen as a way to promote both mastering of chronic conditions and also as a way to generate and build upon positive experiences and emotions for the user. Furthermore, the *Empathy Simulator* idea proposed a technology-mediated reflection of the experiences and sensations of others, promoting better understanding and empathy.

The ideas created during the workshop should be seen as overall concepts that have the potential to be further adapted and expanded, using principles of positive computing and positive technology to increase positive user experiences and user engagement [31]. Some approaches that are proposed in the literature that could be applied in this and/or similar studies are, for example, implementing a flexible design that adjusts to different situations and user characteristics and including social and cognitive prompts to keep people engaged with technology (eg, praise, rewards, or reminders) [31].

Limitations

Although the number of participants was similar to the sample sizes reported in other related studies, the results were obtained as part of one workshop in one specific context. Additionally, the sample of participants was self-selected and some of the participants took part in earlier studies on personal strengths, which could have influenced participants' engagement and interest with the theme of the workshop and the methods that we used. The great variation in the participants backgrounds could be seen as a limitation since the number of each type of participant per group was not large. Also, not all groups had equal distribution of participants with the same backgrounds which could potentially have influenced lower engagement of participants who were underrepresented in the group; however, on the other hand, this could have the positive effect of generating a wider variety of ideas that incorporate stronger viewpoints from various types of stakeholders.

Mixing participants in heterogenous groups during group work activities could potentially have introduced power imbalance in the groups and affect participants' open participation and

engagement during workshop. For example, a health care provider is usually seen by patients as having a power role, and as a result, patients may not feel as comfortable reporting dissatisfaction or frustration with their health care providers and whole health care systems in the presence of other health care providers [70]. However, if organized in the right manner, heterogenous groups can be highly effective and constructive by letting the participants exchange stories and build on different knowledge and needs stemming from their different backgrounds and experiences [71]. Therefore, to minimize the potential limitations of heterogenous group work in our study, different measures were applied: the rules of conduct that promote joined work and cooperation were clearly defined at the start of the workshop; the group work and activities was designed to promote participation, collaboration, and sharing ideas; and facilitators were trained to facilitate openness and active participation of all participants.

Conclusions

In this study, we combined methods from participatory design, service design, and appreciative inquiry to jointly, with

stakeholders, explore the requirements and codesign ideas regarding the use of technology as a facilitator for mobilizing the personal strengths required for overcoming the everyday challenges of people with chronic illness. Combining these approaches enabled us to create a positive and open environment where participants were encouraged and challenged to explore new ways of thinking that went beyond merely addressing the requirements for using a new technology. It enabled them to create new ideas regarding how technology can be designed to help them build on their values, potentials, and strengths, and it supported them in focusing more on these in everyday life.

The presented ideas and user requirements, combined with the insights from relevant theories (eg, positive psychology, self-management models) and the related literature, can be used to guide and inform the further development of self-management tools that promote a more person-centered strength-based approach. The findings can also be used as a starting point for additional designs of positive participatory workshops, which focus on identifying and co-creating ideas to develop and design future innovative strengths-based interventions, further promoting user engagement and positive experience.

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Conflicts of Interest

None declared.

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Original Paper

Investigating Associations Between Changes in Mobile Phone Use and Emotions Using the Experience Sampling Method: Pilot Study

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Abstract

Background: The use of mobile phones has become, especially for young people, an integrated part of everyday life. Using the experience sampling method (ESM) may provide further insight on the association between mobile phone use and mental health.

Objective: The objective of this study was to examine associations between mobile phone use and subtle changes in mental state.

Methods: The ESM-based PsyMate app was installed on the mobile phones of 2 healthy 20-year-old participants. Over a period of 3 months, participants rated their mental states at 10 semirandom moments in the flow of daily life. Each assessment included present state emotions, environmental circumstances, and phone use.

Results: Multilevel regression analyses indicated that an increase in mobile phone use was associated with a small increase in negative affect (particularly feeling bored and feeling lonely; $P < .001$) and small decreases in positive affect ($P = .002$) and concentration ($P = .001$). Treating the data as 2 separate $N = 1$ studies revealed that the association with negative affect was present in both participants, whereas the associations with positive affect and concentration were evident in only 1 of the 2 participants.

Conclusions: This pilot study suggests that mobile phone use may be associated with person-specific and group-level changes in emotional state. A larger study is required to study these associations, possible causality, and factors driving underlying heterogeneity in the pattern of associations.

Trial registration: ClinicalTrials.gov NCT03221985; <https://clinicaltrials.gov/ct2/show/NCT03221985> (archived by WebCite at <http://www.webcitation.org/6zJnp61Wj>)

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KEYWORDS

mobile phone; experience sampling method; emotions; affect; concentration

Introduction

Given widespread use of mobile phones, research has been conducted to investigate possible side effects. For example,

mobile phone use is associated with cyberbullying [1] and slower response while driving [2]. Furthermore, mobile phone use may be excessive or even compulsive, which was coined as “problematic mobile phone use” [3]. At least 11 different

questionnaires have been used to test the construct of mobile phone use addiction [3-14], mostly based on criteria for dependence as described in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR) and now the DSM-5, which has comparable dependence criteria [15]. The psychological mechanism driving mobile phone addiction, dubbed nomophobia (the fear of being out of mobile phone contact), was proposed in 2014 [16]. The related fear of missing out (FoMO) was defined as “a pervasive apprehension that others might be having rewarding experiences from which one is absent” [17,18]. In addition to a possible addictive component, associations have been reported between mobile phone use and depression, anxiety, stress, and sleep problems [7,11,19-24]. Estimates of problematic mobile phone use across these different outcomes differ widely, ranging from 0% to 38% [25].

Problematic mobile phone use may be more prevalent in people who have certain personality traits [26]. Lower levels of self esteem were consistently associated with problematic mobile phone use across different studies [3,20,27,28]; higher levels of extraversion were associated with more frequent mobile phone use [3,29].

Although the above studies are examples of a growing body of work examining associations between mobile phone use and psychological constructs, the relation remains uncertain and research focusing on existing categories of psychopathology is inconclusive [30]. Therefore, in this pilot study, we addressed the more basic question of whether mobile phone use would impact daily life variation in core emotions, moving away from psychological constructs like personality traits or diagnostic categories. Given the highly dynamic process of mobile phone use, varying from moment to moment in daily life, the methodology used should be capable of capturing this dynamic process.

Studies in this area usually use traditional retrospective questionnaires that are associated with several well-known forms of bias and cannot capture dynamic variation of mental states associated with daily life phone use [31]. A data acquisition method which is relatively free of these kinds of bias is the experience sampling method (ESM) [32]. ESM is a valid and reliable method which can contribute to the understanding of the relationship between environmental phenomena and mental experience [33]. Another advantage of this method is the ability to detect possible subtle (unconscious) changes in affect in the context of daily life in relation to mobile phone use. There are also other mobile phone apps using ESM [34,35]. A recent Australian study examined the use of such an app for monitoring well-being in context and in real time, including personalized feedback [34].

In order to pilot the use of ESM in the context of mobile phone use, an ESM pilot study (N=2) was conducted in order to examine associations between mobile phone use and subtle changes in mental states. In ESM studies, participants are beeped at semirandom moments to record their in-the-moment emotional and behavioral states several times during the day (usually 6 to 10 times) [33]. In addition, the actual circumstances (where and with whom a participant is) are also rated. This

dynamic repeated measure design allows for prospective modeling of behavioral and affective dynamic patterns during the day as well as for examining associations with context [33].

Guided by previous literature, the following hypotheses were postulated: (1) a general increase of phone use will be associated with higher scores on negative affect, lower levels of positive affect, and lower levels of concentration [21,36] and (2) whenever a person cannot engage in mobile phone use, increased levels of negative affect will ensue.

Methods

Participants

Recruitment took place in September 2016 using posters distributed at Maastricht University Medical Centre in Maastricht, The Netherlands. Inclusion criteria were aged 20 to 25 years, healthy, good understanding of the Dutch language, and mobile phone use. Exclusion criteria were a psychiatric diagnosis and pregnancy. Two healthy, female volunteers, both aged 20 years and students at Maastricht University, were enrolled. Participants were frequent mobile phone users who were used to carrying a mobile phone with them at all times and did not experience their phone use as problematic. Participants were compensated €150 (US \$177).

Procedures

Briefing

During the briefing, participants were helped to download the ESM PsyMate app on their mobile phone (from the App Store or Google Play). They were instructed on how to use the app. It was stressed that participants should not change their daily life routines; they were asked to carry their mobile phone with them at all times in order to miss as few beeps as possible. In addition to the ESM scheme, participants completed separate morning and evening questionnaires. On the morning questionnaire, before the first beep of the day, participants were asked to answer some questions about the quality of sleep and the location of the mobile phone in the past night ([Multimedia Appendix 1](#)). In the evening, after the last beep, some additional questions were asked about the use of the PsyMate app and its possible impact on the participant ([Multimedia Appendix 1](#)). Morning and evening questionnaires were presented to the participants every day of the study. At all times during the study, a researcher (SR) was available for questions. After the briefing session, the study period of 3 months started.

Data Collection

In order to collect ESM data, the PsyMate app [37] was installed on the personal mobile phone of participants. Data collection took place over a period of 3 months. The PsyMate app emitted 10 beeps per day at semirandom intervals in each of ten 90-minute time blocks between 7:30 am and 10:00 pm. The app worked independently of internet connectivity. After each beep, participants were asked to answer the ESM items as soon as possible (thus capturing information about the in-the-moment state). Items should be answered within 15 minutes in order to safeguard real-time assessment [38]. There were 4 positive affect ESM items (cheerful, mentally fit, relaxed, and globally

feeling well), and 6 items indexed negative affect (irritated, bored, lonely, gloomy, stressed, and worried). Next, current context and activities (physical activity, daily life activities, persons present) as well as physical items (tired, level of concentration, and pain) were rated. Finally, mobile phone use since the last beep (frequency, frustration when not able to use the mobile phone) was measured. An overview of ESM items is presented in [Multimedia Appendix 1](#). The affect items were rated on a 7-point Likert scale, ranging from not at all to very much. Mobile phone use was rated as follows: at each beep, the participant was asked to give an estimate of the frequency of mobile phone use between the last beep and the present beep. Zero represents no use, 1 represents once, 2 represents 2 to 5 times, 3 represents 5 to 10 times, and 4 represents more than 10 times. Over the total period, participant 1 had a mean between-beep mobile phone use of 1.72 (SD 1.06) and participant 2 a mean of 0.81 (SD 0.98).

After the 3-month ESM period, a debriefing session was held with both participants. Participants were asked to what degree the past 3 months were representative of their daily life and to what extent PsyMate had interfered with their normal routines.

Data Reduction

App data were directly transferred to an internet cloud when internet connectivity was available. When there was no connection to the internet, data were temporarily stored on the mobile phone. The data of both participants were directly extracted from the cloud and imported in an SPSS Statistics (IBM Corp) datafile.

PsyMate studies have shown that positive and negative affect (PA and NA, respectively) items can be reliably (Cronbach $\alpha > 0.7$) and consistently [33] scaled into 2 factors: a PA and an NA factor.

Analyses

Data on momentary mental state at beep moment t and level of phone use between the last beep ($t-1$) and the present (t) were retrieved in order to model affect parameters as the dependent and phone use as the independent variable in the analyses.

Statistical analyses were conducted with SPSS 24.0 (IBM Corp) [39]. The data were hierarchically structured, since multiple assessments were performed and clustered within days that in turn were clustered within participants. Multilevel random regression analyses were used to test the relationship between mobile phone use and affect, taking the hierarchical structure into account. In order to model time effects, beep number and beep time interval were incorporated as covariates in all analyses. In order to correct for interdependence of the data over successive beeps, an autoregressive (AR1) covariance structure was selected. Since there were 2 participants, allowing for investigation of person-specific patterns, data were also analyzed as 2 $N=1$ studies. To this end, linear regression analyses, using affect as dependent parameter and mobile phone use as predictor, were performed separately for participant 1 and 2. In these regression analyses, beep number and beep time interval were also incorporated as covariates. A 2-sided $P < .05$ was considered statistically significant.

Ethics Statement

Approval was obtained from the medical ethics committee of the Academic Hospital Maastricht on May 19, 2016. All participants provided written informed consent.

Results

Participant 1 used the PsyMate app during 96 days and responded to 399/960 beeps (41.6%). Thus, on average 4.2 out of 10 beeps each day were completed. Participant 2 completed 506/930 beeps (54.4%) or 5.4 beeps out of 10 each day. Guided by previous work with this ESM scheme, a response of 30% to the ESM beeps was considered the minimum for inclusion in the analysis [38].

In order to model change in affect from beep to beep in relation to mobile phone use, an *a priori* limit was set on days with at least 4 completed beeps. In participant 1, 62 of 96 days met this requirement (65% of all the days), with an average of 5 completed beeps per day. In participant 2, 78 out of 93 days (84% of all days) met the requirement, with an average of 6 beeps per day. Setting the *a priori* limit caused an ESM data reduction of 19% in participant 1 and 8% in participant 2.

[Table 1](#) shows that responding to PsyMate beeps generally was not rated as impacting mood or normal phone use. One change was that normally participants would not carry their phones with them at all times, but because of the study they now did so. Furthermore, participants noted that it was tempting to take a look at their phone after a PsyMate beep some of the time. A difference in response between the 2 participants can be noted in FoMO: participant 1 experienced this feeling more often than participant 2.

In [Table 2](#), an overview of the results of multilevel (results of the 2 participants together) and linear (results per participant) regression analyses is provided. The frequency of mobile phone use between the previous and the current beep was modeled as predictor of current affect variables. In the combined dataset, higher levels of mobile phone use were associated with more NA and less PA. Decomposing NA and PA into their separate constituents revealed that bored and lonely stood out in strength of association among the NA items, whereas cheerful, relaxed, and globally feeling well stood out among the PA items. Item concentration was also negatively associated with higher levels of phone use. Analyzing participant data separately revealed that the association between frequency of phone use and NA was consistent across participants. The association with PA was consistent across the 2 participants, although only significant in participant 1. Cohen d was 0.14 for negative affect and 0.11 for positive affect.

The second hypothesis, that when a participant was not allowed to or capable of using a mobile phone, she would report more negative affect parameters, could not be tested due to a lack of data. For example, participant 1 only reported no phone use in 56 beeps, of which only 8 could be attributed to being permitted to use a mobile phone.

Table 1. Results from evening questionnaires of participant 1 (n=52) and participant 2 (n=84).

Question	Participant 1, mean (SD)	Participant 2, mean (SD)
Responding to PsyMate beeps has influenced my mood.	1.54 (1.24)	1.82 (0.88)
Without PsyMate, I would have done other things today.	1.12 (0.83)	1.02 (0.153)
After responding to PsyMate beeps, I used my mobile phone.	2.98 (1.85)	4.11 (1.73)
PsyMate has influenced my normal phone use today.	2.17 (1.32)	1.44 (0.91)
Today, I experienced fear of missing out.	3.62 (1.57)	1.39 (0.70)

Table 2. Estimates of mobile phone use and affect.

Characteristic	Participant 1 and 2		Participant 1		Participant 2	
	Beta coefficient of mobile phone use	<i>t</i> value	Beta coefficient of mobile phone use	<i>t</i> value	Beta coefficient of mobile phone use	<i>t</i> value
Negative affect	0.47	4.07	0.67	2.54	0.33	2.62
Irritated	0.07	1.71	0.06	0.72	0.08	1.94
Bored	0.22	5.37	0.31	3.87	0.14	3.30
Lonely	0.12	4.60	0.22	3.89	0.05	1.76
Sadness	0.05	1.44	0.05	0.62	0.03	0.66
Stressed	0.04	1.19	0.01	0.09	0.01	0.15
Worried	0.03	0.88	0.03	0.43	0.04	0.76
Positive affect	-0.29	-3.09	-0.41	-1.90	-0.08	-0.69
Mentally fit	0.00	0.14	0.04	0.67	0.02	0.74
Cheerful	-0.10	-2.72	-0.16	-2.16	-0.04	-0.85
Relaxed	-0.09	-2.39	-0.19	-2.58	-0.01	-0.27
Globally well	-0.11	-3.37	-0.09	-1.38	-0.06	-1.67
Other						
Tired	0.05	1.18	-0.06	-0.69	0.06	0.89
Concentrating	-0.13	-3.26	-0.26	-3.54	-0.05	-0.97

Discussion

Principal Findings

The main findings of this study: an increase in mobile phone use is associated with a small increase in NA (particularly feeling bored and feeling lonely) and small decreases in PA and concentration.

In this N=2 pilot study, participants answered questions in the PsyMate app about their mental state and mobile phone use over a 3-month period. The goal was to investigate whether an association between the two could be demonstrated as a prelude to a larger study. Guided by previous work, it was hypothesized that a general increase of phone use would be associated with higher scores on NA, lower levels of PA, and lower levels of concentration [21,36]. The results show that these hypotheses were confirmed. Although all of the NA items showed a positive association, the NA items lonely and bored stood out. Based on the literature, it was also expected that other components of NA such as sadness would be significantly associated with mobile phone use. This item was directionally associated with mobile phone use but below the conventional limit of significance. The

significant decrease of PA after an increase of phone use was seen in 3 out of 4 components of PA. While the association with NA was replicated across the 2 participants, the association with PA and concentration appeared to be person-specific. Person-specific moderators may play a role, such as level of self-esteem and extraversion that have been linked to problematic phone use, as well as other personality traits [40]. In the current analysis, participant 1 reported more FoMO. The experience of FoMO may also underlie person-specific results in the association between mental state and mobile phone use.

It was not possible to investigate the hypothesis that not being permitted to use a mobile phone would result in higher levels of NA due to a lack of data resulting in lack of variability.

This study indicates that in-the-moment associations between mobile phone use and affect may be subtle and difficult to report using retrospective reports from cross-sectional questionnaires. Participants in this study appeared to differ in their global and in-the-moment reports. If the outcomes of this study can be replicated in a larger study population, combining group-level and person-specific approaches of analysis, it may be easier to

develop person-specific and evidence-based approaches for problematic mobile phone use.

Limitations

This was a pilot study and results must be considered preliminary. A larger study is required to further study the associations described in this analysis. Second, based on the results from [Table 1](#), it may be hypothesized that the use of a mobile phone ESM app to collect the data may have influenced mobile phone use to some extent, with a potential for bias. To what degree this may impact the results has to be investigated in future studies. Third, in this pilot the level of mobile phone use (in minutes) was estimated at each beep by the participants themselves. It would have been more accurate to also measure

phone use digitally in duration and type (distinguishing between email and social media, for example).

Conclusion

In future research, the above considerations need to be taken into account. In addition, there are some other recommendations. First, it would be instructive to investigate the effects of mobile phone use on the quality of sleep, as an association was suggested in previous studies [21,36]. In this study, the questionnaire was included but analyses could not be performed due to lack of variability in the data. Second, as observed in the evening questionnaire of this ESM pilot, FoMO can vary greatly between individuals and it would be desirable to add this question to the beeps.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PsyMate questionnaires.

[[PDF File \(Adobe PDF File\), 46KB - formative_v2i1e12_app1.pdf](#)]

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Abbreviations

ESM: experience sampling method

FoMO: fear of missing out

NA: negative affect

PA: positive affect

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Original Paper

A Simple Pre-Exposure Prophylaxis (PrEP) Optimization Intervention for Health Care Providers Prescribing PrEP: Pilot Study

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Abstract

Background: Pre-exposure prophylaxis (PrEP) has been shown to be highly effective for the prevention of HIV in clinical trials and demonstration projects, but PrEP uptake and adherence outside of these settings in the United States has been limited. Lack of knowledge and willingness of health care providers (HCPs) to prescribe PrEP is an important barrier to implementation.

Objective: The objective of this study was to describe and examine the feasibility and acceptability of a PrEP Optimization Intervention (PrEP-OI) targeted at HCPs. The ultimate purpose of this intervention was to increase PrEP uptake, adherence, and persistence among those at risk for HIV acquisition.

Methods: This intervention included the following: (1) a Web-based panel management tool called PrEP-Rx, which provides comprehensive HIV risk assessment, automates reminders for follow-up, and reports patients' history of PrEP use; and (2) centralized PrEP coordination by a clinical support staff member (ie, the PrEP coordinator) who can identify individuals at risk for HIV, provide medical insurance navigation, and support multiple HCPs. Feasibility was evaluated based on HCPs' ability to log in to PrEP-Rx and use it as needed. Acceptability was assessed via individual formative qualitative interviews with HCPs after 1 month of the intervention.

Results: The intervention was feasible and acceptable among HCPs (N=6). HCPs identified system-level barriers to PrEP provision, many of which can be addressed by this intervention. HCPs noted that the intervention improved their PrEP knowledge; increased ease of PrEP prescription; and was likely to improve patient engagement and retention in care, enhance communication with patients, and improve patient monitoring and follow-up.

Conclusions: Given the critical role HCPs serve in disseminating PrEP, we created an easy-to-use PrEP optimization intervention deemed feasible and acceptable to providers. Further research on this tool and its ability to impact the PrEP continuum of care is needed.

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KEYWORDS

pre-exposure prophylaxis; PrEP; health care providers; HIV; technology; panel management

Introduction

Pre-exposure prophylaxis (PrEP) has been shown to be highly effective for the prevention of HIV in randomized clinical trials [1-6] and demonstration projects [7-9], but PrEP uptake in the United States has not been concomitant with need [10-12]. Despite data indicating nearly 80,000 individuals starting PrEP by the end of 2015 [13], the US Centers for Disease Control and Prevention (CDC) estimates that there are over 1.2 million adults in the United States at substantial risk for HIV acquisition [14]. Identified barriers to PrEP implementation include the individual's awareness of and willingness to take PrEP and their access to health care and the knowledge and willingness of health care providers (HCPs) to prescribe PrEP [10,15-20]. The prevention of new HIV infections remains a critical public health priority, and PrEP is an essential [21], yet underused, component of the HIV prevention toolkit. As HCPs are important gatekeepers for biomedical HIV prevention efforts in clinical settings and provider knowledge and self-efficacy are important predictors of offering testing [22,23] and prevention modalities, HCPs require support and guidance to optimize the clinical and public health impact of PrEP.

Numerous surveys have been conducted to evaluate HCPs' knowledge of PrEP, barriers to prescribing PrEP, and real-world challenges [10,12,19,20,24-28]. In one survey of Emerging Infections Network members in the United States and Canada [12], only 9% had provided PrEP, and despite the availability of comprehensive guidelines from the CDC [29-32], PrEP practices were variable. When physicians who had indicated that they would not provide PrEP were asked about their barriers to prescribing this medication, 77% stated that they worried about adherence and the risk for future resistance, 57% were concerned about cost and reimbursement issues, 53% did not want to use potentially toxic drugs in healthy persons, and 53% felt there was insufficient evidence for the efficacy of real-world PrEP. A recent paper examined family planning providers' knowledge of and attitudes toward PrEP [17]. Despite the CDC's definition of HIV prevention as a core family planning service, the authors noted that only 38% correctly defined PrEP, 37% understood the effectiveness of PrEP, and only 36% of respondents consulted PrEP guidelines. Most surveys have concluded that more education, provision of guidelines for real-world PrEP delivery, and interventions are needed to provide accurate data and optimize PrEP implementation [10,12,19,20,24,25,27] nationwide. In a recent national survey from 2009 to 2015, only 66% of primary care clinicians were aware of PrEP, although, once defined, 91% indicated a willingness to prescribe PrEP for patients at risk for HIV and expressed an interest in being educated further about PrEP [33].

A descriptive report on the early experiences with PrEP uptake and delivery in San Francisco identified the following priority steps for HCPs to address PrEP delivery barriers and to maximize public health impact: (1) increase PrEP knowledge among HCPs and (2) expand PrEP access by training HCPs and

developing tools to facilitate PrEP delivery in clinical practices [34]. Moreover, based on the framework of the PrEP care continuum [35], increasing PrEP uptake will require HCP education, tools to assess sexual risk, and systems to minimize provider burden. On the basis of these suggestions, innovative and effective approaches are needed to support PrEP implementation by HCPs regardless of their level of experience.

Therefore, we sought to develop a PrEP Optimization Intervention (PrEP-OI) targeted at HCPs with the goal of ultimately improving the PrEP care continuum. PrEP-OI includes the following: (1) an integrated Web-based panel management tool, called PrEP-Rx, which provides structured HIV risk assessment for individuals of all genders and HIV risk factors, automates reminders for laboratory testing and follow-up appointments, and reports patients' current and history of PrEP use; and (2) centralized PrEP coordination overseen by a clinical support staff member (referred to as the PrEP coordinator) who can support multiple HCPs and identify individuals at high risk for HIV through various methods, including structured behavioral surveys, direct patient contact, or by reviewing registries for sexually transmitted infections. Here we describe PrEP-OI and the results of a pilot study to examine its feasibility and acceptability among HCPs prescribing PrEP.

Methods

We developed PrEP-OI (PrEP-Rx and PrEP coordinator) with direct input from HCPs and conducted a pilot study over 1 month to examine intervention feasibility and acceptability in a San Francisco clinic offering PrEP. Our interdisciplinary team consisted of HIV researchers from the University of California, San Francisco (UCSF), Center for AIDS Prevention Studies (CAPS), HIV clinicians from San Francisco General Hospital's HIV clinic (Ward 86), and technology design/development experts (the Information Services Unit) from UCSF. We received funding from the UCSF Center for AIDS Research (grant number P30 AI027763) to design and develop PrEP-Rx and received approval from the UCSF Institutional Review Board to conduct our pilot study.

Description of the Pre-Exposure Prophylaxis Optimization Intervention

PrEP-Rx was created using a Salesforce backend, with the potential to integrate with electronic health record (EHR) for laboratory values and demographic data, and a Qualtrics survey was used to assess risk among potential PrEP users (Figure 1). The hypothetical clinic workflow (Figure 2) demonstrated the need for 3 main components: (1) a mechanism to comprehensively assess HIV risk for individuals of all genders and HIV risk factors; (2) automated reminders for upcoming and overdue laboratory monitoring and follow-up visits to assess adherence and adverse effects and to perform risk reduction counseling; and (3) a website with PrEP educational material (eg, guidelines, publications, conference proceedings) for the ongoing education and training of HCPs.

Figure 1. Architecture of PrEP-Rx.

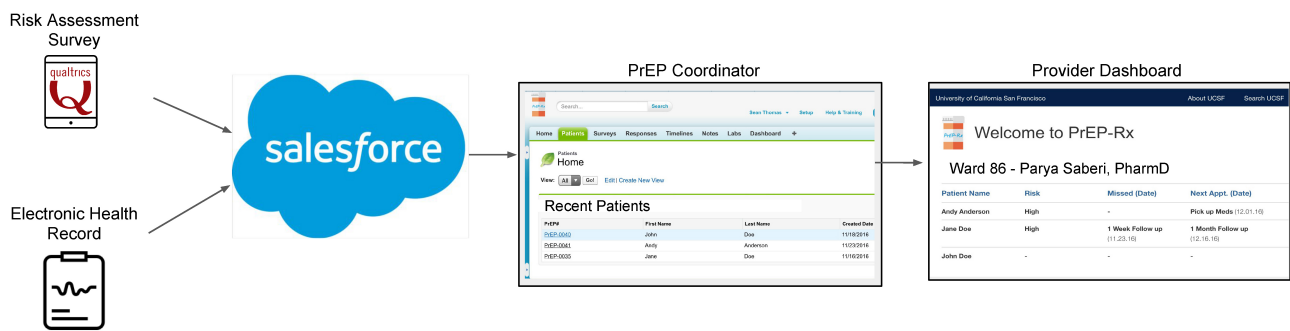
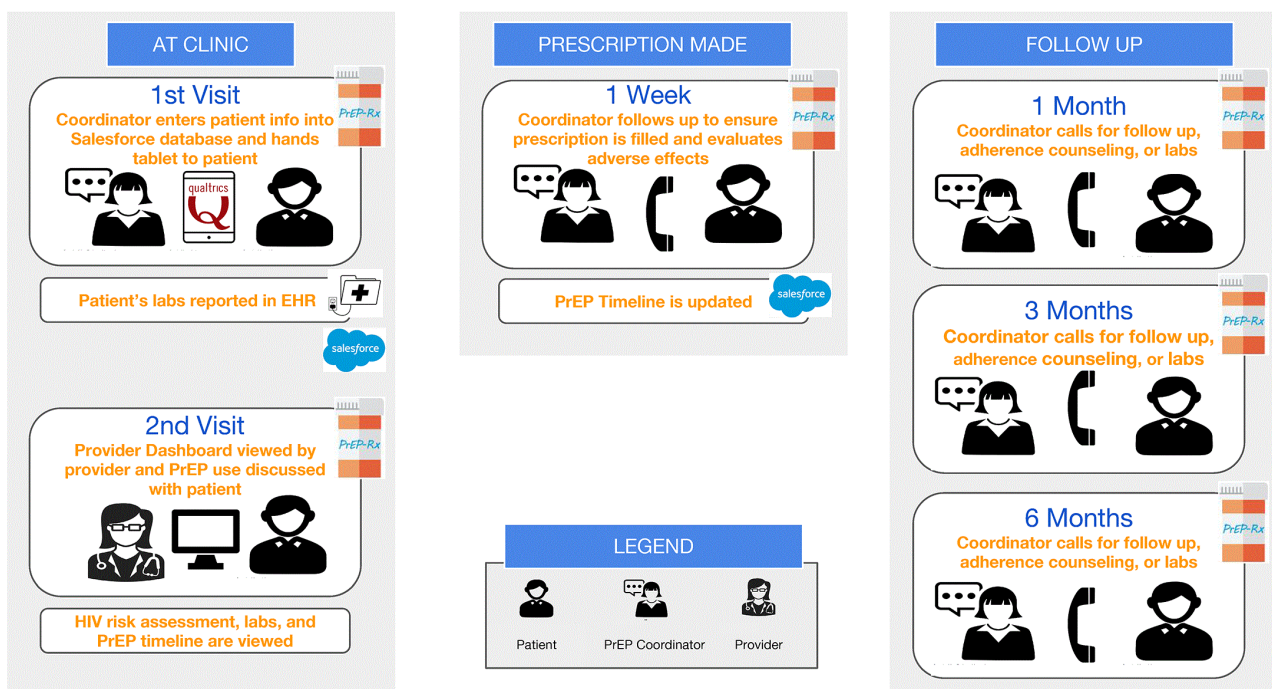


Figure 2. Hypothetical Clinic Work Flow.



A risk assessment questionnaire was created by Drs Saberi and Scott using available published data to capture an individual’s risk profile. The CDC risk index [36] was used for men who have sex with men (MSM). With input from behavioral risk assessment experts at the UCSF Transgender Centers of Excellence and CAPS, we modified this assessment to include questions specific for transgender men and women. Next, using data from the CDC guidelines, we added risk assessment questions for heterosexual men and women [29], and with information from a publication by Smith et al [37], we added questions regarding injection drug use (IDU) risk. In the absence of a uniform rating scale for MSM, IDU, and heterosexual sex, we modified this tool to include 3 tiers of risk: (1) low, (2) medium, and (3) high (Table 1). The CAPS Community Advisory Board reviewed all questions for clarity and cultural appropriateness. We programed this questionnaire into Qualtrics

and integrated the responses with the Salesforce database (Figure 1).

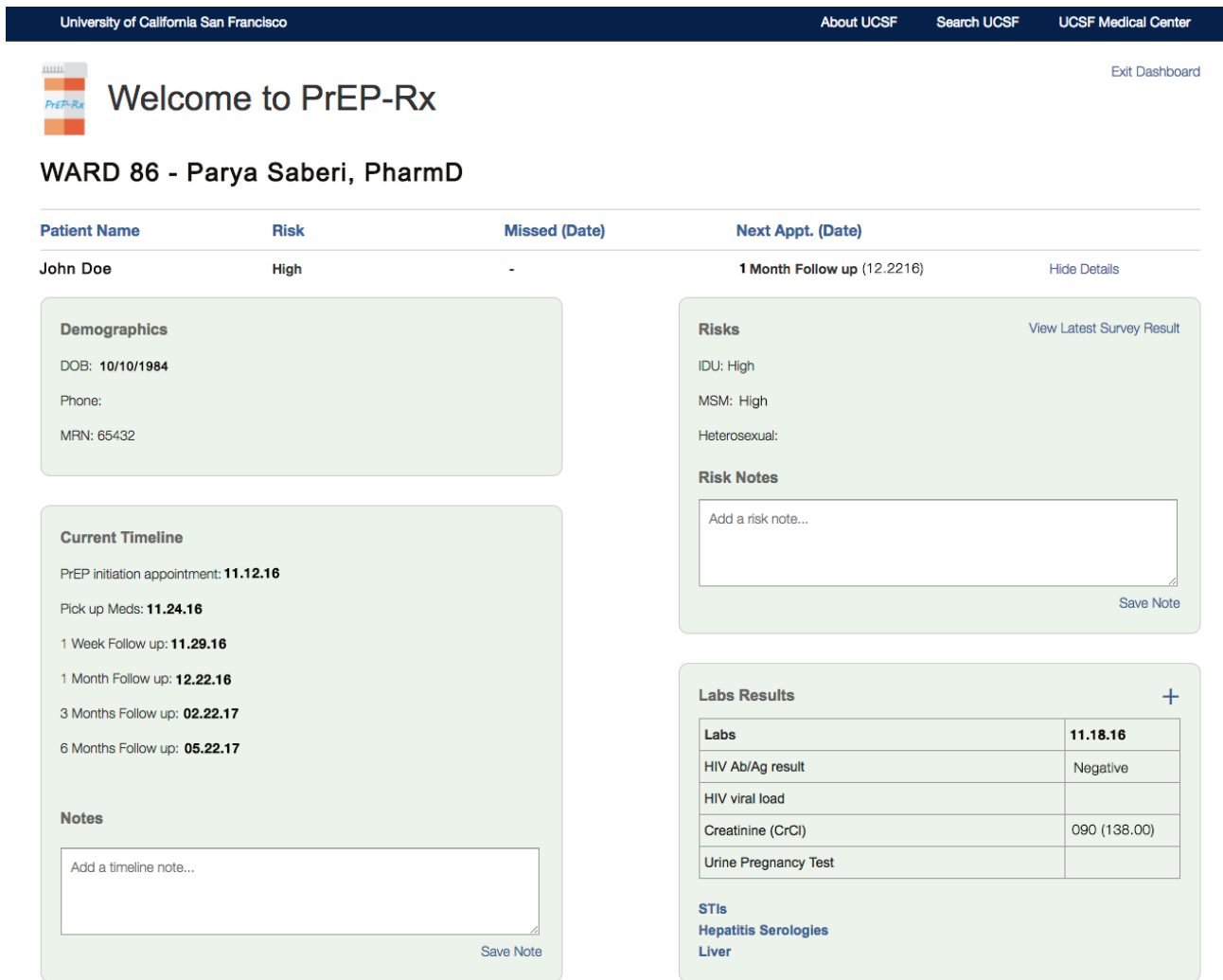
The provider dashboard is a method of summarizing patients’ pertinent information (ie, HIV risk category, prior PrEP use, and laboratory data) in one simple format for the HCP (Figure 3). This dashboard consists of 4 components (in separate boxes) for each patient: (1) demographics (including patient’s name, medical record number, date of birth, and telephone number); (2) PrEP timeline(s) (summary of current and prior PrEP periods of use, including dates of initial PrEP appointment, follow-up appointments, laboratory visits, and reasons for prior PrEP discontinuations, if applicable); (3) risk categories (summary of risk based on the risk assessment questionnaire and the risk assessment category); and (4) laboratory data required for PrEP initiation (including the last 2 laboratory results on file). The HCP can type a note in the *PrEP Timeline* and *Risk* sections to reference in future follow-up visits.

Table 1. Three tiers of HIV risk in PrEP Rx.

Risk	Men who have sex with men	Injection drug use	Heterosexual sex
High risk	<ol style="list-style-type: none"> Age: 18-28 years 10 male sex partners in the past 6 months Any receptive anal sex with a man without a condom >1 HIV+ or HIV status unknown male partner in the past 6 months Any commercial sex work in the past 6 months Any sexually transmitted infection If 2 or more medium-risk factors 	<ol style="list-style-type: none"> Age: <30 years If NOT in methadone maintenance program in the last 6 months If composite injection score (inject heroin, inject cocaine, share cooker, share needles, visit shooting gallery) >1 If 2 or more medium-risk factors 	<ol style="list-style-type: none"> 10 opposite-sex sex partners in the past 6 months (For men only) Any sex without a condom with a woman at high risk for HIV (eg, IDU^a) or HIV+ or HIV status unknown (For women only) Any sex without a condom with a partner at high risk for HIV (eg, IDU or bisexual male) or HIV+ or HIV status unknown Any commercial sex work in the past 6 months If 2 or more medium-risk factors
Medium risk	<ol style="list-style-type: none"> Age: 29-40 years If composite injection score (inject heroin, inject cocaine, share cooker, share needles, visit shooting gallery) =1 1 HIV+ or HIV status unknown male partner in the past 6 months Use of methamphetamine in the past 6 months >1 insertive anal sex without a condom with a man who was HIV+ or HIV status unknown unknown Heavy alcohol use (5-7 days a week and drinks per day \geq4 or 1-7 days per week and \geq6 drinks per day) Use of cocaine/crack or poppers 	<ol style="list-style-type: none"> Age: 30-39 years 6-10 male partners in the past 6 months 	<ol style="list-style-type: none"> 6-10 opposite-sex sex partners in the past 6 months Any sexually transmitted infection
Low risk	Everyone else	Everyone else	Everyone else

^aIDU: injection drug use.

Figure 3. Provider Dashboard.



The PrEP coordinator is responsible for supporting both HCPs and patients in this intervention. The PrEP coordinator enters the patient’s medical record number into PrEP-Rx, which pulls demographic information and laboratory data from the clinic’s EHR (Figure 1). During the patient’s visit with the PrEP coordinator, he/she is handed a tablet to respond to the risk assessment questionnaire. On the basis of the patient’s responses, HIV risk categories are generated and displayed on the provider dashboard, along with the patient’s demographics, laboratory data, and current and/or prior PrEP history (ie, PrEP timeline). The patient then attends an appointment with the HCP where they can discuss the patient’s risk and laboratory test results, desire to initiate PrEP (which can be recorded in the notes section of the provider dashboard), and any questions or concerns about PrEP. On the basis of the PrEP prescription date, PrEP-Rx auto-generates a list of dates for follow-up laboratory tests and appointments based on CDC guidelines. As a result, the PrEP coordinator receives notifications via emails about upcoming or past due visits, allowing her/him to notify the patient and mark these tasks as “done” upon completion.

Finally, to create a system for the ongoing education of HCPs, we created the PrEP-Rx website to host the PrEP knowledge base. The purpose of the knowledge base is to provide access to the most recent publications, ongoing PrEP research, and

conference proceedings. All components of PrEP-Rx are built in an environment that is compliant with the Health Insurance Portability and Accountability Act and meet the highest level of security requirements.

Pilot Study

We conducted a 1-month pilot study to evaluate the feasibility, acceptability, and usability of PrEP-OI at a publicly funded safety-net clinic in San Francisco offering PrEP. Feasibility was evaluated based on HCPs’ ability to log in to PrEP-Rx and use it as needed (based on Google Analytics). The acceptability of PrEP-Rx was assessed in one-on-one formative qualitative interviews with providers who had used PrEP-Rx for 1 month along with PrEP coordination. The main goal of these formative interviews was for providers to give feedback and to assist us in optimizing PrEP-Rx through our iterative design. Questions included the following: (1) experiences with PrEP-Rx (ease/difficulty with initial login and navigation, glitches, and opinions on its interface), (2) how it may have impacted the HCP’s knowledge and ability to prescribe PrEP, (3) experience with the PrEP coordinator, (4) what aspects of PrEP-OI HCPs found favorable and unfavorable, (5) how this intervention can be further streamlined to fit within their workflow, (6) whether they would recommend this intervention to their peers, and (7) whether they would consider continuing to use it in their clinical

practice. Usability was evaluated based on a modified System Usability Scale [38], which evaluates the HCP's desire to use PrEP-Rx, complexity/ease of use, need for technical support, confidence with use, and speed of learning to use PrEP-Rx. Items are scored on a scale of 1-5 (strongly disagree to strongly agree) and summed to provide an overall score ranging from 0 to 100.

Formative qualitative interviews were audio-recorded, transcribed verbatim, and summarized by the first author. Broad themes were then identified and entered into a matrix using Microsoft Excel where columns and rows represented themes and participants, respectively, to facilitate data analysis and the identification of patterns in the distribution of themes [39]. The first author categorized each interview using this matrix, and themes were discussed with the second, third, and last authors. On the basis of these discussions, modifications to the design of PrEP-Rx were identified.

Results

A total of 6 HCPs gave us feedback on their experience with PrEP-OI after 1 month of use in December 2016. HCPs were physicians 83% (5/6) and nurse practitioners 17% (1/6), female 67% (4/6), white 50% (3/6), working in an HIV clinic 100% (6/6), with a mean of 13 years (range 4-17 years) of experience providing care for individuals living with HIV. Approximately 67% (4/6) and 33% (2/6) provided HIV care for 20-49 and greater than or equal to 50 patients living with HIV, respectively. Of the HCPs, 2 (33%) did not have an active PrEP patient at the time of the interview, 3 (50%) were providing PrEP to 1-9 patients, and 1 (17%) was providing PrEP to 10-19 patients.

Using the System Usability Scale, HCPs gave PrEP-Rx a score of 94.6 (standard deviation 6.4). This meant that they strongly agreed that they (1) would like to use PrEP-Rx, (2) thought it was easy to use and did not need to learn a lot before getting started, (3) found the functions well integrated and consistent with the goals of the project, and (4) felt confident using PrEP-Rx without technical support.

The initial meeting with each HCP to describe the purpose of PrEP-Rx, to ensure ability to log in, and to answer any questions took approximately 20 min. All HCPs stated that their initial log in was easy and fast and that the use of a single sign-on service made it easy for them to log in without needing to remember an additional username and password. Of the providers, 1 had difficulty with initial log in due to the use of an old Web browser version. On the basis of Google Analytics, during the 1 month of use, users had 74 PrEP-Rx sessions, and the average session duration was 6:08 minutes. None of the users contacted us during the 1 month of the pilot about inability to log in, glitches, or problems accessing their dashboard.

In one-on-one formative qualitative interviews, HCPs discussed barriers that they had experienced in providing PrEP and gave constructive feedback on improvements to PrEP-Rx. Barriers were categorized into patient-, system-, and societal-level and

summarized in Table 2. HCPs identified the biggest challenge as missed medical visits by patients on PrEP.

HCPs stated that the PrEP-Rx tool is easy to use (HCPs #1, #2, and #3), "clean" (HCPs #1 and #3), "intuitive" (HCP #3), "soothing" (HCP #6), and organized using "boxes so you know where to look for stuff" (HCP #1).

...clean, clear, organized in a manner which I expect to see things, not a lot of wasted space... [HCP #3]

They liked the simple look of PrEP-Rx, stating "I dislike websites that are too slick" (HCP #2).

HCPs unanimously reported that PrEP-Rx has the potential to improve their level of information regarding PrEP, capacity for PrEP provision, and/or motivation to prescribe PrEP. Table 3 summarizes HCPs' statements of the areas that PrEP-OI could impact.

HCPs requested the following modifications to PrEP-Rx: (1) in the Demographics section, the addition of patient's email address and a demographics notes section; (2) in the PrEP Timeline section, addition of the date that the PrEP prescription was written (if different from the initial PrEP appointment); (3) in the Laboratory section, the permanent display of the baseline laboratory values (ie, before PrEP initiation), information about laboratory normal ranges or cutoffs for PrEP prescription, and a laboratory notes section; (4) in the Risk Assessment section, addition of guidance around PrEP medication dosing frequency and number of refills to prescribe upon PrEP initiation and availability of the risk assessment questionnaire in Spanish; (5) on the PrEP-Rx website, addition of pivotal PrEP studies and educational handouts or information that the HCP can give to patients to answer questions (eg, what is PrEP and why is it being prescribed, how is PrEP taken, what to do in case of intolerance, and who to call in case of emergencies); and (6) addition of a new section to track PrEP adherence and persistence.

None of the HCPs had any major concerns regarding the privacy and security of the data; all wanted to continue using PrEP-Rx, and would recommend it to other HCPs and for use in other countries.

I would love to have more opportunity to use it...things like this will help us overcome a lot of limitations in our current system, so I'd love to continue using it. [HCP #6]

I've been thinking in terms of PrEP roll out in places where Internet access is challenging...so there's so much happening in terms of more countries approving PrEP, like Kenya and South Africa. If you think of, in terms of clinics that are already so over-burdened, and what can be helpful for providers, even if it's a lay health worker who is asking questions on a tablet so by the time they get to the provider...I can see it being translatable on a tablet in other countries. [HCP #6]

Table 2. Barriers to the provision of pre-exposure prophylaxis as identified by health care providers.

Category and subcategory	Example quotes
Patient-specific	
Lack of PrEP ^a information or misinformation, especially in monolingual Spanish-speaking patients or immigrants	<i>Uptake in mono-lingual Spanish-speaking patients is very low. It's a hard concept to grasp in terms of: "if I'm not sick, why should I take a pill?" [HCP^b#1]</i>
Patients less concerned about risk of HIV acquisition due to being in a long-term partnership without HIV transmission from seropositive partners	<i>...for other partners of patients of mine, who have chosen not to start, there is some feeling of perhaps being at lower risk because of long-term partnerships and no transmission so far either through suppressed viral load, condoms, or both... [HCP #6]</i>
PrEP nonadherence, nonpersistence, and loss-to-follow-up possibly due to mental health issues, substance use, food insecurity, or homelessness	<i>...potential PrEP clients are on the highly vulnerable end of the spectrum. Several of them who were scheduled to see me for PrEP evaluation never showed up and a number, who showed up for the first visit, never came back for follow-up. [HCP #2]</i> <i>...getting them in to their second visit, one-month visit and three-month visit is challenging. They are first eager but then follow-up is problematic. It may be due to substance use. [HCP #4]</i>
System-specific	
Fractionated medical coverage, especially in those on Medi-Cal and with younger patients	<i>We have a lot of unknowns...We have a lot challenges from an operational public health stand point like how do we keep people accessing PrEP regardless of where they are. Every door should be right door, so people don't lose access to PrEP. [HCP #3]</i> <i>So, if someone has insurance, they have to renew it, particularly if they have Medi-Cal, I believe every 6 months. So, they often will receive a letter and if they don't respond to that letter, they're just dropped. So, they don't really realize what has happened before it's too late. Some pharmacists are great and they'll figure out a bridge while we figure out the insurance, but in many cases people will go without PrEP for weeks to months while we figure out a way to get the insurance back up. So, there's the hassle factor of reinitiating PrEP that for a lot of people is a big barrier. [HCP #3]</i>
HCPs not addressing PrEP or HIV risk	<i>...if you're a providers in a primary care center or another clinic, do they address PrEP with their patients? and I think not in many cases...some of them don't know about it, even though it's been available...it's one more thing you need to deal with and when you have a lot of things on your plate and you only have 15 minutes in many cases, you're going to pick the things you're responsible for: the high blood pressure and diabetes...how many primary care providers actually ask their patients if they're sexually active, have a sexual partner...there's a lot of assumptions made and, unfortunately, it's a topic that if the patient does not bring up, the provider thinks everything is okay... [HCP #1]</i>
Ability to identify and engage people at high risk for HIV acquisition	<i>The first, I supposed, is getting people in for PrEP...identifying people at risk and actually getting them into clinic. [HCP #4]</i>
Delay in getting laboratory results before PrEP initiation	<i>I will say that it's very rare for someone to have tested before they come even though they've usually been given lab orders...but they rarely come in before their first meeting with me...so there is often a delay, so I'll say: "...we'll call you in a day or two...and we'll send in the prescription if everything is looking good." So...there's a delay and we have to go chasing them...Usually it's okay but it would be much more satisfying if we could give them the prescription knowing their results...ideally, they'd do labs in advance and be able to start if everything looks appropriate... [HCP #4]</i>
Societal-specific	
Stigma associated with being on medications for HIV	<i>...this woman who couldn't get PrEP, some of it was because of stigma and also concern for: "Is this medicine for anything other than HIV if I go to the pharmacy and pick it up?" [HCP #6]</i>

^aPrEP: pre-exposure prophylaxis.^bHCPs: health care providers.

Table 3. Potential impacts of the pre-exposure prophylaxis (PrEP) Optimization Intervention on the provision of PrEP.

Intervention component and impact on PrEP ^a prescribing	Example quotes
PrEP-Rx	
Knowledge base providing quick references and information related to PrEP	<i>...it streamlines all the important elements that you'd want to know for a discussion with the patient. It lays out things clearly so it's easy to see all the things in follow-up. Timeline gives a summary and walks you through the steps and is laid out in a structured way. [HCP #3]</i>
Ability to provide all necessary data for all patients on PrEP in 1 comprehensive streamlined format, resulting in increased ease of PrEP prescription and being more effective	<i>...being able to look at the information on risk and timeline and having patients teed up, is very helpful and so much easier than current HER...it makes me so much more effective as a provider of PrEP. [HCP #4]</i>
Allowing for the PrEP coordinator to function more effectively	<i>The survey goes into so much detail that would take a really long time as a provider to go into and it would be unlikely to get into this exact level of detail without a fairly involved visit especially for someone you're meeting for the first time...We're always focused on time as providers, so overcoming that hurdle of how many different screens do I need to click through to figure out...all their labs, trying to have all their follow-up, and really just the survey being so detailed. That would overcome a lot of the energy to do this in a reasonable amount of time for the provider and the patient. [HCP #6]</i>
PrEP coordinator	
Increasing patient engagement in health care and retention	<i>[the PrEP coordinator] is the "glue" as far as getting the person in and encouraging them to come in...it is undoable without [the PrEP coordinator]. [HCP #4]</i>
Improving communication between health care providers and patients	<i>...having multiple touch points for the patient can be really helpful...the more likely you are to get someone engaged and sustained... [HCP #6]</i>
PrEP Rx + PrEP coordinator	
Helping keep patients healthy by improving monitoring and follow-up	<i>...it motivates in as much as it's linked to the patient. Because for providers that's where our motivation is: to keep our patients healthy and happy...I think that thinking about how this is helping my patients and how this is helping reduce their HIV risk, is a motivation for me... [HCP #3]</i>
Reducing loss to follow-up	<i>It makes me capable and motivates me because I know my patients are getting good care and know when my patients have fallen out of care. [HCP #4]</i>

^aPrEP: pre-exposure prophylaxis.

Discussion

We created the PrEP-OI, which includes a clinical staff member supporting HCPs (ie, the PrEP coordinator) and an easy-to-use Web-based tool (ie, PrEP-Rx), with guidance from HCPs. We then conducted a pilot study to examine the feasibility and acceptability of this intervention among 6 HCPs prescribing PrEP with varying levels of PrEP experience. The results of our pilot study reveal that this intervention is feasible to implement in clinical settings, and acceptable among HCPs regardless of their level of PrEP experience. Overall, HCPs identified several system-level barriers to PrEP provision (eg, HCPs not addressing HIV risk in routine practice, identification and engagement of people at high risk for HIV acquisition, and insurance navigation), many of which can be addressed with PrEP-OI. Additionally, the intervention was noted to improve HCPs' PrEP knowledge and information and increase ease of PrEP prescription, and deemed likely to increase patient engagement and retention in care, improve communication between HCPs and patients, and improve quality of PrEP monitoring.

HCPs rated PrEP-Rx highly on the System Usability Scale and had favorable reviews of its look, feel, and functionality. There were no major privacy concerns, and all HCPs wanted to continue its use in their clinical practice. HCPs requested several additions to the Demographics, PrEP Timeline, Risk

Assessment, and Laboratory sections, as well as a new section on PrEP adherence and additional information for patients and HCPs on the PrEP-Rx website.

Our intervention was pilot-tested in a clinic that employs panel management strategies. Panel management is defined as a "set of tools and processes for population care that are applied systematically at the level of a primary care panel" [40,41]. It is an approach to ensure that patients are up-to-date on their care and can receive additional support if required. Panel management can involve clinical support staff using chronic disease registries, EHRs, and other data-reporting tools to identify missed opportunities for disease prevention and treatment. These support staff are the liaison between the HCP and the patient and communicate and reinforce recommendations from HCPs or guidelines to the patient. Panel management strategies have been used in many settings to improve rates of vaccination, bone density screening for the elderly, hypertension treatment, and so on [42,43]. Successful panel management programs employ computerized clinical support tools to provide relevant care reminders, data registries, and performance feedback [44]. These electronic clinical tools are associated with improved health care management [45]. In our study, we leverage panel management strategies including a staff member (ie, PrEP coordinator) and a clinical support tool (ie, PrEP-Rx) to serve a goal of enhancing PrEP initiation and appropriate

monitoring and follow-up. To our knowledge, this is the first study examining these strategies in the setting of HIV PrEP.

The development of PrEP-OI highlights the importance of joint efforts between academia, industry, and community partners. Using the framework of the PrEP care continuum [35], we chose to focus on the role of the HCP in being educated about PrEP, screening for high-risk behaviors, prescribing PrEP, and conducting ongoing monitoring and follow-up with the help of the PrEP coordinator. The PrEP coordinator is responsible for verifying patients' insurance and eligibility status, scheduling appointments, evaluating HIV risk using the risk assessment questionnaire, following up with patients, and conducting medication and adherence counseling. PrEP-Rx is an electronic tool that provides education for HCPs, allows for the assessment of HIV risk in a comprehensive manner, tracks monitoring and follow-up visits, and summarizes details related to HIV risk, pertinent laboratory results, and patients' current and/or prior PrEP use.

Limitations of our study include a small sample of HCPs at a clinic in a single geographic region over a short timeframe. Clinicians in this clinic were HIV specialists and received support from the PrEP coordinator. Therefore, our results may not be generalizable to other cities or clinics. A randomized trial of several primary care clinics in the San Francisco Bay Area to examine PrEP uptake and persistence over longer periods of time with this PrEP intervention is in progress.

PrEP-OI, including a PrEP coordinator and PrEP-Rx, has the potential to enhance PrEP uptake, adherence, and persistence along the PrEP care continuum [35] and improve HCPs' knowledge and prescribing practices. Studies have highlighted the cost-effectiveness of PrEP in target populations [46-48]; however, given the high upfront costs, PrEP scale-up may not be feasible in many settings. Additionally, despite an increase in PrEP uptake in San Francisco, most recent data indicate that

demand currently exceeds the supply of providers who prescribe PrEP [49]. Therefore, the automation of risk assessment, risk calculation, and reminders for monitoring and follow-up in addition to the assistance of a designated clinic staff to oversee these efforts and assist with establishment of medical coverage has the potential to reduce costs associated with clinician time and clinic resources.

Due to expanding access to Web-based and mobile technologies for decision support, HCPs are increasingly using online resources [50]. These technologies have been in the form of remote monitoring technologies [51], computerized decision support systems [52], and mHealth technologies (including geographic information systems) [53]. Many studies have reported providers' acceptance of online and mobile technologies and demonstrated promising results, such as improved retention in care for their patients. Therefore, providing support to HCPs is essential for effective PrEP implementation as they are the supply link for those interested in initiating PrEP. PrEP-OI has the potential for improving the efficiency and quality of this "supply" link by assisting HCPs in prescribing PrEP.

As a next step, we will evaluate the efficacy of PrEP-OI to increase PrEP prescriptions and PrEP persistence through a stepped-wedge design among primary care clinics in San Francisco. Given the need for efficient and targeted identification of those at high risk for HIV acquisition, establishment of medical coverage, standardized and comprehensive HIV risk assessment, efficiency in HCP-patient communication around HIV risk and PrEP use, and appropriate monitoring and follow-up, the proposed PrEP-OI has the potential to significantly enhance the HIV PrEP continuum of care. If successful, our goal is to implement this intervention in other health systems, in settings outside of San Francisco, and in international settings.

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Conflicts of Interest

None declared.

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Abbreviations

CAPS: Center for AIDS Prevention Studies
CDC: US Centers for Disease Control and Prevention
EHR: electronic health record
HCP: health care provider
IDU: injection drug use
MSM: men who have sex with men
PrEP: pre-exposure prophylaxis
PrEP-OI: PrEP Optimization Intervention
UCSF: University of California, San Francisco

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Original Paper

A Computer-Assisted Personal Interview App in Research Electronic Data Capture for Administering Time Trade-off Surveys (REDCap): Development and Pretest

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Abstract

Background: The time trade-off (TTO) task is a method of eliciting health utility scores, which range from 0 (equivalent to death) to 1 (equivalent to perfect health). These scores numerically represent a person's health-related quality of life. Software apps exist to administer the TTO task; however, most of these apps are poorly documented and unavailable to researchers.

Objective: To fill the void, we developed an online app to administer the TTO task for a research study that is examining general public proxy health-related quality of life estimates for persons with Alzheimer's disease. This manuscript describes the development and pretest of the app.

Methods: We used Research Electronic Data Capture (REDCap) to build the TTO app. The app's modular structure and REDCap's object-oriented environment facilitated development. After the TTO app was built, we recruited a purposive sample of 11 members of the general public to pretest its functionality and ease of use.

Results: Feedback from the pretest group was positive. Minor modifications included clarity enhancements, such as rearranging some paragraph text into bullet points, labeling the app to delineate different question sections, and revising or deleting text. We also added a research question to enable the identification of respondents who know someone with Alzheimer's disease.

Conclusions: We developed an online app to administer the TTO task. Other researchers may access and customize the app for their own research purposes.

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KEYWORDS

computer-assisted personal interview; health-related quality-of-life; REDCap; time trade-off

Introduction

Health-related quality of life (HRQoL) is an individual's normative perception of how disease and treatment affect their

physical, functional, psychological, and social well-being [1]. HRQoL can be measured using health utility scores, which lie on an interval scale ranging from 0 (equivalent to death) to 1 (equivalent to full health).

Numerous methods exist to elicit health utility scores [2,3]. One method is the time trade-off (TTO) method [4], which has three variants: conventional [4], lead-time [5], and composite [6]. Regardless of the variant, the basic premise of TTO remains the same: individuals read a brief description of a health state and choose between two (usually hypothetical) outcomes (ie, Life A or Life B). For example, Life A involves living in a full health state for x years, followed by death. Life B involves living in the health state in question for a fixed number of years (t , usually 10 years), followed by death. The lead-time and composite TTO approaches involve adding additional years of life in full health (l) to both Life A and Life B [3].

After being presented with Life A and Life B, individuals may choose Life A, Life B, or they can say that the two options are equivalent. When individuals choose Life A or B, they are presented with a second iteration where t in Life B is held constant, but x in Life A is varied to reflect a changing length of time in full health. Once again, individuals are asked to choose between Life A or B, or equivalence. Subsequent iterations involve further variations of x in Life A, while t in Life B is always held constant. The iterations continue until individuals indicate that Life A and Life B are equivalent, that is, they are indifferent between the two choices. Once the point of indifference is known, researchers use a formula to calculate the health utility score. The formula differs according to the TTO variant [4-6].

Early protocols called for the TTO task to be administered using a paper-and-pencil format in face-to-face interviews [7]. Interviewers used props such as cards, colored envelopes, and custom-made boards with sliding scales to depict health states and the number of years spent in Life A and Life B. The sliding scales permitted interviewers to visually illustrate differences between the various iterations of Life A and Life B.

To standardize the TTO task and ease the burden of using multiple props to administer the activity, researchers developed computer-assisted personal interview (CAPI) software such as U-titer [8] and iMPACT3 [9] to replace the paper-and-pencil format. The EuroQol Group currently uses CAPI software (EuroQol Valuation Technology [EQ-VT]) [10-12] to administer the TTO task in studies designed to value health states for the EQ-5D [13,14] (a 5-item questionnaire created to measure HRQoL). Despite the documented existence of these three software apps, U-titer and iMPACT3 do not appear to be available any longer. The EQ-VT's technical specifications have not been published, and the software does not appear to be available on the EuroQol Group's website [15].

The Need for a Computer-Assisted Personal Interview Time Trade-Off App

Our interest in TTO emerges from research examining whether the general public can act as a proxy and estimate HRQoL in place of persons with Alzheimer's disease (AD) [16]. We plan to ask members of the general public to read descriptions of the mild, moderate, and severe health states of AD. Subsequently, they will perform the TTO task for each health state and generate health utility scores for each state. The health utility scores from the general public will be compared to a set of similarly elicited scores from persons with AD. We have already established that

the general public can use health state descriptions to discriminate between mild, moderate, and severe AD [16].

To enable the interviewing of participants in multiple locations, we decided the TTO task should be administered using CAPI rather than paper-and-pencil. We wanted interviewers to carry only a laptop between locations, instead of bulky sets of forms, props, and writing materials.

Prior to developing our own CAPI app, we reviewed the literature to assess whether existing software could serve our purpose. We found 13 TTO studies that reported using CAPI software during in-person interviews: 7 studies used the EQ-VT [11,12,17-21] and 6 did not describe the specific software [22-27]. Of these 6 studies, one [23] cited a previous study [28] as the source of the CAPI software. The previous study contained screenshots of the software but no technical details. Another 2 of the 6 studies reported using hard-copy visual aids to conduct the TTO task, with CAPI software reserved for data entry only [24,25]. A total of 22 other studies used Internet-based CAPI software, where participants logged onto websites and completed the TTO task on their own, without an interviewer present [22,29-49]. Five [30-34] of these 22 studies provided screenshots of the software, but none of the 22 studies described the technical details of the software.

The lack of information on existing CAPI software led us to develop our own Web-based app with a point-and-click interface to administer the TTO task. This paper describes the technical details and pretest of the app. At the outset, we specified two prerequisites for the app. First, the mild, moderate, and severe health states of AD would have to be presented to study participants in one of six random orders to help minimize biases due to ordering effects. This is because we will ask members of the general public and persons with AD to perform the TTO task for all three AD health states. Second, the app would start the lead-time TTO iterations at a value of 20 years in perfect health followed by death for Life A ($x=10$; $l=10$). The static Life B comparator would be 10 years in perfect health, followed by 10 years in the AD health state in question ($t=10$), and then death. [Multimedia Appendix 1](#) shows the iterations in our software. Health utility scores would be calculated using the following formula: $(x-l)/t$, with x being the amount of time in perfect health (Life A) at the point of indifference between Life A and Life B. The formula permits the calculation of health utility scores less than 0, which represent health states worse than death (eg, persistent vegetative state).

Our TTO app is still in its formative stages. The content of the app is based on established lead-time TTO methods [5] that have been implemented in a large valuation study conducted by one of the co-authors (FX) [50]. We report on the development and initial pretest results for the app, which is Web-based and freely available to all potential users.

Methods

We used the Research Electronic Data Capture (REDCap) app [51] to build the TTO app. REDCap is a secured Web-based app that allows researchers to create CAPI apps for collecting, storing, and manipulating research data. REDCap is hosted on

the server of the University of Waterloo, and we selected it as the preferred platform because of the following features: (1) minimal programming requirements, (2) easy accessibility to the TTO app across academic departments and institutions (at the time of writing, REDCap has 1911 active institutional partners), (3) flexibility in defining user privileges, such as limited/temporary privileges, (4) real-time data format/range validation, (5) data export options for common statistical software packages (eg, SPSS, SAS, R), (6) software and support for no charge, (7) modest hardware and software requirements, and (8) availability as a mobile app.

The TTO app was designed in a modular format. Its overall structure is presented in [Figure 1](#). The app's modular structure and REDCap's object-oriented environment facilitate the app's ready customization to meet researchers' needs ([Figure 2](#)). In addition to accessibility through the project home page, the TTO-CAPI eXtensible markup language (XML) file and installation manual are included as [Multimedia Appendices 2](#) and [3](#) to guarantee the availability of the software in the future. The detailed methodology to construct the TTO app follows.

Time Trade-Off Software

As shown in [Figure 1](#), there are four data collection instruments in the TTO app:

1. Preliminary information: demographic data (ie, age, gender, education level, income level), knowing anyone with AD, and EQ-5D-5L (5L indicates 5 response options per question); this instrument assigns a unique identification number to each record (study participant) in the background
2. Mild AD: Mild AD TTO data; EQ-5D-5L data (participants answer the EQ-5D-5L as if they had AD according to the health state description just read [all three health states])
3. Moderate AD: Moderate AD TTO data; EQ-5D-5L data
4. Severe AD: Severe AD TTO data; EQ-5D-5L data

In each of the three AD instruments (numbers 2-4 above), questions appear in an order based on the end-user responses to TTO iterations shown in [Multimedia Appendix 1](#). In REDCap, each singular data entry is called a *field*. Various types of project fields were used to house questions and then combined in sequence one after the other to form the instruments. The following project fields were used to design the instruments: text box, multiple-choice radio buttons, multiple-choice drop-down list, yes-no, descriptive text, and calculated field. Hypertext markup language (HTML) tags were used to customize the appearance of the text in each of the instruments.

Figure 1. Modular structure of the time trade-off (TTO) app. AD: Alzheimer’s disease; EQ-5D: EuroQol 5-dimension.

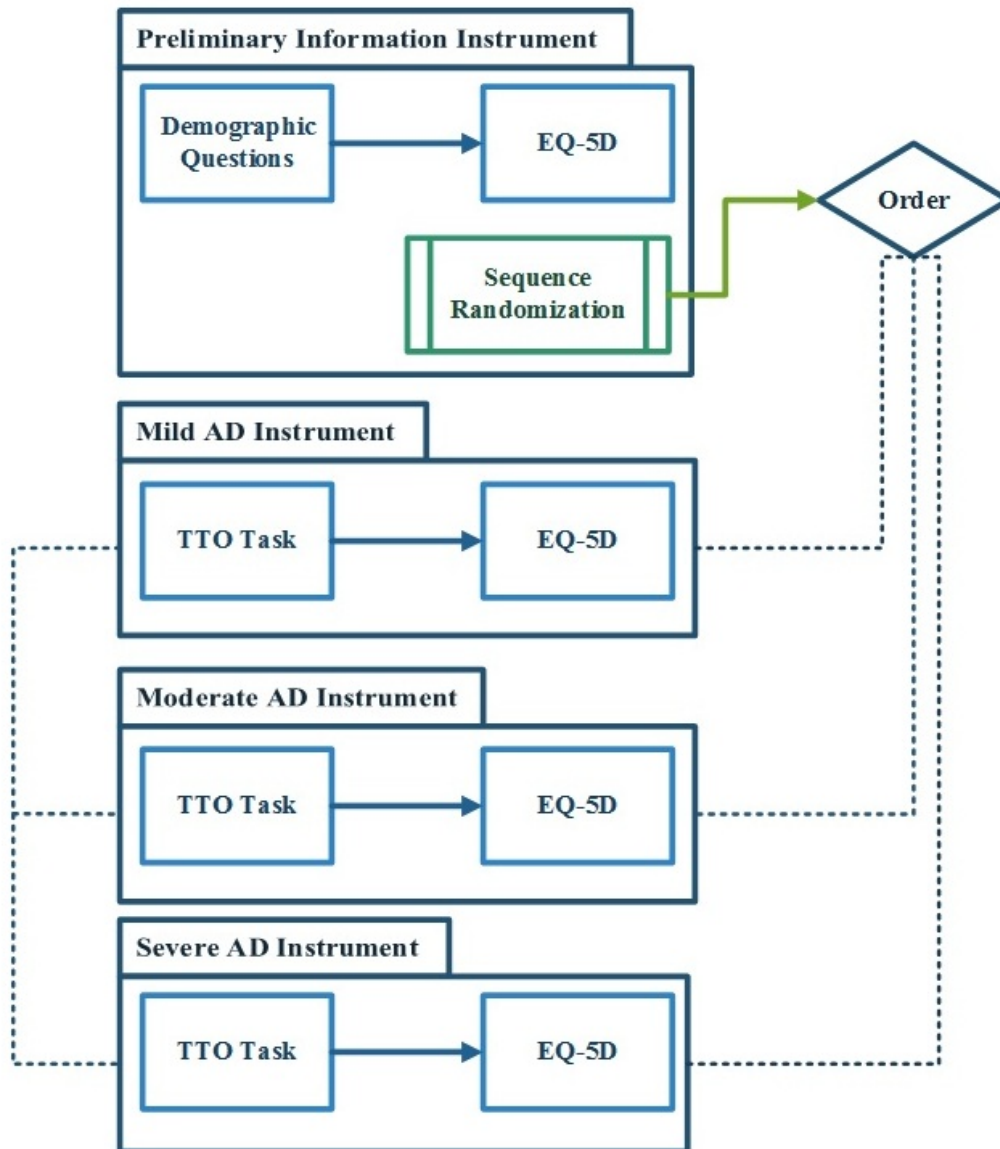


Figure 2. Workflow for accessing the time trade-off (TTO) app. REDCap: Research Electronic Data Capture.

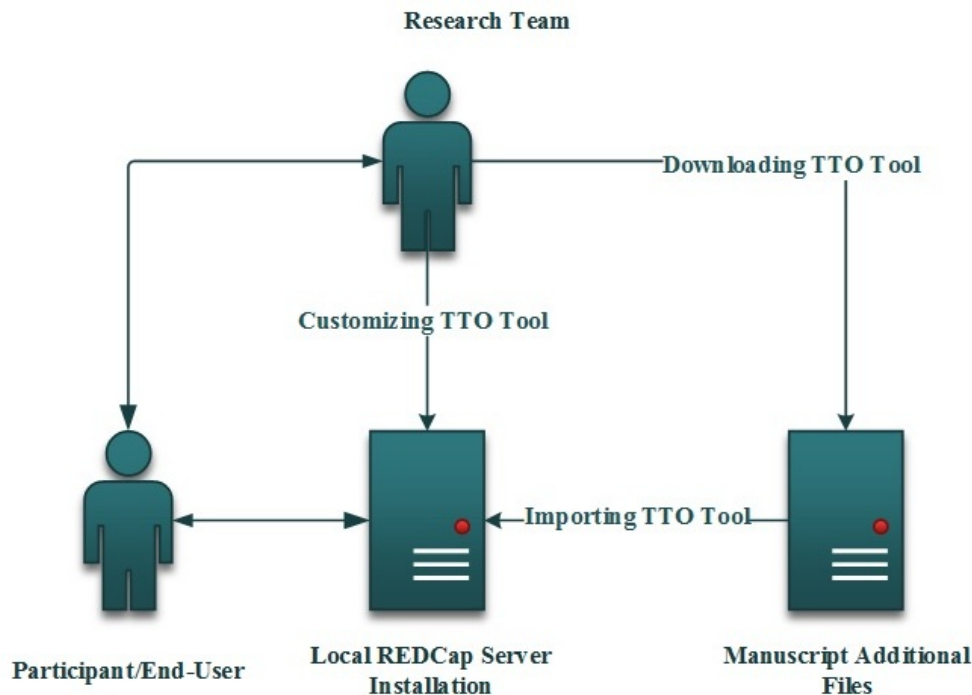
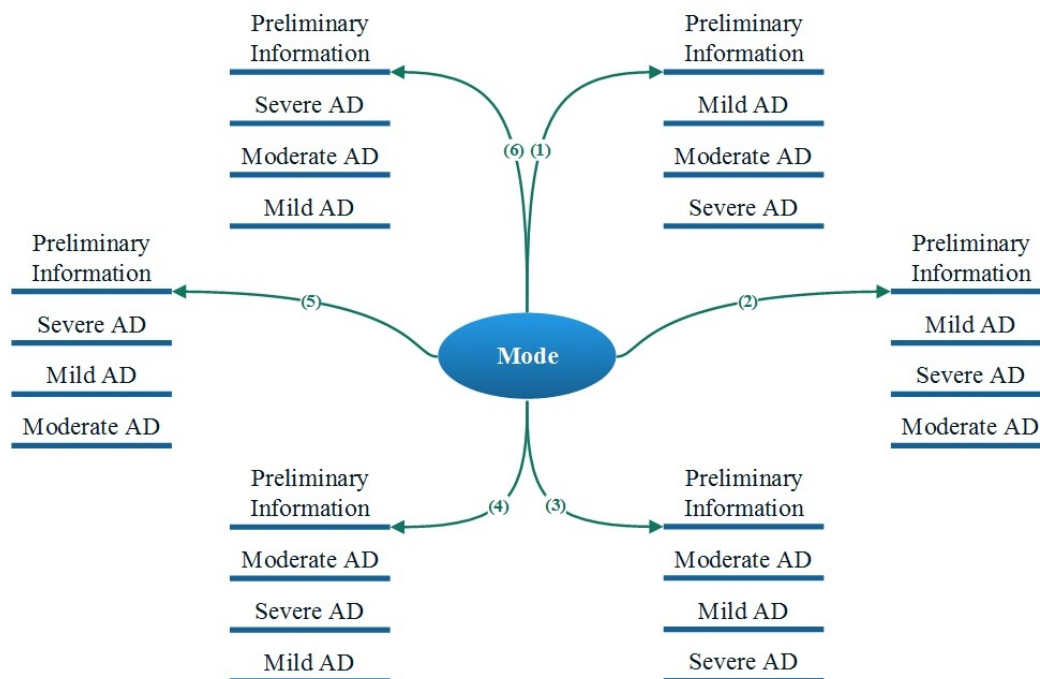


Figure 3. Six possible navigation options between Alzheimer's disease (AD) instruments based on mode.



We employed two logic options in the TTO app:

1. Survey queue: a set of navigation conditions was defined to ensure the three TTO tasks would appear in a uniformly random sequence (Figure 3). Table 1 shows the conditions fixed for each instrument. We used an “auto start” feature to enable smooth and immediate navigation between modules. Uniform randomization was done by defining a variable named “mod_6” in the Preliminary information instrument. This variable could take a value from 1-6 and represent one of the six possible orders of AD tasks shown

in Figure 3. The completion of a task was monitored by a flag named “part *i* _complete”, where *i* is the task number that can take a value from 1-3 for mild, moderate, and severe AD, respectively. The following values were used for the flag status: Complete=2; Incomplete=0.

2. Branching logic: used to (1) control the order of questions in the TTO task, (2) initiate logical error check pop-up texts (eg, in situations when users choose life with AD as being more desirable than a state of full health; see Figure 4), and (3) demonstrate users’ progression toward completing the survey.

Table 1. Survey queue conditions for Alzheimer's disease (AD) instruments.

Instruments	Conditions
Mild AD	<p>WHEN</p> <p>Preliminary Information is complete</p> <p>AND</p> <p>([mod6]^a<“3”) or ([mod6]=“3” and ([part2_complete]+[part3_complete]^b=“2”)) or (([mod6]=“4” or [mod6]=“6”) and ([part2_complete]^c+ [part3_complete]=“4”)) or ([mod6]=“5” and ([part2_complete]+[part3_complete]=“2”))</p>
Moderate AD	<p>WHEN</p> <p>Preliminary Information is complete</p> <p>AND</p> <p>([mod6]=“3”) or ([mod6]=“4”) or ([mod6]=“1” and ([part1_complete]+[part3_complete]=“2”)) or (([mod6]=“2” or [mod6]=“5”) and ([part3_complete]+[part1_complete]=“4”)) or ([mod6]=“6” and ([part1_complete]^d+ [part3_complete]=“2”))</p>
Severe AD	<p>WHEN</p> <p>Preliminary Information is complete</p> <p>AND</p> <p>([mod6]=“5”) or ([mod6]=“6”) or ([mod6]=“2” and ([part1_complete]+[part2_complete]=“2”)) or (([mod6]=“1” or [mod6]=“3”) and ([part2_complete]+[part1_complete]=“4”)) or ([mod6]=“4” and ([part1_complete]+[part2_complete]=“2”))</p>

^aMod6: randomization variable.

^bSevere AD task flag.

^cModerate AD task flag.

^dMild AD task flag.

The end-user can get access to the survey through a public uniform resource locator (URL) or quick response (QR) code. Researchers can export the collected data from all instruments at once without being affected by the randomized order of the TTO tasks. Researchers can also export the data from specific instruments or fields separately (Figure 5).

For building the TTO app, REDCap Version 6.12.0 was installed on the isysign webserver, which provides high security for hosted projects. We assigned different levels of data access rights to research team members, who had access to the project only through their individual usernames and passwords.

One of the issues in the design of the TTO app was the possibility of incorrect data entry in ordinary text fields by the end-user. This problem was avoided using the *validation* option in each field. This option ensures end-users can enter only free-form text in predefined formats. Otherwise, a pop-up alert will inform the end-user of the correct format (Figure 6). This option is not only available for the format of the data but can also be used to minimize the problem of outliers by defining a valid range for numeric free-text fields such as age.

Before publishing the app for pretesting, the research team tested the accuracy and reliability of the app's iteration and randomization sequences. The team also reviewed the user interface from various perspectives, including consistency of appearance, clarity of cues, and simplicity of user engagement.

Pretest

Following the development of the software, members of the research team recruited a purposive sample of the general public to provide quality assurance feedback on the survey. These pretest participants were recruited from the researchers' social networks (eg, friends, family, landlords). None of the pretest participants had an academic background. Each participant met with an interviewer for a one-on-one interview, during which the interviewer explained the purpose of the pretest, that is, to get feedback on the comprehensibility of the survey questions and the TTO task, as well as to assess the appearance and functionality of the online survey. The interviewers gave participants control over a laptop, and the participants completed the survey at their own pace.

Figure 4. Screenshot of a logical error check for the pop-up text.

Life A
You will live in perfect health for the next 20 years and then you will die of natural causes.

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Number of Years

Life B
You will live in perfect health for the next 10 years, then you will live with Alzheimer's disease as described in the summary for another 10 years, and then you will die of natural causes.

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Number of Years

Do you prefer Life A or Life B, or do you think Life A and Life B are the same as one another?

* must provide value

Prefer Life A
 Prefer Life B
 Life A and Life B are equivalent

reset

Your option means that you would prefer living with Alzheimer's disease rather than living in full health. If this is your real opinion, please click "Next Page". Otherwise, you can click "Reset" to reset the task. Thank you!

<< Previous Page Next Page >>

Figure 5. Record export dashboard.

Data Exports, Reports, and Stats

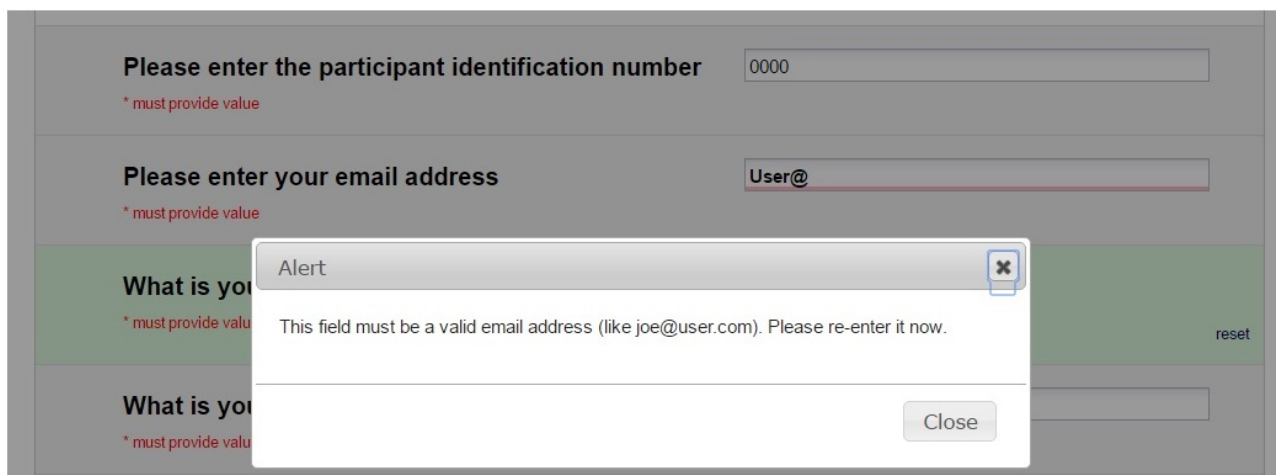
VIDEO: How to use Data Exports, Reports, and Stats

- + Create New Report
- My Reports & Exports
- Other Export Options

This module allows you to easily view reports of your data, inspect plots and descriptive statistics of your data, as well as export your data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis (if you have such privileges). If you wish to export your "entire" data set or view it as a report, then Report A is the best and quickest way. However, if you want to view or export data from only specific instruments (or events) on the fly, then Report B is the best choice. You may also create your own custom reports below (if you have such privileges) in which you can filter the report to specific fields, records, or events using a vast array of filtering tools to make sure you get the exact data you want. Once you have created a report, you may view it as a webpage, export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics for that report.

My Reports & Exports				
	Report name	View/Export Options	Management Options	Report ID (auto-generated)
A	All data (all records and fields)	View Report Export Data Stats & Charts		
B	Selected instruments (all records)	Make custom selections		
+ Create New Report				

Figure 6. Screenshot of a pop-up alert for incorrect free-text entry by end-user for email address.



The pretests followed the method of cognitive interviewing [52]. As participants conducted the TTO task for the first AD health state, the interviewers asked them a series of scripted questions about whether they understood the description of the health state and the difference between Life A and Life B. After completing the first TTO task, the participants were asked to describe what they had just done using their own words. The interviewers encouraged participants to verbally express any thoughts that came to mind (ie, think aloud [53]) as they performed the TTO task for the remaining two health states. After participants finished the survey, they were asked to comment on the similarities and differences between the three health state descriptions. The interviewers also elicited feedback about the following components of the survey: the visual aids used to depict Life A and Life B, the appearance of the webpages and fonts, and the wording used to articulate the questions. After aggregating and discussing the pretest feedback, the researchers revised the survey.

We considered the pretest participants to be part of the research team. While these individuals had to complete the survey, they were told at the outset that their thoughts about the survey were of interest, not their responses to specific survey questions. The interviewers informed participants that their responses to specific survey questions would not be used in later research, nor would these responses be published anywhere.

Ethics

Research ethics approval was obtained from the University of Waterloo's Office of Research Ethics (study #21461) and the Hamilton Integrated Research Ethics Board.

Results

We pretested the TTO app on 11 members of the general public who had not previously seen the app or responded to a TTO survey. Nine pretest participants were female, the median age of the 11 participants was 46 years (range 21-59 years), and none of the participants had a university degree. A member of the research team (GPM) and a student volunteer who was trained by the research team conducted the pretests. The pretest interviewers summarized their findings, which were discussed

by the research team. The findings and discussion led to six modifications of the TTO app:

1. To enhance readability, the scenarios describing the mild, moderate, and severe AD health states were rewritten in bullet-point form, rather than in paragraph form.
2. To assess whether participants' responses to the TTO task might be influenced by their experiences with AD, a question about knowing someone with AD was inserted into the Preliminary information instrument.
3. To help participants identify different parts of the survey, the scenarios were labeled as Description 1, 2, or 3.
4. To enhance the empathy of the TTO task, a phrase comparing life with AD to a state worse than death was deleted from the app.
5. To enrich the descriptions of Life A and Life B, the text was modified to indicate that death will occur from natural causes after the specified number of years spent in full health or with AD.
6. To enhance comprehensibility, a phrase in the TTO response options was changed from "Life A and Life B are the same" to "Life A and Life B are equivalent".

The pretest participants reported understanding the substantive differences between scenarios. One participant found the need to value Life A in comparison to Life B as cognitively challenging, though this was not an issue with the online app but with her comprehension of the TTO task itself. The iterations functioned as described in [Multimedia Appendix 1](#).

Discussion

Principal Considerations

We will use the TTO app in a research study that examines whether the general public can provide proxy HRQoL estimates in place of persons with AD. Due to cognitive impairment, many persons with AD are unable to estimate their own HRQoL using instruments such as the EQ-5D [54,55]. Family caregivers sometimes act as proxies, but they often integrate their own life experiences (eg, the burdens and stresses of caregiving) into the proxy assessments and underestimate the HRQoL of their loved ones with AD [56-62]. To the best of our knowledge, no

one has examined whether the general public can provide a better set of proxy HRQoL estimates than caregivers in AD.

The TTO app is publicly available for other researchers to adapt to their own studies. As described above, existing CAPI software to conduct the TTO task is poorly documented in the literature and not readily available for researchers to access. Our app fills a gap for researchers who require a means of administering the TTO task in their studies.

The pretest interviewers found the app worked well with regard to presenting all of the information necessary to conduct the TTO task, that is, the scenarios describing the three AD health states, the diagrammatic representations of Life A and Life B, and the questions about participants' preferences for Life A or Life B. Additionally, the app worked quickly on a variety of public (eg, university) and private (eg, personal residence) wireless Internet connections. We did not notice any difference in performance on laptops running Windows, OS X, or Linux operating systems.

The use of laptops provides flexibility in conducting interviews. Interviewers can turn the laptops over to participants and allow the TTO task to be performed in a completely self-administered fashion. Interviewers can also operate the point-and-click interface to record participants' responses and help them navigate the task. This versatility is especially important when conducting research in populations that may be less familiar with technology (eg, seniors) or that may experience challenges in using technology (eg, persons with AD).

The use of REDCap is timely given other developments in the HRQoL field. Recently, the EuroQoL Group released REDCap versions of the EQ-5D in over 50 languages to facilitate the collection of HRQoL data [63].

The TTO app described in this manuscript will facilitate the conduct of high-quality cost-utility analyses, which are undertaken to assess the costs and benefits of new health technologies. The health utility scores generated from the TTO task are an essential ingredient of these analyses. Cost-utility

analyses are increasing in frequency and can influence public sector treatment reimbursement decisions and health program priority setting [64].

Limitations

The pretest sample was one of convenience and may therefore be unrepresentative of average members of the general public. However, the pretest specifically excluded people with academic backgrounds to enable us to collect feedback on the app from individuals who would reflect a variety of lay opinions. Also, cognitive interviewing methods do not require the recruitment of representative samples nor do they specifically call for the use of formal qualitative analytical approaches [65,66]. In this research, we did not focus on analyzing pretest participants' specific health utilities because the objective of the work was to develop and test an online TTO app. We have already shown in previous research that members of the general public can differentiate between AD health states [16].

The TTO app was developed to meet the needs of a specific research protocol. Therefore, the app does not contain multiple means of eliciting health utilities (eg, visual analogue scale or standard gamble approach [67]) nor does it include multiple methods of iterating between Life A and Life B (eg, titration, bisection [3]). Some users may find REDCap's graphic capabilities uncustomizable to their needs.

The TTO app is still preliminary and may undergo further refinement as we move forward with our study of general public proxy HRQoL estimates in AD. However, our work demonstrates that researchers can easily use REDCap to computerize the TTO task and create a useful online CAPI app.

Conclusions

We developed an online app to administer the TTO task. Other researchers may access and alter the app for their own research purposes. Our app fills an operational gap in eliciting health utility scores because existing TTO apps are poorly documented and inaccessible to researchers. Researchers may contact us for information on how to use the app in their projects.

Acknowledgments

We wish to thank the pretest participants for their helpful comments on the TTO survey and also thank Vanessa De Rubeis for administering pretest interviews.

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Authors' Contributions

MO and FX conceived the purpose of the TTO survey and supervised the CAPI software design. AS programmed the TTO survey and performed ongoing technical tests and bug fixing. GPM and AS assessed the initial suitability of the REDCap app. GPM and XJ reviewed the CAPI software for functionality (eg, randomization, skip patterns). GPM administered pretest interviews. MO and FX alpha tested the software. MO led the writing of the manuscript, and all authors contributed to the writing of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Time trade-off iteration.

[[PDF File \(Adobe PDF File\), 25KB - formative_v2i1e3_app1.pdf](#)]

Multimedia Appendix 2

TTO-CAPI XML file.

[[PDF File \(Adobe PDF File\), 10MB - formative_v2i1e3_app2.pdf](#)]

Multimedia Appendix 3

TTO-CAPI installation on local REDCap™ server (manual).

[[PDF File \(Adobe PDF File\), 189KB - formative_v2i1e3_app3.pdf](#)]

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Abbreviations

AD: Alzheimer's disease
CAPI: computer-assisted personal interview
EQ-5D: EuroQol 5-dimension
EQ-5D-5L: EuroQol 5-dimension 5-level
EQ-VT: EuroQol Valuation Technology
HRQoL: health-related quality of life
REDCap: Research Electronic Data Capture
TTO: time trade-off

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Original Paper

Understanding the Acceptance of an eHealth Technology in the Early Stages of Development: An End-User Walkthrough Approach and Two Case Studies

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Abstract

Background: Studies that focus on the acceptance of an electronic health (eHealth) technology generally make use of surveys. However, results of such studies hold little value for a redesign, as they focus only on quantifying end-user appreciation of general factors (eg, perceived usefulness).

Objective: We present a method for understanding end-user acceptance of an eHealth technology, early in the development process: The eHealth End-User Walkthrough.

Methods: During a walkthrough, a participant is guided by using the technology via a scenario, a persona, and a low-fidelity prototype. A participant is questioned about factors that may affect acceptance during and after the demonstration. We show the value of the method via two case studies.

Results: During the case studies, participants commented on whether they intend to use a technology and why they would (not) use its main features. They also provided redesign advice or input for additional functions. Finally, the sessions provide guidance for the generation of business models and implementation plans.

Conclusions: The eHealth End-User Walkthrough can aid design teams in understanding the acceptance of their eHealth application in a very early stage of the design process. Consequently, it can prevent a mismatch between technology and end-users' needs, wishes and context.

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KEYWORDS

eHealth; acceptance; design; walkthrough; agile design

Introduction

Background

Every new technology that is being developed or introduced faces challenges concerning end-user acceptance. When the train was introduced in the early 19th century, people were reluctant to use it, as they were afraid their bodies would melt going that fast (30 km/hour). Also, when the telephone first became available, people were not eager to install one in their

home, as they feared it would attract lightning. Although these examples are historical and seem funny now, we have to deal with similar issues today.

Having a clear overview of the facilitators and barriers towards use is crucial for technology design and the development of a successful implementation strategy. Electronic health (eHealth; "health services and information delivered or enhanced through the internet and related technologies" [1]) is no exception. Numerous studies have identified factors that determine end-user

acceptance of specific eHealth technologies and applications. Perceived usefulness was found to affect physicians' intention to use telemedicine [2]. Organizational facilitators were identified as the most important antecedent of healthcare professionals' intention to use a telemonitoring application for chronic patients in primary care [3]. Perceived usefulness and self-efficacy came out as the two main drivers for Singaporean women's intention to use smartphones for seeking health information [4]. Moreover, the acceptance of eHealth among patients with chronic respiratory diseases depends on disease specifics, demographics, and Information Communication Technology (ICT) use [5]. This list is, of course, only a snapshot of the available studies on the topic.

The majority of studies that focus on explaining the end-user acceptance of eHealth use the Technology Acceptance Model (TAM) [6] or the Unified Theory of Acceptance and Use of Technology (UTAUT) [7] as a basis [8,9]. Throughout the last decades, hundreds of variants of TAM and UTAUT were investigated for explaining technology acceptance, with a wide variety of adaptations in healthcare as well [10-13]. Surveys with rating scales are now the preferred data collection method. Despite their widespread use, the use of TAM and UTAUT-based surveys has also received critique. Several authors [14-16] argue that the results of these studies hold little value for developing implementation plans. The models focus predominantly on technological factors and not on the person or organizational characteristics. Next, the very general factors people use to explain the intention to use, such as perceived usefulness and perceived ease of use in TAM, are of little use to a technology design team [17-19]. They are very well suited to make a general overview of the beliefs and attitudes that affect the intention to use, but it is difficult to derive actionable (re)design advice from the findings of such studies. After all, a statement that a technology should be "useful" holds little value for system (re)design. What makes a technology useful? Should it allow a significant degree of control, or should it provide a specific feature? Without more actionable insights, results from these studies hold little practical value for technology design.

In this article, we present a method that can explore a wide range of previously unknown factors that may affect end-user acceptance of an eHealth technology in the early stages of the development process: the eHealth End-user Walkthrough (EEW). Applying the method, we posit, results in actionable results, as it can deliver redesign advice targeted at specific features or steps in the service model. TAM and UTAUT-based surveys, which are quantitative, confirmative methods, are unable to do so, as they can only state generally whether an eHealth technology is, for example, useful or easy to use. Using two case studies, we demonstrate its use and will answer our research question: how well does the EEW identify issues that hinder or facilitate end-user acceptance of a future eHealth technology?

This article is organized as follows. In the Methods section, we present a guide towards applying the method and discuss its place in the agile, human-centered design process for eHealth. The Results section includes the results of two case studies in which the method was applied. One study centered around the development of a large screen that acts as a central hub for

disclosing eHealth applications for patients with a chronic disease or age-related impairments. The other one focused on the development of an online platform to support elderly knowledge workers in maintaining a healthy working routine. In the Discussion section, we reflect on the usefulness of the method in the two cases and discuss its advantages and drawbacks.

Methods

The eHealth End-User Walkthrough

The EEW is a method that allows a design team to quickly assess end-user acceptance of an eHealth application in the early phases of the design process. As such, it fits perfectly in a human-centered or agile design process. The latter has become very popular in recent years and advocates the continuous use of quick design-evaluation-redesign cycles [20]. Figure 1 shows the place of the EEW within the human-centered design process (as proposed by ISO standard 9241-210: Human-centered design for interactive systems [21]), namely as a way to evaluate the design regarding end-user acceptance.

During an EEW, a participant is presented with a simple prototype of the future technology, explained how the technology works, and questioned about relevant acceptance factors. To facilitate such an evaluation, the EEW builds forth on various design and evaluation methods (listed in Table 1).

During an EEW, the methods above are combined. A designated end-user of an eHealth technology is guided through its use employing a storyboard that shows how a persona uses the technology within the designated context of use. A participant is interviewed about factors that may inhibit or encourage acceptance, both during and after the demonstration. By combining these methods, the main functionalities of a future technology can be easily and vividly explained to novice end-users, while the data gathering methods are geared towards eliciting end-users' opinion on these features.

Conducting an eHealth End-User Walkthrough

The following steps need to be taken to prepare an EEW (summarized in Figure 2).

First, one creates a persona that represents the designated end-user, or multiple personas when there are different types of primary end-users (eg, patients and care professionals, or older adults with and without cognitive impairments). For a practical guide on persona development for eHealth, see [27]. Second, the design team should select the most important factors that potentially affect end-user acceptance of the eHealth service. These can be derived from the standard models that explain technology acceptance (factors like ease of use and perceived usefulness), but we advise to focus on factors that are directly linked towards specific features or scenarios of use (eg, trust, controllability). Third, a scenario is written that describes the main features of the technology and the features that may profoundly influence the decision of the end-user to (not) accept a technology (eg, a feature that may be considered privacy-infringing). The scenario features the persona(s) from the first step.

Figure 1. The human-centered design process and the place of the eHealth End-User Walkthrough (compare to ISO 9241-210 [21]).

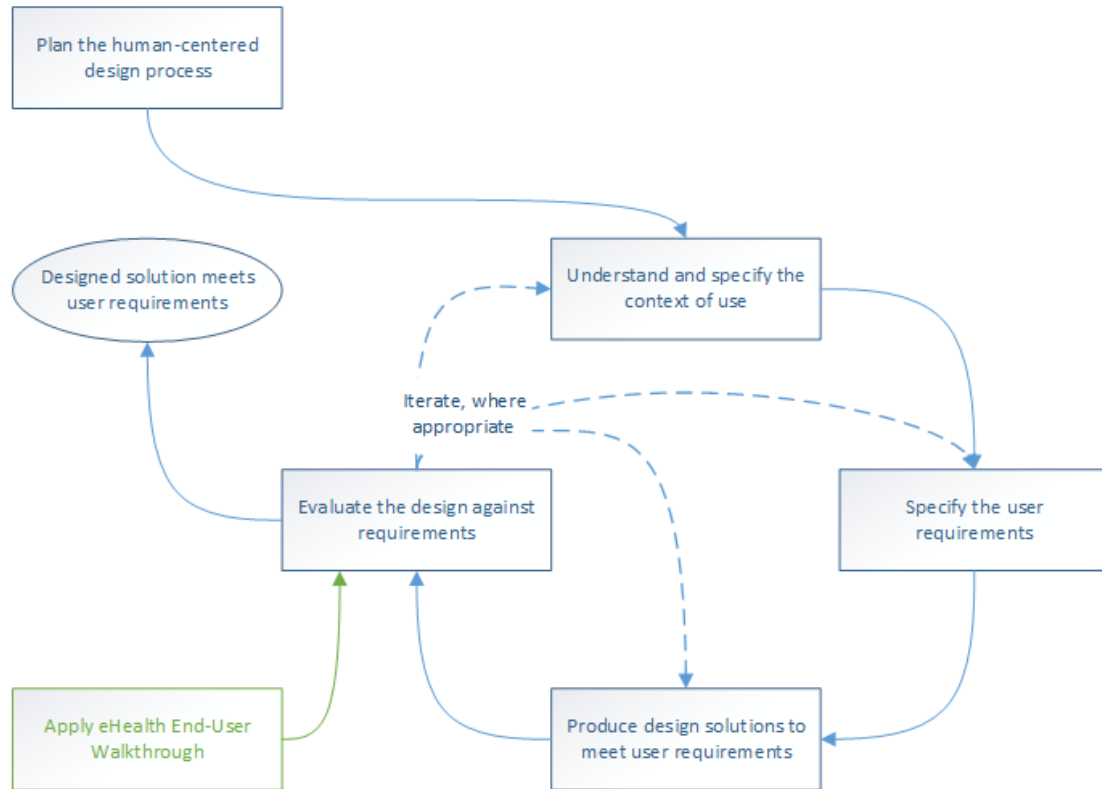
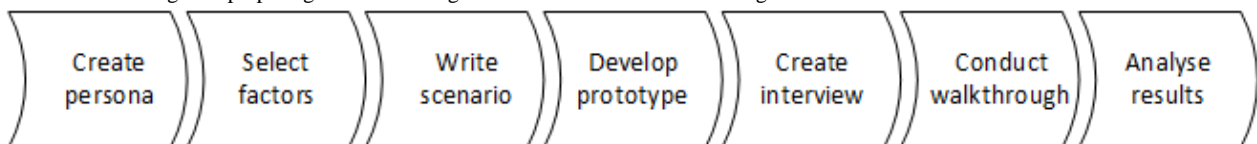


Table 1. Methods that form the basis for an eHealth End-User Walkthrough.

Method	Description
Scenario development	A scenario is “a concrete description of an activity that the users engage in when performing specific tasks [22]” by use of the technology and takes a narrative form.
Personas	Personas are descriptions of fictitious users whose characteristics resemble the average for an end-user (sub)population [23]. They are often short and quite frivolous and used by the design team to talk about their end-users (reasoning that it’s easier to discuss what “Miriam” would like, rather than what “the average user” would like).
Storyboarding	A storyboard is a short, often graphical, narrative [24] which is cut into scenes (it is closely related to film-making).
Walkthroughs	During a walkthrough, potential end-users are presented prototypical screens of the final digital service and are asked to comment on them, mostly on their graphical design and usability [25].
Interviewing	Where discussions take place to elicit end-users’ rationale regarding the acceptance of specific technology features [26].

Figure 2. The main stages of preparing and conducting an eHealth End-User Walkthrough.



Fourth, a storyboard or low-fidelity prototype (either digital or on paper) is made. This strengthens the high-level scenario by providing visual representations of the features under investigation. Simple drawings or prototypes can provide suitable means to elicit feedback from end-users about the role each feature plays in the coming about of acceptance, without diverting to irrelevant details (such as the navigation within an eHealth application, which should be evaluated during a usability test with a high-fidelity prototype) [28,29]. Fifth and finally, an interview setup that questions acceptance factors is written. Factors that are linked to a specific feature or aspect of

the scenario of use should be questioned whenever the feature or scenario-aspect comes up during the walkthrough. General factors (eg, perceived usefulness, willingness to pay) should be questioned at the end of the walkthrough.

Conducting an EEW can be done in a lab or at the home of a participant by a single researcher. Audio-recordings of the session will suffice for data analysis. During a session, the researcher should introduce the persona and should explain the technology by narrating the scenario. As soon as a main feature has been discussed, the researcher should pose the questions

that relate to this feature. This way, all the main features of the technology should be introduced and discussed. At the end of a session, the researcher should question the participant about the general acceptance factors that the design team identified (step 2).

It is difficult, if not impossible, to state beforehand how many participants should be included in an EEW. This number depends on a range of factors, such as the diversity of the anticipated end-user population, the complexity of the technology under investigation, or the number of participants to which the design team has access. For the case of usability testing, it has been advised to include as many participants as budget and time allows while including 10 participants will ensure that the majority of critical issues will be identified [30]. We hypothesize that the same advice holds for an EEW.

The qualitative data collected should be analyzed systematically, in order to be of value for the design team. We recommend to transcribe the audio recordings and to apply inductive thematic analysis, whereby themes emerge from the data [31]. Analysis should have three goals. One, it should make clear how participants appreciate the main features that are presented during the EEW. Two, it should list the factors that affect this appreciation (what is also called functional analysis [32]). Three, participants' intention to use the technology as a whole, and the factors that inhibit or driver this acceptance, should be uncovered (also called sensitizing concept analysis [32]). Ultimately, results should acknowledge the validity of the technology's functional requirements or should allow to improve them.

Case Study 1

Funded under the European Commission's FP7 framework, eWALL is a large-scale integration project in which various eHealth applications are delivered to older adults or patients with a chronic disease. The project's primary objective was to create a "digital wall" that would allow end-users to access various health services easily. Focus was given to unobtrusively collecting health information from the patient as well as to provide feedback and coaching in those areas in which the user needed support the most. Using a large, touch-screen based user interface that was designed to look like a retro design living room, patients with a chronic disease or older adults with age-related impairments were able to self-manage their health [33]. The eWALL platform integrates different eHealth services, such as domotics, physical activity sensors, online web services, and medical devices (blood pressure and oxygen saturation measurement devices). They are then disclosed to the end-user via a single interface and single sign-on. Figure 3 displays how the design team envisioned eWALL to be present in the home of an end-user.

The end-user walkthrough of eWALL was supported by the persona of Michael (Figure 4). During a walkthrough, we questioned the participants, for each feature, about (1) their first impression of the feature, (2) whether the mock-up provided enough information to understand the functionality of the feature, and (3) their opinion of the feature in terms of relevant acceptance factors (eg, privacy, obtrusiveness of the technology).

At the end of the walkthrough, we questioned the participants about several acceptance factors concerning the total eWALL technology, like learnability and controllability. We also asked them to advise the developers.

Figure 3. Early design sketch of the eWALL situated in a person's home.



Figure 4. The eWALL persona Michael.

As examples, we focus this case description on the participants' appreciation of the eWALL main screen and sleep monitoring feature. The main screen displayed all of the eWALL functionalities, grouped into metaphors. Applications which mainly provide data overviews and monitoring outcomes are represented as books, while those which involve user, or smart home actions are represented as household items. It was shown to the participants, accompanied by the following explanation: "This is what Michael can see on his screen. He can touch the different items and open applications this way." Then, we asked them "what do you think is behind each item on the screen?" After discussing the main screen, we took the participants along the different features of eWALL. When we embarked upon the sleep monitoring feature (which was depicted as a book, see Figure 5 for two pages within the book), we asked the participants a series of questions. The team of evaluators devised these questions to assess the general impression of participants (questions 1 and 2), to elicit factors that could affect acceptance of the feature (questions 3 and 4), and to question the topic of privacy (questions 5 and 6), which we anticipated would be important when deciding to accept the technology or not:

1. What is your first impression?
2. Do you think you understand what you are looking at?
3. Do you like what you see?
4. Do you think this information is useful?
5. How would it make you feel if this kind of information about you is collected?
6. Can you imagine that you would share this information with your family, your general practitioner, community nurse, or home care assistant?

Participants were recruited via a panel, consisting of older adults who indicated that they want to participate in research on the topic of technology for health.

Case Study 2

Funded within the context of the European Active and Assisted Living (AAL) program, the Pearl project aimed to develop a suite of technologies to support older knowledge workers (aged 50 years and older). It sought to make them less sedentary, to help them to adopt a healthy physical activity pattern during working hours and to remain cognitively fit. This was done through task management functionalities, cognitive games, a

physical exercise prompter, etc. All features could be accessed via a PC desktop application or a smartphone app. Data was collected by means of activity sensors, mobile phone prompts, and the digital agenda of the end-user.

During an EEW, participants were guided through the technology via the story of the persona Suzy. Then, with each participant per Pearl feature we discussed the following topics (1) their first impression of the feature, (2) whether the mock-up provided enough information to understand the functionality of the feature, and (3) whether the feature meets the expectations of the participants regarding its functionality. We posed questions (1) and (2) to assess the first, general impression of the feature. With question (3) we aimed to elicit factors that might hinder or facilitate acceptance of the specific feature. After walking through all the different features, we questioned the participants about the Pearl system in general, including aspects like their intention to use the technology and the preferred mode of introduction (prescribed by the employer, only upon the employee's request). This way, we aimed to elicit factors that affect end-user acceptance of the Pearl technology as a whole.

As an example, we discuss the participants' appreciation of Pearl's exercise prompter. This feature provides an end-user with suggestions for physical exercise after a period of physical inactivity at the workplace and when the digital agenda of the end-user indicates that there is no ongoing appointment or activity (Figure 6). At this point, we told the participants that "Because Suzy worked very hard all morning, she forgot to be physically active now and then. The Pearl system has noticed this long period of sitting, and that is why it suggests for a physical exercise. These suggestions are only given because Suzy indicated in her system settings that she thinks it is important to remain physically fit." Participants were recruited via a convenience sample and consisted of co-workers of 50 years and older. They were not involved in the Pearl project, nor had they any knowledge of it beforehand.

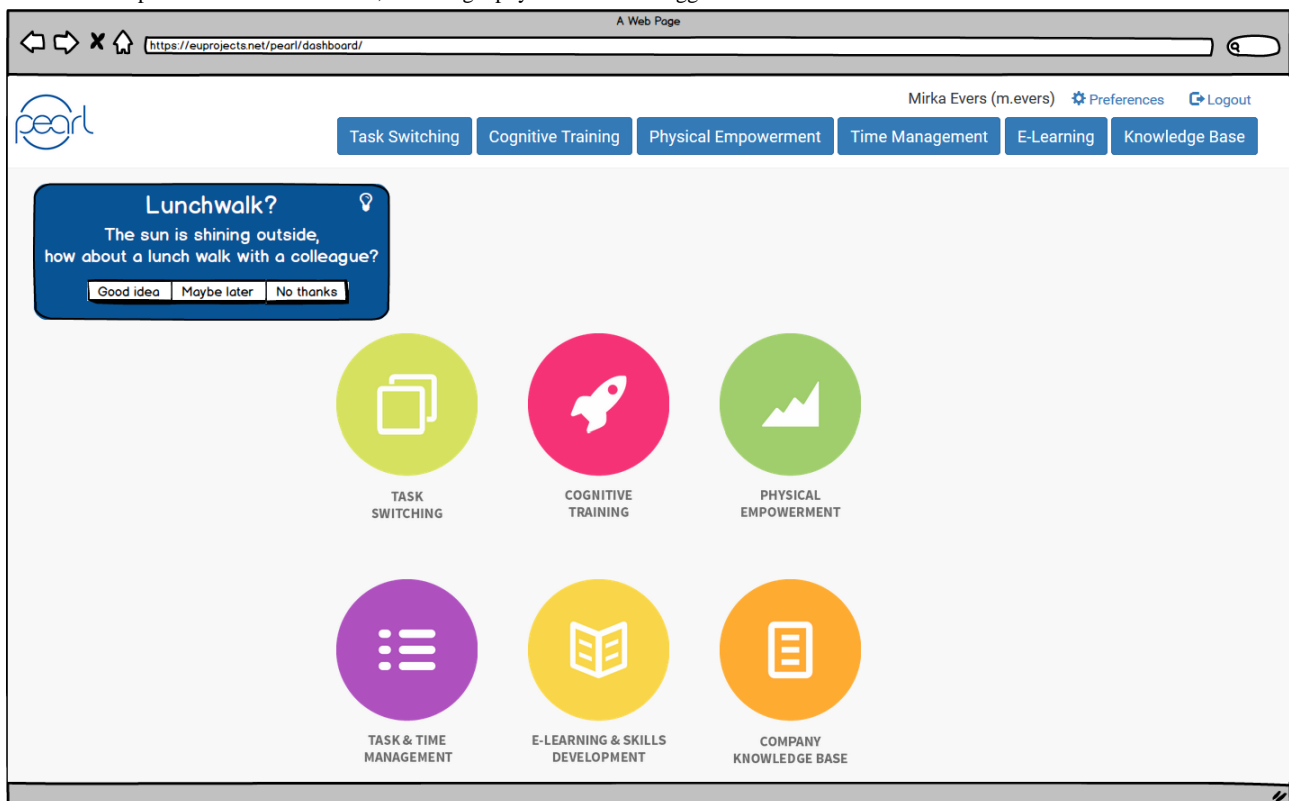
Ethics

The cases studies that are reported on in this article were exempt from Medical Ethical Approval by the Medical Ethical Committee Twente, the Netherlands. All participants provided informed consent, before their participation.

Figure 5. The eWALL sleep diary, whereby each episode of sleep or interruption of sleep is presented in text and cat icons.



Figure 6. Mock-up of Pearl’s main interface, including a physical exercise suggestion



Results

Case Study 1

A total of 8 persons with age-related impairments, living in the surroundings of Enschede, the Netherlands, took part in the end-user walkthrough of eWALL. From these 5/8 (63%) of them were male, 3/8 (38%) were female. Their ages ranged

from 66 to 88 years. In this results section, we report the participants’ reactions towards the main screen and sleep monitoring feature of eWall (as examples of the complete walkthroughs). Finally, we provide participants’ answers to the closing questions of each session.

Reactions Towards eWall's Main Screen

All participants associated the different items on the main screen with the correct functionality, except for the window (which displays the weather conditions outside the end-user's home). The participants did not associate the weather in the window with the actual weather outside. The participants also gave other suggestions (1) to show family members (especially grandchildren) in the picture frame, (2) to remove the phone (as it was too old-fashioned), and (3) to show upcoming appointments, reminders for taking medications, and mealtimes in the clock.

Appreciation of eWall's Sleep Monitoring Feature

When we questioned the participants about their first, general impression, most of them replied that they thought positively of the sleep monitoring feature (it is noteworthy that none of them had chronic sleep problems). Privacy (the possibility to control who is and who is not allowed to view personal information) arose immediately as a primary concern. Two participants did not feel comfortable with the idea of being monitored while sleeping. The remaining six participants were fine with being observed but would restrict sharing this information to close family and their general practitioner.

I don't mind (if this information is collected). But when it's saved and it is useful for a doctor or someone similar, I would like to share this. [Male participant, 67 years]

Then, we questioned the participants' intention to use this feature. We did this to elicit factors that could affect acceptance. The majority of the participants indicated that they would not use the sleep monitoring functionality on a daily basis. They stated that they know themselves whether or not they slept well, and do not need technology for this. Finally, the participants suggested several improvements for the interface, such as summarizing nightly awakenings and sleep periods (instead of displaying them one by one) and making it possible to view last night's information in one screen (thereby preventing the need to scroll).

Participants' Replies to Closing Questions

At the end of the walkthrough, we discussed the use of eWall in general. First, we asked participants about the anticipated ease of use of using eWall in general (their thoughts on how difficult they expected it to be when (learning to) work with eWall). All participants indicated that they thought learning to work with eWALL would be easy. Next, we asked them whether they thought the technology would be easy to use in practice. Reactions were mixed. Most persons stated they thought it would be easy, the others did not think so. They attributed this to a lack of motivation to log their data and to use the technology diligently.

(Whether or not you use eWall) depends on how consequent a person is. You need to be motivated and disciplined. [Male participant, 67 years]

As we were specifically interested in the issue of controllability (the extent to which an end-user can determine him or herself what the technology does), we asked the participants explicitly

about their thoughts on this topic. Most participants were convinced they would be able to control eWALL, while some participants were unsure. When we questioned the intention to use the technology as a whole, some participants indicated that they would like to use eWALL. For example, one person indicated he would do so when he is homebound, while some participants were indecisive, and others stated they would not like to use eWALL (because they thought it was dull and should be improved, or because the visuals were not appealing). The participants had different advice for the developers. These included the ability to personalize the contents of the picture frame (eg, to display familiar pictures or persons, for people with cognitive decline). Some participants asked for a different visual style (stating that the current one was old-fashioned). There was one participant that sought the guarantee that the data would be stored safely (not accessible to outsiders). Other participants gave advice for successful implementation (only offer it in situations where somebody needs support, and to provide proper training before installation).

Case Study 2

In total, 6 older office workers, working as knowledge workers in the surroundings of Enschede, the Netherlands, participated in the end-user walkthrough of the Pearl technology. Of these 5/6 (83%) were male, 1/6 (17%) was female, and collectively they had a mean age of 53 years (SD 10.8 years). In this section, we present Pearl's exercise prompter functionality and the closing questions of each session.

Participants' Appreciation of the Pearl Exercise Prompter

First, we questioned the participants' first impression of the feature. Most participants had a good first impression of the exercise prompter. When asked about the understandability of the feature, the participants stated that the activity suggestion, generated by the prompter, was clearly illustrated and formulated. They particularly valued the option to unobtrusively receive these physical activity suggestions via their mobile phone (ie, not disturbing their ongoing work). Also, the three answering options: "Good idea," "Maybe later," and "No thanks," were perceived quite well because it left them the choice of whether they wanted to adhere to the suggestion or not. Finally, we asked the participants whether the feature meets their expectations. Most participants expected that the prompter can help them to be more aware of their current physical activity behavior and consequently, become more active during the working day.

You get a short notification that you need to take a break. The sun is shining, so go for a walk. Maybe you won't pay any attention to it. But I know I actually need to do this. Maybe when I get this in front of me on my screen, that I think: yes, I have to do this. [...] Because I know it all, but I don't do it. I'll just do this, and I'll just do that. And before you know it, an hour has passed already and you won't do it anymore. [Female participant]

The participants also gave several recommendations for improving the functionality, like indicating the time it takes to

complete the suggested physical exercise, making it possible for the end-user to indicate whether s/he wants to exercise alone or with colleagues, adding functionality that makes it easier to organize a lunch walk, and suggestions should be explicitly linked towards physical activity goals (eg, steps to be made on a day).

Participants' Replies to Closing Questions

participants indicated that they would like to use the Pearl system once available. Those that were willing to do so, especially liked the possibility to become more physically active, thereby making this the most essential functionality. Those that did not want to use the technology indicated that they believed they were not in the designated target group. They thought of themselves as healthy or stated that they would find it difficult to blend in the use of the technology in their working routines.

Most participants thought that the employer should provide such a technology because it concerns the older employee's health during working hours. Others thought it was the older employee's responsibility to look after his /her health and whether to use such a technological aid or not.

Well, I think it would be a good thing when employers offer this service during an annual evaluation. When problems arise. That they can offer this as a possible solution. [Male participant]

Discussion

Principal Findings

In this article, we have introduced an agile method for testing the end-user acceptance of an eHealth innovation, while in the early stages of development: the EEW. The method has the goal to collect information about end-user acceptance of a new eHealth technology and its main features. This information can help the design team in deciding which features to implement or not, and how to design these functionalities.

We ended the introduction of this article with the following research question: how well does the EEW identify issues that hinder or facilitate end-user acceptance of a future eHealth technology? During the application of the method in two case studies, we learned that it allows participants to understand the workings and use of a future technology, to formulate an opinion about their personal use of a new eHealth technology and to explain their intention to use it. For example, we found that a sleep diary that works with a sensor in the bed led to concerns about privacy. The participants however also provided us with input for devising a control panel for data sharing that allows them to determine themselves who is (not) allowed to inspect this data, thereby making this functionality less privacy-infringing. Next, the evaluations provided the design teams with input for new functionality that would make the technology more valuable to end-users. Finally, the sessions provided input for implementation plans and business models. Participants' input allowed us to narrow down the designated end-user population and to select the optimal introduction strategy (eg, in our evaluation of the platform for older office workers, the majority opinion was that the employer should provide it, and not purchased by the older office worker

him/herself). These experiences allow us to answer the research question positively. Applying the method maps the different factors that hinder or facilitate end-user acceptance of a future eHealth technology and provides (re)design input for improving the technology and the service and business model that accompany it. As such, the EEW is a contribution to the methodological toolkit that design teams can use in the design phase of the different eHealth development frameworks, such as the Center for eHealth Research (CeHReS) roadmap [34] or Integrate, Design, Assess, and Share (IDEAS) [35]. It allows the design team to test whether their implementation of crucial functional requirements is in line with end-user wishes or whether a feature that can be considered to be a technology push is acceptable [36]. By challenging design decisions this way, a technology push without the appropriate amount of user involvement, which the eHealth sector is prone to and which leads to low uptake of the technology [37,38], can be prevented. Ideally, an EEW is conducted whenever there is only a simple prototype of the new technology ready. At this stage, design decisions can be altered at relatively low costs [39]. A side-benefit of involving potential end-users at this early stage is that they will feel committed to the to-be-developed technology, and will, therefore, be more eager to aid the design team throughout the rest of the development process [40].

The type of information that one gathers from an EEW makes it stand out from the popular approaches towards studying end-user acceptance of eHealth. These studies mostly use a quantitative approach and can confirm the influence of factors that are hypothesized to affect end-user acceptance. For example, Zhang and colleagues [41] studied the role of self-efficacy and end-users' belief in mHealth's capability to avert negative threats to one's health. This was done within the context of TAM. From this study, they recommend mHealth developers "to simplify the operations of mHealth services to improve users' sense of self-efficacy". Such general advice will be very difficult to translate into specific functionality or interface and interaction design. While studies such as these are beneficial for developing plans for eHealth implementation on a policy level, applying the EEW will be a far more valuable approach for design teams that wish to understand the end-user acceptance of their future eHealth technology and wish to translate this into actionable design recommendations. This finding is in line with the critique that has been voiced about the use of quantitative studies, based on TAM or UTAUT, for informing technology design [17,18]. Using the method can also serve a goal besides generating redesign input. Namely, it can provide insight into what makes up general factors, such as ease of use and perceived usefulness, within the context of eHealth. Alternatively, it can uncover factors that affect acceptance that were previously unknown. As such, using the EEW can enrich the current insights we have about end-user acceptance of eHealth technology.

Limitations

Of course, the EEW also has its limitations. As the new eHealth innovation has to be explained in simple terms, via a scenario and low-fidelity prototype, it is difficult to put complex technology to the test (eg, decision support functionalities that predict the best treatment options for patients and that apply

complicated algorithms). Participants will have a hard time understanding how such sophisticated technology works and what type of output they are being confronted with. For testing these functionalities, interacting with a high-fidelity or Wizard-of-Oz prototype will be far more useful; this allows the prospective end-users to experience the technology directly [42]. Next, when using the technology within the eHealth context, one should be aware of some pitfalls. Some eHealth technologies may provide functionality or health advice that is good for the end-user but not necessarily liked by him or her (eg, the advice to be more physically active instead of watching television). In such cases, end-user feedback should not be taken as the most critical driver for redesign. Another topic is the business model behind the eHealth service. Within the care sector, the means to finance a digital service is often a complicated one and difficult to understand by the individual patient. While the EEW can question willingness to pay from the patient's perspective, studying financing of the service from multiple perspectives will be difficult. Finally, the generalizability of the results of an EEW is limited. Such evaluations will be done with a limited number of participants and will focus solemnly on one specific eHealth technology. Therefore, one should be very cautious about generalizing the results of an evaluation to eHealth technology in general, or a subset thereof. However, we see the EEW as a method that is

to be used for generating redesign input, rather than basic scientific knowledge and thus, do not consider this a significant drawback.

Conclusions

By introducing the EEW, we have expanded the toolkit of user-centered design methods for eHealth development. The method facilitates (1) easy communication with novices about a future eHealth technology, (2) the identification of factors that can hinder or support end-user acceptance of a future eHealth technology, and (3) an early and cheap possibility for testing functional design decisions.

Previously, acceptance studies were mainly of a confirmative nature, using quantitative methods, which limited their results concerning actionable (re)design advice. Ultimately, the EEW can help to improve unacceptable technology or features that work detrimental for end-user acceptance, and can thereby prevent a mismatch between the needs and expectations of end-users on the one hand, and technological functions on the other. A mismatch that is generally considered to be a significant threat towards the success of eHealth [43,44]. We hope that this article has inspired other researchers to use the EEW as well, and we look forward to learning from their experiences with the method.

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Conflicts of Interest

None declared.

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Abbreviations

- AAL:** European Active and Assisted Living program
CeHReS: Center for eHealth Research
EEW: eHealth End-User Walkthrough
eHealth: electronic health
ICT: Information Communication Technology
IDEAS: integrate, design, assess, and share
TAM: Technology Acceptance Model
UTAUT: Unified Theory of Acceptance and Use of Technology

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